HOUSE OF COMMONS
CHAMBRE DES COMMUNES
CANADA

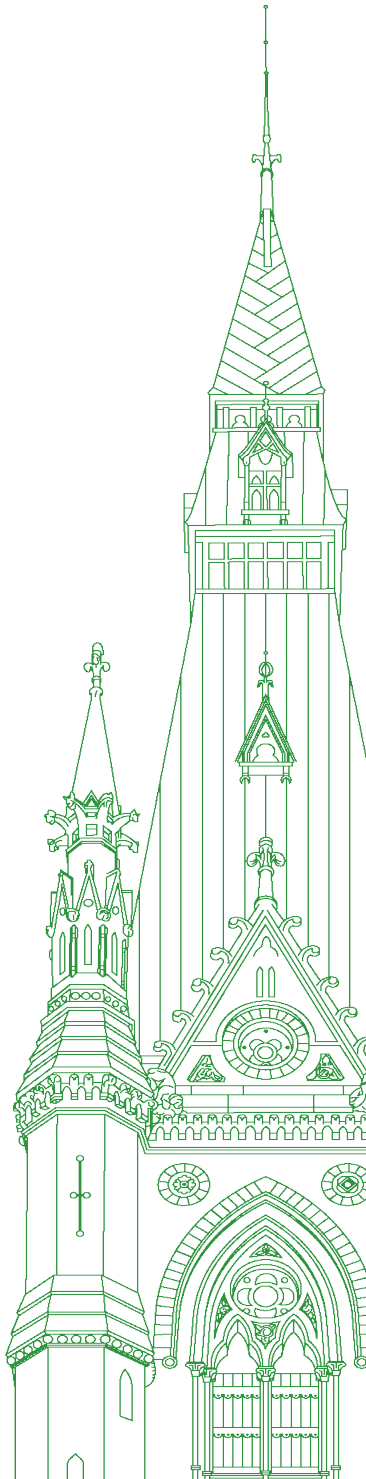
44th PARLIAMENT, 1st SESSION

Standing Committee on Health

EVIDENCE

NUMBER 067

Tuesday, May 9, 2023



Chair: Mr. Sean Casey

Standing Committee on Health

Tuesday, May 9, 2023

● (1100)

[*English*]

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

Welcome to meeting number 67 of the House of Commons Standing Committee on Health. Today we continue our study of the oversight of medical devices and a breast implant registry. Our two-hour panel will include researchers and professional organizations. Today's meeting is taking place in a hybrid format, pursuant to the House order of June 23, 2022.

I have a few brief comments for the benefit of witnesses. For those participating remotely, you have at the bottom of your screen the choice of floor, English or French. For those in the room, you have an earpiece. You can select the desired channel on the microphone set in front of you. For those participating remotely, please refrain from taking screenshots or photos of your screen. Today's proceedings will be made available on the House of Commons website.

In accordance with our routine motion, I am 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 by video conference: Dr. Jan Willem Cohen Tervaert, a professor of medicine at the University of Alberta; Dr. Steven Morris, president of the Canadian Society of Plastic Surgeons; and Dr. Lorraine Greaves, chair of the scientific advisory committee on health products for women.

Thank you to all for taking the time to appear today.

We will start with Dr. Cohen Tervaert, who has five minutes for an opening statement.

Welcome to the committee. The floor is yours.

Dr. Jan Willem Cohen Tervaert (Professor of Medicine, University of Alberta, As an Individual): Thank you, Mr. Chairman.

My name is Jan Willem Cohen Tervaert. I'm a professor of medicine at the University of Alberta and also emeritus professor in medicine and immunology of Maastricht University in the Netherlands. Currently I'm also a member of the expert panel on medical devices of the European community.

I did my training and education in the Netherlands, but after finishing my M.D. and Ph.D., I was invited to work at Harvard University in Boston in the United States. In 1993, I returned to the Netherlands on a fellowship from the Netherlands academy of science.

At that time, I started my clinics for patients with autoimmune complaints associated with breast implants. Based on this experience, I am pleased to share with members of the Standing Committee on Health some background information on the safety or "unsafety" of breast implants.

First of all, there have been several scandals with breast implants. Breast implant products are not always in compliance with international norms and standards. For example, there were three scandals: in 2010 with the Poly Implant Prothèse, PIP, from France; in 2015 with Silimed, a company from Brazil; and in 2021, BellaGel from Korea.

Furthermore, the Dutch National Institute for Public Health and the Environment published in 2015 a market surveillance study that demonstrated that the technical findings for all 10 manufacturers that have a market for breast implants in the Netherlands were not in order, and in one case there was even a very high level of contaminants in the breast implants.

Finally, in 2018, as is well known, the International Consortium of Investigative Journalists released the "Implant Files", demonstrating many shortcomings in breast implant clinical trials.

Currently what diseases are associated with breast implants? There are three different types. First is the malignant disease. In 1997, specific implant-associated malignant disease was first reported, so-called anaplastic large cell lymphoma: BIA-ALCL. Based on the Dutch mandatory registry for pathology specimens, Daphne de Jong et al. demonstrated clearly already in 2008 that BIA-ALCL in the Netherlands was caused by breast implants.

In 2011, the FDA issued a warning but stated that it was not possible to identify a possible association between breast implants and BIA-ALCL. Since most patients with ALCL had textured implants, the FDA and Health Canada requested that Allergan in 2019 recall its textured implants.

More recently, in 2023, the FDA and Health Canada issued a safety communication that also other lymphomas and breast implant-associated squamous cell carcinoma may occur in patients with breast implants. Although an accurate estimation of how often these malignant tumours occur in patients with SBI does not exist, ALCL researchers calculate the risk to be one in 2,832 women.

Apart from malignancies, there are also various autoimmune diseases that are reported to occur more frequently in patients with breast implants. Also, here the estimated risk is very difficult to quantify, and it was for a long time debated whether breast implants were even really a risk factor for the development of these autoimmune diseases.

In 2018, however, a very large study from Israel convincingly demonstrated that autoimmune diseases occur more often in patients with breast implants than in women without these implants. Patients with breast implants appear to have a 45% higher risk of developing autoimmune diseases such as sarcoidosis, systemic sclerosis, multiple sclerosis, rheumatoid arthritis and other autoimmune diseases. Just as has been found for malignancies, most diseases occur more than 10 years after the implantation.

Finally, there's a third group of diseases. Patients with breast implants often have symptoms suggestive of an abnormally functioning autonomous nervous system. Symptoms that these women have include severe fatigue, widespread pain in muscles and joints, severe dry eyes, severe dry mouth, feverish feelings and cognitive impairment.

● (1105)

Nowadays this disease is called breast implant illness or autoinflammatory/autoimmune syndrome induced by adjuvants due to silicone incompatibility. The symptoms also occur, generally, seven to 10 years after the breast placements, and in 80% of the cases there is an amelioration or disappearance of the symptoms after explantation. Although an accurate estimation of how often this occurs does not exist, our studies suggest that one in four women, so 25%, may develop at least three symptoms, suggestive of this disease, 10 years after breast implants.

Why do we need a national breast implant registry? It is estimated that about 3% to 4% of women in western countries have breast implants. About 70% are placed because of cosmetic reasons, whereas 30% are placed because of a reconstruction after a mastectomy. When the PIP implants were recalled in the Netherlands, there was only a voluntary registration, a so-called opt-in registration, and this meant that only 10% to 20% of the women with PIP implants could be traced.

Furthermore, with a registry, there's a possibility to calculate how often local and systemic complications really occur after a breast placement.

Since there were never randomized and controlled clinical trials performed to demonstrate the possible safety, or unsafety, of breast implants before they were registered, we currently only have post-marketing surveillance to monitor their safety. Manufacturers need to conduct these studies, and plastic surgeons need to report events to the manufacturers. Unfortunately, there are no criteria for these reports. Reports are only infrequently made by surgeons. The reports are not peer-reviewed, and they are not open to the public.

Because there are several signals that breast implants may not always be safe, it is prudent to start with a registry as soon as possible. As discussed, this should not be a voluntary opt-in registry, but a mandatory opt-out registry, where only the patient, and not the surgeon, has the choice to participate or not.

What are the requirements for a registry?

● (1110)

The Chair: Dr. Tervaert, we're well past time if you could conclude.

You'll get lots of chances to elaborate during the questions and answers.

Dr. Jan Willem Cohen Tervaert: There are a few things.

Regarding the opt-out system, the dataset that can be used should be the same as the one in Australia and the Netherlands, but there should also be a PROMs dataset. That's patient-reported outcome measures.

Compliance with the mandatory registry could be an issue. In the Netherlands, it's arranged that all hospitals and private clinics have the legal responsibility for the registration. In addition, compliance to the registry is a requirement for renewing the licences of plastic surgeons.

To facilitate the registry, manufacturers should be asked to develop bar codes on the implants, so that with bar code scanning modules, the registry can be done without mistakes.

The funding of a registry could be an issue. In the Netherlands, it's established that patients pay $40 Canadian extra for the surgery. Patients with breast reconstruction get this reimbursed by their health insurance.

In conclusion, breast implants are high-risk medical devices. Long-term sound epidemiological data are not available, despite the fact these breast implants have been on the market for more than 60 years.

Recalls have been made in the past, and are probably needed in the future. Recalls are not successful if there's no good registry. It is my opinion that there's an urgent need to start a national breast registry. The registry should be used by all surgeons that place implants. The registry will provide us with better information about the diseases that are associated and/or caused by these implants.

Thank you very much, Mr. Chairman.

The Chair: Thank you, Doctor.

Next, we're going to hear from the president of the Canadian Society of Plastic Surgeons, Dr. Steven Morris.

Dr. Morris, you have the floor.

Dr. Steven Morris (President, Canadian Society of Plastic Surgeons): Great. Thank you.

I would like to thank the committee for the opportunity to appear here today and provide some information regarding breast implants. I agree with my colleague that the regulation of surgical implants is key to patient safety.

I'm Steve Morris. I am a plastic and reconstructive surgeon. I've been working in Halifax for 30 years. I have a research lab, and I've been doing laboratory research for the last 25 or so years. Currently, I am president of the Canadian Society of Plastic Surgeons.

I started my residency in the 1980s. At the time, breast implants were flawed. Results were poor and unpredictable. Gradually, the implant manufacturers improved the devices and results improved. Due to concerns about safety, in 1992 there was a moratorium placed on silicone gel implants. In order to do any kind of reconstruction, we had to use saline-filled implants for a period of time. The problem with saline-filled implants is that there's a 1% failure rate per implant per year. Spontaneous rupture is a consistent issue. Gradually, silicone implants were allowed back on the market, and Health Canada basically put the onus on the implant manufacturers to collect data.

Just to back up a bit, what do we use breast implants for? I do a lot of breast reconstructive surgeries using implants. There are congenital causes for breast deformity, such as hypoplasia, asymmetry or other more unusual breast deformities. Transgender patients require breast implants. Finally, there's cosmetic breast augmentation. The number of these procedures varies from surgeon to surgeon in different practices.

There's always been some level of concern about breast implant safety. In the 1980s-style implant, there was an unacceptably high rate of implant rupture. As the manufacturers tried to achieve a better implant, they made the capsule thinner and thinner and the silicone more viscous. This ended up causing a lot of ruptures.

Silicone has been of concern because of what it could do in the body. Generally, silicone was first selected because it's relatively biologically inert, but there is always a capsule around any implanted device. Whatever the type of implant in the body, there's always a capsule around it. That seems to cause a lot of the problems in a certain subset of the patients.

When the moratorium was announced in 1992, there were hundreds of research projects looking at the safety, particularly looking at the autoimmune. At that time, there was no convincing evidence. That's why Health Canada allowed the implants back on the market, with the understanding that the implant manufacturers were going to study the data. That's why we're here today.

It's said that the best time to plant a tree is 30 years ago, and the second-best time to plant a tree is today. It's the same with this registry. Today is the best time to start moving forward with this issue: We would have excellent data by now.

BIA, or breast implant-associated, ALCL is a large, very serious tumour caused by breast implants. Again, textured implants were associated with it in the highest numbers, but there's no doubt that there's a relationship between anaplastic large cell lymphoma, which is a form of non-Hodgkin's lymphoma, and the implants. That's the reason they were taken off the market in 2019. If we'd had that data, when we first got an inkling of ALCL, we could have alerted all those patients and all those surgeons, explanted those implants and stopped the production of them, setting back the clock about 10 years. We lost that opportunity—or more.

Unfortunately, right now there is no good way to track the number of patients who have received these types of implants. A registry would have accomplished this easily. In every surgical procedure, the surgeon is required to disclose to the patient the cost-benefit analysis of the operation. What are the risks? What's the financial cost? What pain and suffering will be associated with this? What's the goal of the operation? If we do not have adequate data on breast implants, we can't correctly advise our patients. As surgeons, we want to achieve excellent results every day, but we want to do it safely.

In this patient population, believe it or not, after what you've just heard, we get great results very consistently. I've been practising for 30 years. If I'd had terrible results and patients who were badly affected, I would have stopped doing these types of surgeries a long time ago. Clearly, we're getting great results most of the time.

● (1115)

Then there are cases we don't know about. We've lost them to follow-up or what have you.

In order to provide optimal and safe patient care, I think we need to create a national breast implant registry. I had a quote from one of the papers I read in preparation for this, which is that the obligation for patient safety lies not with the doctor who uses the medical device, but with the government that regulates the medical device.

The Chair: Thank you, Dr. Morris.

Finally, we go to Dr. Lorraine Greaves, the chair of the scientific advisory committee on health products for women, who is appearing virtually.

Welcome to the committee, Dr. Greaves. You have the floor.

Dr. Lorraine Greaves (Chair, Scientific Advisory Committee on Health Products for Women): Thank you very much.

In addition to chairing the scientific advisory committee on health products for women, I am also a senior investigator at the Centre of Excellence for Women's Health, which is based in Vancouver, and a clinical professor at UBC in the faculty of medicine. I'm a medical sociologist, so I am trained to analyze the links between health and various systems.

There is no doubt that a breast implant registry would benefit Canadians and that all measures should be taken to establish one. However, such a registry is just one example of the need for a comprehensive system for tracking and monitoring medical devices in Canada. I want to briefly address both aspects.

Women's health has a long history of neglect. That has included exclusion from clinical trials, under-researching of key health issues specific to women and under-researching of women's presentation of shared health issues, such as cardiovascular disease, as just one example. This is a result of a long-term systemic bias in health research and in treatment.

Remedial actions have been taken by the Government of Canada around this neglect, one of which has been the funding of the centres of excellence program between 1996 and 2012. There were five centres and a working group on health protection. The latter group, including the centre that I established in Vancouver, did do two reports that were of relevance to the issue of breast implants. They are linked in the written remarks I sent to the clerk.

A joint research program is the second initiative to remediate this problem. Health Canada and the CIHR launched this between 2019 and 2020 to address key policy issues. It was called SGBA+, or sex and gender based analysis plus, health policy-research partnerships.

Two of the seven projects under that particular program are of relevance to today. One, done by Anna Gagliardi at the Women's College Hospital and her team, analyzed the management of medical devices in Canada from an SGBA+ perspective. She recommended a complete revision of documentation and procedures, and certainly SGBA+ training for industry. I led a team doing a parallel piece of work on SGBA+ on the management of prescribed drugs. We had similar recommendations, including the mandatory inclusion of sex-related data and gender-related data—the former beginning in 2023—on submissions for drugs and devices. These both speak to some of the oversights that we have in our current system.

The establishment of the scientific advisory committee is the third example. We're mandated to advise on better management of drugs and devices that affect women. We have identified numerous issues with respect to both, and we have made those recommendations in concert with various planning efforts from Health Canada.

With respect to the registry, as you've heard so far, the issue of the registry is extraordinarily important to those women who have had an implant, and in particular to those women who have had problems. You've heard about the problems. At the committee level, we have heard testimony from some of the women who have had problems, which is utterly moving and often relays catastrophic, life-changing issues.

The registry is of keen importance to clinicians and researchers as well, as it will provide more robust data.

The request for a breast implant registry in Canada dates back over 33 years. As the last speaker said, that would have been the time to establish this. These include reports, special advisory committees, expert committees, at least two legislative bills, testimony and recommendations from consumer advocates. Most recently, we had a best brains exchange in March of this year, and now you have embarked on this study. I submitted a PowerPoint from the best brains exchange to you for background. You will see the timeline there.

However, we still don't have a registry, even though many other countries do. It's well past time to establish one. Discussions about logistics and pros and cons, and arguments about objectives and complexity prevail, but 33 years is a long time to work out a system.

● (1120)

It's ample time. It should include registration of all implants sold in Canada—implanted, replaced and explanted in both private and public health care facilities, including recall information.

The members of the SAC, the scientific advisory committee, are an esteemed and experienced group of clinicians, scientists, consumer advocates and researchers. We have recommended action. We were engaged in the best brains exchange.

A registry would finally provide a denominator for calculating risk. We don't have that at the moment. Therefore, we can't calculate risk, which underpins informed consent. That affects clinicians. It also affects women. We don't know the number, the total number, of devices implanted or explanted, replaced, failed or succeeded, so we can't do this. This lack of evidence, I would suggest, supersedes even the strongest consent forms.

It should also provide data for research to understand the dynamics of breast implant usage, something that gets very little discussion. CIHR should be encouraged to utilize the registry data, should we get one, to produce research for the public domain.

If implants and when implants take place in private clinics, follow-up health care utilization is in the public domain, so this is an issue for all Canadians.

We've also recommended improved communication with clinicians and potential recipients of implants, including robust information about consumer experiences; reasons and motivations for seeking implants; alternatives to implants; lifespan of devices; and relevant qualitative research. Even non-problematic implants expire and require replacement. Women need to anticipate this and learn about alternatives to breast implants.

We don't generally do that at the moment, but at root, by and large—

● (1125)

The Chair: Dr. Greaves, can I get you to wrap up? We're past time, and we have a bunch of MPs who are really anxious to ask questions.

Dr. Lorraine Greaves: Okay, I will.

By and large, this is a non-medically necessary procedure.

I'll just wrap up by saying a few words about postmarket vigilance on all devices. Vanessa's Law came into effect in 2019, mandating hospitals to report adverse reactions. There have been promises to extend this to long-term care and private clinics. We need that. We need that to support a robust registry.

Second, Canada does not yet have mandatory sex- and gender-related reporting of data in submissions by industry for devices or drugs, despite a federal SGBA+ policy. Therefore, we don't have adequate warning labels and consumer and clinician monographs.

Promises have been made to improve this. Some promises have been fulfilled, but there's a long way to go. It is extremely important that, even though the pace of these commitments has been slower than we thought, these goals should not be eliminated or reduced by departmental budget cuts.

I will conclude by saying that it's past time to have a registry. It's past time to compel parties to take these important steps on medical devices.

Thank you very much.

The Chair: Thank you, Dr. Greaves.

We'll now begin with rounds of questions, starting with the Conservatives.

Dr. Kitchen, you have six minutes, please.

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

Thank you to all the witnesses. I really appreciate your expertise and your dedication to the area. I do appreciate that.

As our chair indicated, we're eager to ask questions. I have so many that I just don't know where to start.

I'll start with Dr. Cohen Tervaert.

You talked a little bit about RCTs, randomized controlled trials, and about how we don't have any along those lines. Because we're looking at this from a registry point of view, I'm wondering how you see collecting the data—assuming we're collecting that data—would be of value to produce that RCT research.

Dr. Jan Willem Cohen Tervaert: Of course, first of all, it's a recall registry, but you can implement PROMs—patient reports of outcome measurements—on the questionnaires that patients have. For instance, in the Netherlands, they are currently doing that. They are registering all kinds of complaints from patients to see how often breast implant illness occurs, how often autoimmune diseases occur and how often ALCL occurs.

Those are things that can be implemented in the registry. It needs extra effort, a lot of work, but it can be done and it should be done.

Mr. Robert Kitchen: Thank you.

Last week, we had Dr. Nicolaidis speaking to us here. What I took from part of his conversation was that there are no studies being done by the industry and the companies. The studies being done are by the practitioners who are utilizing those devices.

The question I have is on concerns about the research being biased, in any nature, because of that background. Do you have any comments on that?

● (1130)

Dr. Jan Willem Cohen Tervaert: Many publications on breast implants are heavily sponsored by the industry.

I must confess that I, myself, was also offered a grant from the industry, but I would have had to sign an agreement that I could never publish anything without their consent. I refused that. That's not ethical. It's not done by the industry for medicine, but for medical devices it seems to be more harsh in these kinds of subjects than others.

There are very few well-granted studies performed because it's difficult to get a grant for such studies. You have to go to CIHR, which is difficult for such a not well-developed field.

Mr. Robert Kitchen: Thank you.

What I hear around the room—from the three of you—is that there's obviously an interest in creating this registry. I'm just putting that out there. Ultimately, I'm hearing there's value to that.

Dr. Greaves, you presented a PowerPoint presentation. It talked about things you looked at that would be required for a successful breast registry. I'll read them quickly: “Clear objectives; Stable long term funding; Independent—financially, technically, but responsive to stakeholders; Simple interface/data upload; Opt out; Concise data requirements; Clean data which can be utilized/reported easily”.

I'm pulling that up from one of those slides.

I want to focus on the opt-out aspect. We've heard from many of you about whether we should be opting out or opting in, and about the concerns we have about, number one, informed consent of the patient and, number two, privacy issues.

I'll start with Dr. Morris. Would you like to speak to that?

Dr. Steven Morris: Yes. That's an excellent question.

The data is extremely clear about it. Opt-in has about a 20% uptake with patients. Opt-out has about 80% or 90% success in getting the data. If you're going to do the study.... I wouldn't even suggest doing the study if it's opt-in, because they fail.

One of the advantages of our waiting for 30 years to get this started is that there is lots of published data out there from other countries that have done all the trial and error. There are some excellent studies on the other registries around the world, which we can learn from. Germany and Italy have taken the approach of making the registry mandatory. It's not even opt-out. It's mandatory for the surgeons and patients, which is something to discuss.

I think patient confidentiality is always important in any database of patient-related data. In the case of having a national registry, it would be paramount to the success of the registry. Obviously, clinical data, particularly with this type of subject, which is very sensitive.... A lot of people don't want to have that data out there. You would have to mandate very rigid patient confidentiality parameters in addition to making it opt-out.

Mr. Robert Kitchen: Thank you.

Dr. Greaves, if you want to—

The Chair: Thank you, Dr. Kitchen. You're out of time.

Mr. Robert Kitchen: I'm sorry. I had so much, but not enough time.

Thank you very much

The Chair: It's over to Ms. Sidhu for six minutes.

Ms. Sonia Sidhu (Brampton South, Lib.): Thank you, Mr. Chair.

Thank you to all the witnesses for being here.

I also want to wish everyone a happy National Nursing Week.

My question is for Dr. Morris.

You were talking about Italy and Germany. We heard about the opt-out option in the Netherlands, where all plastic surgeons are required to register their implants in the system, except for when the patient refuses to include it in the registry.

Do you think this is the model that should be implemented? What are your thoughts on the Netherlands model?

Dr. Steven Morris: First of all, I'll make a disclosure. I am not an expert in registries, but I think there's lots of published literature on them. I think what I would advocate for is developing a steering committee that makes those tough choices about registries, because I heard the ideals about the registries and those seemed to make a lot of sense, and that's what's published.

I think the Netherlands is one of the big four in the world. The U.K., Netherlands, Australia and the U.S. are the four models of registries. I think the first thing we should do if we go this route is to make ours better. Draw on the experiences of other registries and make it even better.

One of the things that is important to the registry is to get the uptake of the surgeons entering the data, because they have to do all the data entry. If you have it on a smartphone, have an app, they would be mandated, as my colleague said, to make the registration. You have to have a stick to make everybody comply, but I think it's very important to come up with a very definite plan.

● (1135)

Ms. Sonia Sidhu: As a follow-up, how would people who opt out find out about recalls? We have heard that women are just now finding out that their implants were recalled in 2018 or 2019, and they had no idea that they got recalled. What are your thoughts on that?

Dr. Steven Morris: It's not a good situation, because in the breast augmentation population it's often young women who are quite mobile, who might have the surgery done in one city and move to a different city for a job, or for family, or what have you. Even though they might have best intentions for follow-up and the surgeon may offer them follow-up, for one reason or another they have no follow-up.

Medical records are like tax returns. You have about a seven-year window in which you're supposed to maintain medical records, whereas with an implant, possibly, it's a forever rule. This is because, as Dr. Tervaert said, a lot of these conditions related to the implant seem to be latent effects, so that they might be 10, 20 or 30 years later.

Ms. Sonia Sidhu: My next question is for Dr. Tervaert.

Dr. Tervaert, is there any specific techniques or approach that health care professionals can use to address the challenge of the mammogram for women who have breast implants?

Dr. Jan Willem Cohen Tervaert: I'm sorry...?

Ms. Sonia Sidhu: They can get abnormalities. When the breast implant population goes for mammograms, I know there are challenges.

Dr. Jan Willem Cohen Tervaert: Yes, those are the challenges with breast implants and mammograms. Breast implants, especially the older breast implants, are leaking, and if you have the pressure of a mammogram it can cause more leakage and you can rupture the breast implant. The FDA warns against this, and I personally also warn my patients. Ultrasounds seem to be the best screening method for breast implants, and MRI is another option but an expensive option.

However, ultrasound should be a very good alternative, and it is not yet the rule to have that in Canada.

Ms. Sonia Sidhu: Dr. Morris, do you want to add to that?

Dr. Steven Morris: I would just add that clinically the radiologists say there's really no problem. What they do is additional views to look around the implant in the breast, so the radiologists are quite comfortable doing mammography on implants.

Dr. Jan Willem Cohen Tervaert: Yes, but I see it the other way. Many patients tell me that their problems actually start after the mammogram, so I'm not sure that radiologists see that.

Ms. Sonia Sidhu: I want to ask this question of both of you.

How would a breast implant registry help with monitoring and tracking cases of BIA-ALCL?

Dr. Jan Willem Cohen Tervaert: For ALCL, it's clear that if you combine pathology data with the breast implant registry, it would be easy to see exactly which breast implant was used. For instance, it's been considered that it's mostly a macrotextured issue, because an allergen was blamed for that. However, the Korea scandal in 2021 was actually that microtextured implants also can cause ALCL. That was the implant that was specifically made in Korea, but also the manufacturer was causing fault and did not have a really microtextured envelope originally from the technical files, which they should have done.

It's important to go back and see exactly which implant caused the ALCL.

● (1140)

Ms. Sonia Sidhu: Do you want to add to that, Dr. Morris?

Dr. Steven Morris: Thank you.

All I would add is that, if you have a registry of a million patients, and say 100,000 had a certain type of implant that was associated with an issue, then almost immediately you could contact those 100,000 patients, with whatever number of surgeons, to highlight that this is a risk and offer early surveillance.

Much like breast cancer and lung cancer, early diagnosis is going to improve the results of the treatment for the cancer that results.

Obviously then, if there's a cluster of cases, you can take that implant off the market.

The Chair: Thank you, Dr. Morris.

[*Translation*]

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

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

Dr. Greaves, I'm pleasantly surprised at your position on the need for a registry, but, at the same time, it puzzles me.

I have here the Overall Summary of Advice from the virtual meeting of the Scientific Advisory Committee on February 23 2021. It contains several recommendations, including this one:

> 5. Revisit possibilities surrounding the development of a registry to track the use (effectiveness, safety) of high-risk devices.

That seems like a much weaker position than the one you are taking today.

Did the scientific advisory committee you are part of hold another meeting to strengthen its position?

[*English*]

Dr. Lorraine Greaves: Thank you for that question.

We have been in a variety of discussions over the past three years at the committee, reviewing the issue of whether or not there should be mandatory data provided on a variety of drugs.

[*Translation*]

Mr. Luc Thériault: There is no interpretation.

[*English*]

The Chair: Dr. Greaves, hang on for one second.

[*Translation*]

Is there a problem with interpretation?

Mr. Luc Thériault: Interpretation is working now.

However, the witness will have to start again from the beginning.

[*English*]

The Chair: Dr. Greaves, could you answer the question from the top? We lost translation momentarily.

Dr. Lorraine Greaves: Sure.

At the committee, we've had a number of discussions about devices, including breast implants. We heard testimony from patients at the committee about both cancer-related issues as well as more general issues, and consumer advocacy. We recommended that we revisit the possibility of developing the registry to track the use, effectiveness and safety of breast implants.

The committee members are well aware that these efforts to establish a registry have been ongoing for over 33 years. We want that revisited. That is one of the reasons that the best brains exchange was scheduled for March of this year.

We also recommended that there be a retrospective case study—

[*Translation*]

Mr. Luc Thériault: I'm sorry, but I don't have a lot of time.

The recommendation goes back to February 2021; it's now May 2023. We heard from Mr. David Boudreau from Health Canada, and he seemed quite concerned about the technical elements and the practicalities of creating a registry.

If we need a registry, don't you feel that we're dragging our feet? That's my first question.

I have a second question. Apart from the February 2021 meeting, did you discuss breast implants at any of the other meetings which are on the list I have here?

[*English*]

Dr. Lorraine Greaves: We have discussed breast implants, in the context of discussing medical devices in the medical device action plan, numerous times. The details of that might not appear in the actual minutes because they are summaries. However, we have recommended that the breast implant registry be revisited.

We've also recommended that breast implants be considered as a retrospective case study, to investigate exactly how they were regulated in Canada and to identify the gaps that led to the current situation. We've certainly recommended that we provide more information to consumers on a much wider array of evidence. That is going to require, as I mentioned in my presentation, not just data from a registry, but also more specific qualitative and quantitative research on the issue that is in the public domain and that is publicly funded.

● (1145)

[*Translation*]

Mr. Luc Thériault: Could you please submit to the committee the minutes of all your scientific advisory committee proceedings? There were meetings on May 16 and 17, October 29 and 30, 2021, February 23, 2021, June 2021, February 2022, and November 2022. You also mentioned March; Im assuming that was in 2023.

We requested this over a month ago, but have not received anything yet. It would be interesting for us to read.

[*English*]

Dr. Lorraine Greaves: I think they are all on the website and publicly available.

[*Translation*]

Mr. Luc Thériault: No, I'm sorry, but it's not available on the website. We did our research. We were told to write to a particular address. What is available are the summaries. That's what you just mentioned. I am asking for all of the minutes, in other words, all of the proceedings.

[*English*]

Dr. Lorraine Greaves: Okay.

[*Translation*]

Mr. Luc Thériault: Mr. Cohen Tervaert will be pleased, because on February 21, you recommended the creation of research funds to improve the evidence collected on implant-related adverse events.

Since February 2021, has work started on that recommendation?

[*English*]

Dr. Lorraine Greaves: Not to my knowledge.

[*Translation*]

Mr. Luc Thériault: Health Canada is considering the creation of a fund to cover the costs of damages. Has there been any progress on this front since February 2021?

[*English*]

Dr. Lorraine Greaves: Not to my knowledge, although we did recommend that.

[*Translation*]

Mr. Luc Thériault: The retrospective case study you mentioned a little earlier is ongoing, isn't it?

[*English*]

Dr. Lorraine Greaves: Not to my knowledge.

[*Translation*]

Mr. Luc Thériault: All right.

How much time do I have left, Mr. Chair?

The Chair: Your time is up. Thank you very much, Mr. Thériault.

[*English*]

Next we have Mr. Davies for six minutes, please.

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

Thank you to all the witnesses for being here.

Can any of you give our committee a general idea of how many Canadian women have been injured by breast implants?

Dr. Jan Willem Cohen Tervaert: I tried to calculate that. From the other experiments in other countries, it's calculated that about 25% of the patients with breast implants have issues that might be due to the implants.

Mr. Don Davies: For those of us who aren't used to medical epidemiology and risk factors, is that considered a high risk for what can sometimes be, I guess, an elective surgery?

Dr. Jan Willem Cohen Tervaert: It's an extremely high risk.

Mr. Don Davies: Thank you.

Dr. Cohen Tervaert, staying with you, if I had your words correct, you said there were some issues with implant trials. I imagine these were the clinical trials that were probably done by the manufacturers.

Can you expand a little bit on that? What were the issues with the implant trials?

Dr. Jan Willem Cohen Tervaert: The FDA recommended trials when the ban was lifted. However, these trials were not done and were not done properly.

We had an FDA meeting, I think, three or four years ago where I was also a witness. There, many patients came forward and said they participated in these trials, but as soon as they developed complications, they were sent out of the trial because they had complications. Those are not proper trials.

Mr. Don Davies: Who was conducting those trials?

Dr. Jan Willem Cohen Tervaert: It was Mentor and Allergan.

Mr. Don Davies: You've identified three major potential negative problems from breast implants: one, malignant disease breast implant ALCL; two, autoimmune disorders; and three, so-called breast implant illness.

Is there an implant on the market today that significantly avoids these three risks?

● (1150)

Dr. Jan Willem Cohen Tervaert: No. We did do a comparative study, where we compared the modern implants with the implants that were in place 20 years ago, and we saw the same symptoms occurring in the patients. There was no difference in implant quality. Although the manufacturers always state that their implants are better and better, we don't see that from the rheumatological or autoimmune field.

Mr. Don Davies: I'm going to ask an obvious question as a lay person.

We have a device that causes an extremely high rate of serious problems. I take it that you would agree with me that the cancer, the autoimmune disorders and the autoimmune nervous disorders are fairly serious—are they not?

Dr. Jan Willem Cohen Tervaert: Causality is an issue here always. The malignant disease is clearly caused by a specific mutation that occurs that is not seen in other forms of ALCL. The causality of breast implant illness by breast implants is still debated. I recently put up research where we showed with current Bradford Hill criteria—which are the criteria that we use to support causality—that breast implant illness is, indeed, caused by the breast implants.

Let's go back to the discussion about smoking. In the late 19th century, it was already clear that some patients who smoked did get lung cancer. However, it lasted until 1960 when causality was proven, and that was Dr. Bradford Hill who did that. It is very difficult to fight against the manufacturers.

Mr. Don Davies: Sure.

Then, if I understand you correctly, the BIA-ALCL is one version. There is a causative aspect established. The Israeli study, a large-scale study, said that there's a 45% higher risk in women with breast implants to get AI disorders over those who don't have implants, and 25% of women would have three symptoms or more after 10 years after their breast implants in terms of autoimmune disorders.

The question I'd ask is this: Should we be allowing these to be implanted at all, given those health impacts, at least for people who don't have a medical indication for one?

Dr. Jan Willem Cohen Tervaert: I'm not the one who decides that, but clearly my statement is always this: If we are continuing to give breast implants to healthy people, they should be well informed. Preferably, I would say, “You are a guinea pig, and if you want to participate in this study, yes, you're allowed.”

Mr. Don Davies: I have an awkward question, Doctor. Do you have a daughter?

Dr. Jan Willem Cohen Tervaert: Yes.

Mr. Don Davies: Would you recommend that she get breast implants?

Dr. Jan Willem Cohen Tervaert: Never.

Mr. Don Davies: Dr. Morris, you indicated that there was a higher failure rate when we switched from silicone gel to saline. Is that because the envelope was different? One would think.... I mean, it's the same material, saline or silicone. I understand they have different impacts, but why would the switch to saline result in greater failures in the envelope?

Dr. Steven Morris: I don't think I said that.

In the nineties, when the moratorium took place, silicone gel implants were taken off the market. When patients had need of further surgery, we could only offer saline-filled implants. As a result of that, we all have a lot of experience with patients having their implants done and everything going fine, and then they have a sudden deflation one to 20 years later. That was an issue because it's a sudden failure. It's a complete failure. It's a very obvious failure.

Circling back to the complications issue, when you hear a number.... I do an operation—deep inferior epigastric artery perforator flap from the abdomen to reconstruct the breast—that is the alternative. As we've heard, what are the alternatives to using an implant?

In a woman who has had a mastectomy, my options are an implant or tissue. The implant is a one-hour operation and the results are pretty good most of the time. The other option is a four-, six- or eight-hour highly invasive tissue transfer operation. I present that to them. There are pros and cons to both. Patients, for their own self, have the choice of not having a breast reconstruction after mastectomies—which some choose, and that's perfectly reasonable—or they'll decide to have an implant put in, with a full discussion of the risks of that procedure, or they'll have the bigger operation.

On the bigger operation that I do, from the abdomen, in studies it has a 50% complication rate, which.... What surgeon is ever going to do a 50% complication operation? That's crazy. The thing is that, in those studies, in that 50%, are little things like an abscess to a little stitch or suture lines that are a little thick or other things. When you hear numbers like 25%, that's not a 25% serious complication rate. We think the ALCL is higher than we initially thought. Maybe one in 300 is the highest estimate I've heard, which is 0.3%, still very alarmingly high for that complication, but the other serious complications are hard to pin down. like, for example, the autoimmune. We have one of the world's experts here, and he'll tell you that it comes in all kinds of forms.

On BII, we had a scientific director at our national meeting this year and we had a full session on BII. Basically, does it exist? What are the diagnostic criteria? What's the test for it? There is no consensus at all. The first question was, does it exist? Most people weren't sure that it actually exists. There were certainly no diagnostic criteria, and there is no test to confirm it.

When you're talking about a 20% complication rate, that's not a 25% serious complication rate. There's never been a study in the literature that has ever implied that.

● (1155)

The Chair: Thank you, Dr. Morris.

Next is Mr. Jeneroux, please, for five minutes.

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

I also want to follow my good friend, Ms. Sidhu, in wishing everybody a happy nurses' week.

I have a quick story, Mr. Chair. Last week, we saw national physicians appreciation day. I think many of you know that my wife is a physician. I sent her a note saying, “Happy Physicians Appreciation Day”. She sent me a note back saying, “Thank you, and I hope I can reciprocate on national politicians appreciation day”.

Voices: Oh, oh!

Mr. Matt Jeneroux: I don't know if you've experienced that yet, Mr. Chair, but I have yet to experience it.

An hon. member: April Fool's Day.

The Chair: It sounds like a great idea for a private member's bill.

Mr. Matt Jeneroux: Yes, sure. You lead with that, Mr. Chair, and we'll see how that goes.

Getting back to the issue at hand, we had in front of us last week a Dr. Lennox. He was suggesting that there was an informal registry that already exists throughout his colleagues—he's through UBC—and obviously it's not publicly funded. Also, I'm looking at some of the other countries here: Sweden, the United States and Netherlands. They are all funded either by associations or by something similar.

I don't think the issue is so much.... On this committee, we've heard from all sides who want to ensure we're doing everything we can to protect those who are experiencing these illnesses. Going forward to your tree analogy, Dr. Morris, I thought that was rather apt. How do we get there? I guess that is the question facing this committee, at least in my opinion.

On the private versus publicly funded piece, I heard Dr. Greaves touch on the publicly funded piece. I might start with you, Dr. Greaves, and then go around to the two in the room here in getting the pros and cons for us to assess this question.

Dr. Lorraine Greaves: Thank you.

I think your witnesses last week talked about the various pros and cons of models for registries. As one of the prior witnesses today said, that's not my area of expertise, but I do think that aspects of public oversight are extremely important here in terms of making these registries mandatory and making sure that clinicians report quickly, especially about adverse events, but also in making sure that recalls happen.

I think that the Australian registry is publicly funded, and this does not mean that the government runs it, of course. It means that the funding appears and is sent to managers of registries, such as universities in the case of Australia, and in other cases, it's sent to professional associations.

I think the question of who runs it is different from who funds it, but I think, too, that it inspires some confidence in Canadians and the Canadian public. I think there needs to be the heft of the Government of Canada behind such a registry, and I think that, fortunately, the one advantage of waiting 33 years to do this is that there are extremely good records and now investigations and reviews—

● (1200)

Mr. Matt Jeneroux: I only have about a minute left, but I appreciate that.

Dr. Lorraine Greaves: I think we could rely on that.

Mr. Matt Jeneroux: I think that's a good assessment, for sure. Maybe we can move to Dr. Cohen Tervaert for comment.

Dr. Jan Willem Cohen Tervaert: I wasn't involved in the Dutch registry. In the Netherlands, the medical specialists affirmed the starting of the registry and then patients were invited to pay for it. That's mandatory. They do not opt out, but also, if they opt out, they still have to pay the $40 extra. Of course, for patients with cancer, it's reimbursed by health insurance, and for those patients who do it with cosmetic, it's not.

Mr. Matt Jeneroux: Dr. Morris, you indicated that you weren't an expert. Do you have any thoughts?

Dr. Steven Morris: I think that the European model.... There's a price per data point, so to speak, and the surgeons do the work of putting the data in. I think you need the legislative stick to ensure compliance, and there's going to be a cost to it. I think it has to be nationally run to ensure the trust of our patients that it's legitimate, but it's—

Mr. Matt Jeneroux: Is that CIHR, then, in your opinion?

Dr. Steven Morris: It could be. I'm not going to go there. I think you need your best people working on that, but I think it needs to be nationally run. The implant manufacturers will pass on the cost, so if you tax them $25 per implant, it goes into the fund and pays for the thing. Either way, government is going to pay for it, because half of the implants that are used for reconstructive purposes will come out of the public purse anyway.

The Chair: Thank you, Dr. Morris.

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

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

Thank you to everyone for appearing today.

Dr. Tervaert, in the middle of your presentation, I think you were going to talk about requirements for registries, and you had to shorten that. I'll give you a minute or so to elaborate on that.

Dr. Jan Willem Cohen Tervaert: Yes, one thing that is important is, of course, privacy. In the Netherlands, it is arranged that the patient data are anonymous. With up-to-date encryption, that's a very good idea, and that gives privacy a good perspective.

The other thing that is important is which data should be used. There is international consensus on the data. In Australia and the Netherlands, the same data are more or less registered, but, in addition, there should be a committee to look at the PROMs, the patient-reported outcome measurements, which are very important, I think.

Mr. Brendan Hanley: Thank you.

Dr. Morris and Dr. Cohen Tervaert, you both mentioned the basic categories of reasons for implants.

Dr. Morris, I'm wondering whether the reason for an implant, I guess, almost like the premorbid condition.... Are there differences in complications per category of reasons for implants? Maybe either of you could comment on that, or is this another area where we just don't have enough data?

Dr. Steven Morris: You know, I've been going to meetings and hearing papers on breast implants and breast reconstruction for 30 years. There's never been a consensus on anything. In fact, different surgeons will argue for different implant types.

Again, we just don't have enough data to make sweeping cases for that. There are certain body types that seem to lend themselves to certain localized complications, but these big things that we don't really know about seem to be random.

● (1205)

Dr. Jan Willem Cohen Tervaert: There are some recent updates.

There's a paper that's in press now from the first registry. This is a combined paper from the Australian, Dutch and Swedish registries, in combination with the small registry from the United States. In the United States, only 3% of the registry is done.

That paper clearly shows that complications are much higher in the reconstructive patients than in the cosmetic patients. There are about 15% reoperations within two years for the reconstructive patients versus only 3% in the cosmetic patients.

Importantly, however, we always say that 30% is reconstructive and 70% is cosmetic. In these registries, it was different. It was only 8% reconstructive and 92% was actually cosmetic, so we may underestimate the cosmetic number of breast implants a lot.

These registries now show that it's probably much higher for cosmetic and not reconstructive.

Mr. Brendan Hanley: Dr. Morris, in your practice do you see differences in outcomes?

Dr. Steven Morris: That's the problem with the data. Every surgeon has their own skewed patient experience. Mine has been mostly reconstructive over time. That's how useful it is to hear an isolated paper from an isolated surgeon at an isolated meeting. It's helpful. It's entertaining, but it's not useful.

Voices: Oh, oh!

Mr. Brendan Hanley: It's always refreshing to have someone understand their own limitations as an individual.

Dr. Greaves, you're a social science researcher and an expert in women's health. Do you see the fact that we don't have a breast implant registry as a gender equity issue? Is it more just that we have a general regulatory gap or maybe a lack of diligence or attention on monitoring medical device complications overall?

Dr. Lorraine Greaves: Both of those things are true.

It is a gender equity issue. Thirty years ago.... Some of the regulations surrounding breast implants—they're on the timeline in the document I gave you—clearly illustrate that you were late to including breast implants, among other devices, in regulations in Canada.

I think the overarching issue about medical devices in general is also true. We need vast improvements in those systems. Not the least is including sex- and gender-related issues in the data, and making more attempts to measure those things in submissions by industry and other areas.

I think the business of utilizing breast implants needs to be addressed in research—qualitative as well as quantitative—on what the reasons and motivations are. I think we have a responsibility via Health Canada and other efforts in Canada to spread knowledge and raise questions about the usage of implants and whether or not there are alternatives for women as they choose either cosmetic or reconstruction.

The Chair: Thank you, Dr. Greaves.

[*Translation*]

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

Mr. Luc Thériault: Thank you, Mr. Chair. I will try to be brief.

My question is for Dr. Cohen Tervaert.

When he appeared before our committee, Mr. Boudreau from Health Canada told us that there was not enough evidence to recognize breast implant disease as the Food and Drug Administration does.

You published an article in the Expert Review of Clinical Immunology entitled "*Breast implant illness: scientific evidence of its existence*". I would ask you to submit it to the committee. You can share with us what you concluded in your article.

I was saying to Mr. Boudreau that when you don't have the evidence, but you have to ensure the safety of women with respect to a high-risk device, you apply the precautionary principle.

What do you think of that?

[*English*]

Dr. Jan Willem Cohen Tervaert: I totally agree.

One of the issues in breast implant illness is that it's clear that patients do better after explantation. Most symptoms disappear. We recently published, just a few months ago, that a rechallenge, meaning when they had another implant, caused a failure in 70% of the cases. That's a very hard argument for scientific evidence: challenge, dechallenge and rechallenge.

I think Health Canada is wrong. There is a clear issue with breast implant illness. In the field of autoimmune disease, it's not debated. It's clear that there is a disease. More and more we are now going into the pathology of this disease. At the latest conference in Athens, there were posters, discussions of animal models, where, if you inject the serum of patients into animals, they can develop a similar disease as what has been shown in breast implant illness.

It's a matter of time, I think, to convince the world that it is a specific disease that can be treated with explantation.

● (1210)

The Chair: Thank you, Dr. Cohen Tervaert.

We'll have Mr. Davies, please, for two and a half minutes.

Mr. Don Davies: Thank you.

Dr. Cohen Tervaert, just picking up on my colleague's question, I think a physician's first admonition is to do no harm.

Unless I'm hearing wrong, I'm hearing a little bit of difference of opinion between Dr. Morris and you on how solidly these connections may have been made.

My question would be this: Do we know enough? Is there enough in the literature right now to at least give your average doctor or breast implant surgeon enough information to suggest that there is a significant risk of illness if they implant these devices in women or other people?

Dr. Jan Willem Cohen Tervaert: Yes, it's clear. In the Netherlands, already in 2013, the health authorities warned all plastic surgeons about breast implant illness, especially among those patients who have a history of allergies. Another important group of ladies are those who already have an autoimmune disease, or those who have a family full of autoimmune diseases. Those are clearly described risk factors. Of course, we need more research to develop better markers for who is really prone to develop this disease.

Yes, there should be warnings.

Mr. Don Davies: I'm curious. What is the state of a warning in Canada today? What's the guideline?

What would your average Canadian plastic surgeon be telling a woman or other person who may be coming for breast implants? Are they going through these three diseases? Do they have to do that? What are they telling them?

Dr. Jan Willem Cohen Tervaert: That's a question for Dr. Morris.

Dr. Steven Morris: In an informed-consent situation regarding a breast implant, a surgeon would generally discuss capsular contracture, number one; malposition or mechanical issues with not getting a great result; infection; hematoma, which is the collection of blood around the implant; scar-related issues; and extrusion, which is historical and I don't think that happens currently. We would discuss the rare chance of other things, such as anaplastic large cell lymphoma or autoimmune things, or other things we don't know yet. We don't know everything in surgery. With any of our surgeries, particularly ones in which you put something in the body that is meant to stay there permanently, we don't know everything about these things.

On breast implant illness, I've been doing breast implant surgeries for 30 years. We only heard about it really in the last five years. Before that, I had lots of breast implant patients I followed annually, and they had no problems at all.

What's the subset? Who's at risk? If someone has a history of autoimmune disease, that would certainly ring some alarm bells, but we really don't know. It's not that we're concealing it. We're not the implant manufacturers; we have nothing to gain. We're responding to patients who come to us wanting certain procedures.

Mr. Don Davies: Don't plastic surgeons have something to gain?

The Chair: Thank you, Mr. Davies. You're past time.

We'll have Mr. Aboultaif, please, for five minutes.

Mr. Ziad Aboultaif (Edmonton Manning, CPC): Thank you.

Thanks to the witnesses this morning. I have a few short questions for a few short answers, if that's okay. Forgive me, because I do have a lot of questions to follow.

The first question to all of you is this: Is a registry a must—yes or no?

Dr. Jan Willem Cohen Tervaert: Yes.

Dr. Steven Morris: Yes.

Dr. Lorraine Greaves: Yes.

Mr. Ziad Aboultaif: Should the registry cover implants done outside Canada?

Dr. Jan Willem Cohen Tervaert: Yes.

Dr. Lorraine Greaves: Yes.

● (1215)

Dr. Steven Morris: We should have an international registry, yes.

Mr. Ziad Aboultaif: There are many stakeholders regarding the registry, some for and some against. Who do you think would not prefer to have a registry, or would not be siding with having a registry in Canada?

Dr. Steven Morris: The main obstacle to creating a registry has always been funding. How do you organize it? How do you make it truly national? Those are things we can overcome.

Dr. Jan Willem Cohen Tervaert: It's the surgeons, especially surgeons working in private clinics who may be a little more difficult. That's why in the Netherlands they say that you will lose your licence if you don't do the registry.

Dr. Lorraine Greaves: I would agree. Those surgeries taking place in private clinics are probably the hardest ones to follow, and there may be the most resistance there.

Mr. Ziad Aboultaif: There was mention that it's been 33 years since the first discussion on having a registry, and so far nothing has been done. In the meantime, by the time we agree on a registry, and with all the complications of finding the proper legislation, can government regulations or ministry regulations replace some of the conditions that a registry can provide?

Dr. Jan Willem Cohen Tervaert: It's a governmental issue to have licences for private clinics. We have to realize that there has already been a registry for hip and knee implants for a long time. In many countries, there are cancer registries, so why not for this?

Dr. Steven Morris: Compliance is always a problem with a registry, and without 90%-plus compliance, the registry would have little value. It could be criticized, or it could be doubted. In order to have the trust of the Canadian population for the safety of breast implants, it's inherently the government's responsibility to provide that. I think you have a big stick in terms of legislation to ensure compliance.

Dr. Lorraine Greaves: As I mentioned already, the improvement of mandatory reporting of adverse events for all medical devices needs to happen quickly. In particular, it needs to be extended past hospitals and manufacturers to individual practitioners, private clinics and private settings, including long-term care homes and private clinics that have been promised but have not happened yet.

The other aspect of this is the consumer. Up until recently, the way to file an adverse event report for a consumer was very hard to understand and was quite obscure. That's been improved, but there's a long way to go to make that a much more publicly and well-understood system, so we could also get more reporting that way.

Mr. Ziad Aboultaif: Thank you, and feel free not to answer the next question.

Is the industry in favour of a registry, yes or no?

Dr. Steven Morris: I have never asked them.

Dr. Lorraine Greaves: I can't speak for the industry, obviously. I have seen examples where the industry has been supportive, but I don't have an answer to that.

Mr. Ziad Aboultaif: Dr. Tervaert, in terms of ASIA, which is a term you've used, can you expand on the impacts that different properties of breast implants have in relation to an increased susceptibility to develop ASIA?

Dr. Jan Willem Cohen Tervaert: When you implant anything in a human body, there is an immune reaction to that, so it's not specific to only breast implants. We see this more often in breast implants than in other implants, but it's still not specific. It is also the same inflammation that actually causes the contractures and the same inflammation finally causes ALCL. ALCL is, in fact, a mistake of the immune system by attacking. Dividing cells then go wrong and it's a lymphoma. It is a similar mechanism that is occurring in these patients.

● (1220)

Mr. Ziad Aboultaif: If there is—

The Chair: Thank you. That's your time.

Mr. van Koeverden, you have five minutes, please.

Mr. Adam van Koeverden (Milton, Lib.): Thank you very much, Mr. Chair.

Thank you to our witnesses. It's been extremely interesting.

I'd like to join my colleagues in first acknowledging that this is National Nursing Week. Thank you for bringing that up.

I would also like to say this to Dr. Tervaert, since last week was the Dutch Heritage Day in Canada and Liberation Day in Holland: As a Canadian of Dutch descent, I feel an obligation to say happy Dutch Heritage Day to you.

I think now that we've had a few meetings on this issue, it's less about the “if” and now about the “how”. We've kind of gotten over whether or not this would be a necessary implementation or consideration. Now we're starting to discuss the nuts and the bolts and the next steps.

I think it's important to acknowledge that Canada has some fairly unique challenges around health data. Federalism gets in the way of a lot of great ideas sometimes. In Canada, we have a patchwork of data privacy laws across the country. We're quite behind—a decade behind, if not more—in terms of being able to make that data interoperable and able to communicate.

I did have a recent meeting with some AI specialists to discuss the fact that there might be a faster solution to that than waiting 10 years for all of the systems to be changed. It's worth acknowledging that our government recognized the challenges with respect to data back in February and made data a pillar of our $198.6-billion investment over the next decade in our health care system with standardized health data and digital tools.

At the same time, the collection, the use and the disclosure of all of that data is still up to various provinces and territorial jurisdictions that don't necessarily talk to each other in the right language or in the same language. Moreover, those regulations are governed by provinces and territories in that health privacy legislation.

These are challenges unique to Canada. It's often said that Canada is 13 countries that pretend and try to be one. These are the challenges that face us as legislators. The fact that these privacy and data laws vary widely across the country might pose new challenges, but it's something that we need to tackle. For example, some provinces might also have to initiate legislation in order to be in compliance because there are certainly issues with respect to privacy. It will require more than one piece of legislation in order to get a registry in every province and territory.

Do you have any suggestions or solutions for overcoming some of these jurisdictional issues in the context of a registry in Canada?

That's a question for anybody, in fairly broad strokes. For example, have you ever been to a provincial committee meeting like this to discuss these health concerns?

Dr. Jan Willem Cohen Tervaert: The registration in Alberta is top. It's one of the best in the world. I'm not sure that the other provinces can do the same.

Dr. Lorraine Greaves: I can say that Australia may have addressed some of these questions with interstate issues. That might be worth investigating for the committee.

Secondly, one of the private member's bills that I mentioned in my timeline took place in Ontario, so at least at that point in time, there was some interest in one province around doing this, in addition to what we've already seen happen.

I do think it's an FPT issue, but that should not stop us.

Dr. Steven Morris: I thought this was the place where all those important decisions happened.

Voices: Oh, oh!

Mr. Adam van Koeverden: We try.

The other issue that came up was with respect to cost.

Can you point to any jurisdictions that have overcome these costs? Is it usually a government obligation to pay for these registrations or this registry overall, or is it something that industry or others can accommodate?

● (1225)

Dr. Steven Morris: I think the best approach going forward is at the federal level. Create it as a Government of Canada initiative through whichever agency and then make industry pay for it.

Dr. Jan Willem Cohen Tervaert: I'm not sure that it's making industry.... It's making patients.... I mean it's your choice to do the cosmetic surgery. If you have reconstruction, it will be paid by the insurance.

Mr. Adam van Koeverden: In Alberta, Dr. Tervaert, you mentioned it's world class. How is it paid for in Alberta?

Dr. Jan Willem Cohen Tervaert: It's not clear. I don't know.

The Chair: Thank you both.

We'll go over to Dr. Ellis, please, for five minutes.

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

Thanks to the witnesses for being here.

We've talked about this issue for a very long time. Part of the question I have is this: Why wouldn't we do this? Here we are. We've been putting implants in people for decades now. We obviously know they're foreign objects. Why would we not want to track that and have more science?

From my perspective, it seems really quite simple. Maybe we're just arguing about perfection being the enemy of progress.

I'd love to hear from the witnesses. Do you have any objections to doing this? What would be the downside of doing it?

Maybe we can start with you, Dr. Morris.

Dr. Steven Morris: Dr. Ellis, my fellow Nova Scotian, there are a lot of obstacles. That's why it hasn't been done. It's tough. It's going to be a tough, uphill slog to get everybody on board.

The best brains session was excellent, but there were perspectives on it that I hadn't even thought of before. I think we have to get everybody to the table who has something to offer, improve the registries that are out there internationally, figure out the funding model and execute it. The surgeons will come on board, as in the Netherlands, when it's mandatory. There will be immediate compliance with that. I think everyone gets that we need the data, and the only way to get the data is to roll up our sleeves and do it. Then have constant surveillance on it.

Inertia is the hardest thing to overcome.

Dr. Lorraine Greaves: I would agree with you that perfection is in the way here of launching something. I don't think it should be.

I prefer to think about this from the point of view of the women and other patients who are receiving these. To me, we have a huge obligation to them that we have not fulfilled over the last 30 years. That needs to be done, even with an imperfect registry.

Dr. Jan Willem Cohen Tervaert: Yes. I think the big issue, compared to the Netherlands, is that the surgeons who put in the breast implants here are less well organized. In the Netherlands, it's easy to say, "Okay, you lose your licence as a plastic surgeon if you don't agree," but here, that will be a little more difficult, I think.

Mr. Stephen Ellis: Thank you all for the answers.

Through you, Chair, we've heard about an implant registry for orthopaedic devices. Obviously, that has been in existence for some time. In my mind, I can't see a reason why we wouldn't piggyback—I'll use that term—onto such a registry. To say that it already exists.... I realize they're different. That being said, the basic information that's collected....

Perhaps you don't know anything about it, and that's okay, but does that seem a reasonable starting point, considering it already exists at a federal level? Do you have any comments on that?

Let's go in the same order, if we could, please.

Dr. Steven Morris: Thank you.

That's a great model, because they picked up some things that changed patient care and ensured greater safety in the OR. I applaud them for doing that, and I think that would be a great model in Canada to at least study.

Dr. Lorraine Greaves: Yes, I would agree. That and other international examples of breast implant registries are informative here.

I think the issue of health care utilization should concern Health Canada and the rest of us, especially with current crises in the health care system. There are lots of really good motivations for tracking these matters, in addition to trying to reduce the usage of breast implants in general by having much better education for patients.

● (1230)

Dr. Jan Willem Cohen Tervaert: An issue would be medical tourism, at least from Alberta's experience. Many patients had breast implants in Mexico or elsewhere in the world.

Mr. Stephen Ellis: That's a great point. Thank you.

I have one further question, Chair.

Dr. Morris, you talked a lot about the alternatives with respect to reconstruction. Obviously, the newer surgeries, the TRAM flaps, etc., create significant issues in terms of time under anaesthesia, recovery, etc. If we understand that the newer techniques take longer and breast implants are much quicker to be done.... Perhaps that's the reason.

That being said, if we don't see breast implant surgery going away any time soon, we obviously need to sort out some of these issues, like ASIA, BII and ALCL. Does it make sense that we need to study this more closely?

Dr. Steven Morris: Absolutely. I agree completely.

The Chair: Thank you, Dr. Morris and Dr. Ellis.

Dr. Powlowski is next, please, for five minutes.

Mr. Marcus Powlowski (Thunder Bay—Rainy River, Lib.): I have a whole bunch of questions. Some of these didn't come up earlier.

Textured implants, I understand, have a much higher incidence of anaplastic large cell lymphoma, so I assume you're not putting them in anymore. Are you actively taking them out when somebody has an implant?

Dr. Steven Morris: I haven't put any in, so fortunately I don't have to take any out.

Mr. Marcus Powlowski: Are other surgeons...?

Dr. Steven Morris: It's certainly a discussion point. The surgeons who are able to track their patients and have tracked them bring them to the office, have the discussion and explain the situation. However, that leaves about 80% of patients who aren't identified.

Mr. Marcus Powlowski: Okay, that was exactly where I wanted to go.

Right now—or in the past—when a surgeon put in those implants, there was no onus on them to notify the manufacturer that this individual received one of their implants. Is that right?

Dr. Steven Morris: There are multiple layers to the answer.

In Canada, since the 1990 moratorium, we've been delivering our data back to the implant manufacturers, but that was a black hole. We didn't get any data back. The implant manufacturers should have some records of that in Canada, but we don't ever receive that.

Mr. Marcus Powlowski: Some records.... That means that when—and I know you didn't put those implants in—surgeons were putting those implants in, they were expected to.... Were they sending the individuals' names and addresses to the manufacturers of the implants?

Dr. Steven Morris: I believe so.

We've been doing that with our implants with a different company, but I've never received anything back from the company saying, blah, blah, blah. I don't know how long they keep the records, and I don't know what they do with the data, but this committee could find out.

Mr. Marcus Powlowski: Given that they may have a list of people who had that higher risk implant, do you know if the manufacturers have been actively trying to locate and notify those who've had those implants?

Dr. Steven Morris: I'm not sure, but the surgeons I know who had patients like that were going through their records to identify those patients and offer a follow-up.

Mr. Marcus Powlowski: In the absence of the industry's taking this on, it's been left to the individual surgeon—and hopefully most of them had that sense of responsibility—to go through all their records to find out who had these implants and then identify.... Given the fact that we haven't had a registry, this has been the kind of de facto system that people have been using.

Dr. Steven Morris: I can't speak exactly to the details, but I think that's the case.

Mr. Marcus Powlowski: Okay.

I worked in developing countries where I did a fair bit of surgery. I worked a long time in the emergency room. We, as doctors, leave a lot of sutures in people but certainly also coils, stents and replacements. Is there no requirement for the makers of these things that we have historically left in people to do trials beforehand to ensure the safety of what we're putting in people, as they do, for example, in pharmaceuticals, where we have to have phase one, phase two and phase three trials? Is there no equivalent to that for implants?

Dr. Jan Willem Cohen Tervaert: Unfortunately, no.

Mr. Marcus Powlowski: In no jurisdiction in the world is there that requirement.

Dr. Jan Willem Cohen Tervaert: No.

If a stent is already registered, a new stent with a different.... It should only be showed that it's equivalent to the old stent. There are no large, randomized controlled trials before they are entered into the market.

● (1235)

Mr. Marcus Powlowski: In both of your opinions, ought there to be such a requirement before putting such a product on the market?

Dr. Jan Willem Cohen Tervaert: I used to be a member of the committee for pharmaceuticals in the Netherlands. My opinion was always that medical devices should be at the same level as medications, but it's nowhere.

Mr. Marcus Powlowski: Dr. Morris.

Dr. Steven Morris: It makes a lot of sense, and I'm not exactly sure what breast implant manufacturers do before they bring something to market. I don't actually know what they do.

I'm sure they have some beta testers, but I'm not sure how rigorous it is.

Dr. Jan Willem Cohen Tervaert: The history of this comes from the fact that we were so happy with medical devices. There was such an urgent need for these things, for new technology for patients, that the FDA, especially, decided not to have all of these difficult questions before one could be entered in the market.

Mr. Marcus Powlowski: Did I hear you correctly that in the U.S. only 3% of women who have implants—

The Chair: Thank you, Dr. Powlowski.

[*Translation*]

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

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

Dr. Morris, you talked earlier about the barriers to setting up a registry. On the one hand, you're saying that we shouldn't rely too much on manufacturers. That's what your brief says. On the other hand, in response to my colleague Mr. Davies, you said that surgeons have nothing to lose, but if the registry were not mandatory, they would not get on board. I'm not trying to catch you off guard; I just want to understand.

Why would they not get on board? Why would they resist?

[*English*]

Dr. Steven Morris: It's because it's an effort. It's extra work. The surgeons are very reluctant to participate in studies, because it takes an extra effort to collect the data and submit the data. That's obstacle number one in almost all of the clinical studies that I've been around in my experience.

To get good data, you need compliance, and compliance can't be voluntary. My point is that there has to be mandatory compliance amongst the surgeons to collect the data.

[*Translation*]

Mr. Luc Thériault: This resistance might make us question informed consent. Shouldn't there be a standard form in which all the issues are well listed and which should be signed by both the surgeon and the patient?

If it is complicated to participate in a registry, it is also complicated to explain all of the risks associated with implants, right?

Dr. Steven Morris: Yes.

Mr. Luc Thériault: Well, at least that was clear.

You mentioned earlier that there was little data and information. Over the past 10 years, has there been a trend among surgeons to attend symposia to stay informed and receive ongoing training with regard to implant issues, so they can be informed when they talk to their patients?

According to the pharmacological model, pharmaceutical companies are often the ones that provide ongoing training to physicians. I don't think that's a good thing, but that's the reality. Do surgeons have the independence and willingness to seek out more information in the interest of being better informed so they can give a fuller picture to their patients?

[*English*]

The Chair: Could you give us a brief response, if possible?

Dr. Jan Willem Cohen Tervaert: I can answer that question. I've been invited by surgeons to talk about mesh implants. I've been invited by orthopaedic surgeons to talk about orthopaedic implants. I've never been invited by plastic surgeons to give a talk on breast implants.

● (1240)

The Chair: Go ahead very briefly, please.

Dr. Steven Morris: We go to meetings every year and we listen to presentations about safety issues, about which implant is better, about which has the lower complication rate. It's absolutely part of our DNA to always try to do the right operation and use the right materials for it. It's a constant discussion in our specialty. I might go to four or five different scientific meetings a year looking for improved techniques. It's part of what we do all of the time.

The Chair: Thank you, Dr. Morris.

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

Mr. Don Davies: I'm curious as to whether any of you know what the general ballpark global economic value of cosmetic breast implants is, and what that figure might be in Canada.

Dr. Jan Willem Cohen Tervaert: I have a slight idea but I don't know it by heart, so I would have to look it up. It's a lot.

Dr. Steven Morris: In preparing for this appearance, I heard one estimate of two million breast implants per year in the world.

Mr. Don Davies: Do you know what it is in Canada?

Dr. Steven Morris: No. I'm sorry.

Mr. Don Davies: Dr. Greaves, do you happen to know?

Dr. Lorraine Greaves: No, I don't.

Mr. Don Davies: Okay.

I'm trying to figure out who's ultimately responsible for the safety of these devices. Is it the surgeon who puts them in? Is it Health Canada who is charged with regulating these and presumably protecting the public from having unsafe devices implanted in them? Is it the manufacturer, or is it all three?

Dr. Jan Willem Cohen Tervaert: If you compare it with medications, we doctors are responsible for the medication we prescribe, although, of course, the manufacturer has to give the medication as it is. If we prescribe, for instance, penicillin, it should be penicillin. It shouldn't be something else. There is the regulatory factor, but as a doctor, we are responsible for the side effects of the penicillin. We have to explain to a patient that there could be an allergic reaction, and that their allergic reaction could even be very severe.

Mr. Don Davies: Do you see any potential liability of Health Canada by not having a breast implant registry?

Go ahead, Dr. Greaves.

Dr. Lorraine Greaves: Yes, I do. Health Canada is responsible for the management of drugs and devices, among many other things. That means they're responsible for the quality of the submission data they request from industry, the review of it, the collection of adverse events, postmarket vigilance and then reviewing and perhaps amending regulations surrounding devices and drugs as a result of that circle of evidence that is constantly being reviewed.

Health Canada is responsible for that regulation. It is also liable when things go wrong. That's another aspect to this. It's not just on breast implants, by any means, but on all drugs and devices that need to be reviewed. We certainly have a history of examples of that, such as thalidomide drugs, for example. They were used in Canada in the fifties and early sixties and were not used in the U.S.A. because of different regulatory decisions.

Yes, Health Canada is responsible for this.

Mr. Don Davies: Thank you.

The Chair: Thank you, Dr. Greaves.

Dr. Ellis, you have five minutes, please.

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

It's an interesting discussion. I guess I still can't wrap my mind around the fact that surgeons want it and patients probably want it, although they're not really sure they need it. I guess I can't understand why we don't just move on. I realize it's expensive, etc., but it only makes common sense.

I guess the other thing I would point to is that, in my mind, the manufacturers do bear some complicity in this and some reasonable amount of need to be part of the system in the sense that, if you own a car and something happens to it, you get a notice that there's a recall. Your manufacturer sends you a notice telling you that you'd better go in and get it fixed. I realize that there's a middle person in here—namely, a surgeon—and that may make it more difficult.

That being said, Dr. Morris, you talked a bit about the textured implants. Maybe you could tell us a bit about that process.... Obviously, it's not textured in your sense, so it'll keep you away from the manufacturers. However, if you were to choose a particular implant for a patient, tell us a bit about how that's tracked or what's happening at the current time just so that we can understand that.

● (1245)

Dr. Steven Morris: That's a complicated question. You know, if you grow up in a Ford family, you tend to drive a Ford. It's the same kind of analogy.

I'm not.... That's no plug for Ford.

Voices: Oh, oh!

Dr. Steven Morris: You tend to adopt a lot of the things that you saw worked for the surgeon who trained you. I worked with surgeons who liked smooth, round company A implants. That's what I used. I didn't see anything at all those meetings I attended that would dissuade me from that. It was a good choice, because those ones hadn't really caused any problems that we know of.

The textured implants were introduced by the company. It doesn't sound like they went through a rigorous FDA-type drug evaluation, but they were introduced because that interface between the texture and the capsule of the body—the response—was supposed to lessen that capsular contracture. It was all about trying to innovate to reduce a complication, and they created a different complication. It's like introducing a different animal in Australia to get rid of a problem: You create another problem.

The whole choice of implants has historically been surgeon-biased. To answer the earlier question about whether there's bias in the literature, there have been well-documented studies that there's bias in every aspect of the scientific literature, whether it's recognized or not. Industry is a classic example of producing biased research findings.

When you have a patient demand for the service and you have a limited number of options, you pick which one you think is good. You check with your colleagues, you go to meetings and you try to be aware of your patients' needs.

Mr. Stephen Ellis: When you chose that implant A, let's call it, for patient X, there must be a documentation process in the medical record. You document the serial number, the manufacturer and so on. What happens then to that information?

Dr. Steven Morris: I dictate it into the operative record. I provide the patient with a copy of the implant detail, and we send a copy to the implant manufacturer.

I always thought it was a bit odd and that it should maybe go some place other than the company that just sold us the implant, particularly if there were failures. We send them back to the company, but that's not very transparent because we should have access to that data.

Mr. Stephen Ellis: Realistically, Dr. Morris, company A knows that patient X had that particular implant procedure done by you. Theoretically, if there were problems with their implant, could they let the patient know independently of you?

Dr. Steven Morris: I'm not sure they would have all the demographic information, so possibly.

Mr. Stephen Ellis: On the other hand, they could notify your office and say, “This patient 10452 had this particular implant A implanted. We know there are problems with it.” That's another avenue through which this could happen as well.

Dr. Steven Morris: Yes, absolutely.

Mr. Stephen Ellis: All in all, there is a registry of some sort that exists. It's just not accessible to those who might want the scientific data associated with it to perhaps better understand illnesses like BII such as Dr. Tervaert.

Is that fair, Dr. Tervaert?

Dr. Jan Willem Cohen Tervaert: No, I see it the other way.

Patients come to me with complaints. Then I ask what brand they have, and whether it's textured or smooth. Most patients don't know. I ask them if they can contact their plastic surgeon. Even then, several patients come the next time and say that they couldn't find it, that there was no registry and that it's not known.

It is not as perfect as it should be.

Dr. Steven Morris: It's not at all perfect. In fact, with the limitations of the medical records, those records will only stay in the office for seven years. The surgeon may retire, move or die, and the records are lost.

● (1250)

Mr. Stephen Ellis: Thank you.

The Chair: The last round of questions will come from Mr. Jowhari.

After that, there is going to be a request for some documents as well.

Go ahead, Mr. Jowhari.

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

I'll be splitting my time with MP Thériault.

Dr. Morris, I'm going to point my questions at you. You talked about medical tourism. We've seen people travelling to other destinations to combine getting a breast augmentation with having a recreational getaway becoming a lot more prevalent. You talked about Mexico. We know Turkey is becoming a hub for a lot of plastic surgery, as well as Colombia.

What procedures do we need to make sure are in place for those patients who are seeking to get those augmentations or those procedures done to ensure we can get access to those records? Do we have procedures in place to know the type of implant that's been put in there, whether they're approved by Canada, when the procedure was done, and who the doctor was? Can we trace it?

Those are some of the challenges, and I think you touched on them.

You have about a minute to respond to that before I yield the floor to my colleague. I think that's an area we really need to address.

Dr. Steven Morris: It's a very interesting and important question, which I can't answer because these patients don't even come to see the plastic surgeon before they leave. They make contact with a surgeon in a different country, probably because somebody in their family has already been there. I think that is education. I think that we have to get the message out that there are potential consequences.

We see the complications of those procedures. We'll pick up certain complications related to the medical tourism.

Mr. Majid Jowhari: Dr. Tervaert, have you seen anything like that in Holland, and how did you manage it?

Dr. Jan Willem Cohen Tervaert: I've seen that medical tourism is a big issue in Canada as well. We see the complications.

Mr. Majid Jowhari: Okay—

Dr. Jan Willem Cohen Tervaert: Generally, as to your question asking if all these implants are on the market here, the answer is no. They're not.

Mr. Majid Jowhari: Thank you.

That's my two and a half minutes.

I'll yield the floor, Mr. Chair.

[*Translation*]

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

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

Before asking for documents, I'd like to ask you a quick question, Dr. Morris: will you ask Dr. Cohen Tervaert to send out the science so that he can enlighten your surgeons?

Dr. Steven Morris: Absolutely.

Dr. Jan Willem Cohen Tervaert: That's great.

Mr. Luc Thériault: Mr. Chairman, I may have rushed things a little bit earlier. I would like Dr. Greaves to make note of the documents we are asking her to provide.

At the end of the document, there is a Summary of Recommendations by your Scientific Advisory Committee for the February 23, 2021 virtual meeting. It states that the Record of Proceedings is available upon request and asks people to submit their request to the listed email address. We did that over a month ago already, but we have not received anything yet. So I would ask that you send the committee the Record of Proceedings from all of your scientific advisory committee meetings.

Dr. Cohen Tervaert, you told us about a recently published article. I would like to have this article sent to the Committee so that my colleagues and I can review it.

The Chair: All right.

[*English*]

Dr. Powlowski was looking for some documents as well, and then we can wrap it up.

Mr. Marcus Powlowski: Out of this we're going to produce a report that goes to Parliament and which hopefully will be the basis of further government action.

We can take into account both testimony but also what's been submitted. I think it was Dr. Tervaert who mentioned that only 3% of women in the United States who receive implants are part of the registry. If you have any documentation about those numbers and why so few are in the registry please submit it, so it could become part of our report.

Thanks.

● (1255)

The Chair: On that, for all of our witnesses, you absolutely have the right to provide any further materials in written form that you think might be helpful to us, in addition to what's been requested. If you think there's anything else we should have, we'd like to have it.

Colleagues, we have about five minutes remaining.

If there's anybody else who wants to pose a question in the last few minutes, please do. We don't have time for a full round. If not, I have two other items I want to raise before we wrap up.

[*Translation*]

Mr. Thériault, you have the floor.

Mr. Luc Thériault: I would like to return to my question about independent ongoing training offered to surgeons as compared to that offered by industry.

Is industry tied to many of the symposia offered to surgeons to provide ongoing training, as is the case in the pharmaceutical field, or do surgeons have more autonomy and can participate in scientific symposia that are truly independent of industry interests?

[*English*]

Dr. Steven Morris: They're completely independent. Our education doesn't come from industry. It comes from other surgeons. It's frowned upon to have industry supporting educational events, but it was not that uncommon in the past. Maybe 10 or 15 years ago, it would be common for industry to support educational events, but now there's a very strict line separating education from industry.

The Chair: Okay.

I opened this door. Let's go with one question each.

We'll start with Dr. Powlowski, then Dr. Kitchen and then Mr. Davies.

Mr. Marcus Powlowski: I think it was Dr. Tervaert who mentioned breast impact illnesses.

Did you say it was kind of an autonomic neuropathy that was related to inflammation? Is that what it is? Could you please clarify that?

Dr. Jan Willem Cohen Tervaert: It's called dysautonomia. It's something in the autonomous nervous system that goes wrong. For instance, a typical issue is your eyes or mouth being very dry. That's something in the autonomous nervous system, and it can be transferred to animal models.

The Chair: Go ahead, Dr. Kitchen.

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

Thank you all for your presentations. It's greatly appreciated.

My question is actually.... The chair indicated you could submit further information to the committee. I would be interested to know whether you would be prepared to do so and to provide, without going into a great deal of detail, what you think should be collected in that registry—in particular, signs, symptoms and aspects of things you think should be specifically reported, so that data is included.

If you could provide that to the clerk, it would be greatly appreciated.

The Chair: Thank you, Dr. Kitchen.

To wrap up, it's Mr. Davies.

Mr. Don Davies: I just want to give Dr. Greaves a chance for the last word.

Sometimes, when you're the witness online, you don't get the same presence. I want to give you the last minute or so to leave us with your thoughts.

Dr. Lorraine Greaves: Thank you. I appreciate that.

I mentioned a couple of times that I think we have omitted paying any attention to the motivations for requesting implants among patients, whether cosmetic or reconstruction. I think this is a big omission that could go some way to improving the general health of women in Canada and those requiring or requesting implants. Pay some attention to those motivations, and then do some education around them. It's not clear, but some of those motivations are around body image—predominantly the body-image pressures girls and women face that lead to cosmetic requests.

With respect to reconstruction, we know from some cancer survivors that they face the question of whether or not they should reconstruct. The pros and cons of doing that are often related to body-image issues, as well. There's an entire area here that I haven't heard a lot about in research—which was not even discussed today—and that could go a long way to reducing the use of implants.

You heard one of the other witnesses say he would not recommend this to his daughter. I certainly wouldn't recommend this device to anyone I know. The best breast implant is probably one that is avoided. I think we have an obligation to begin to think about that as well and to collect some data on motivations. Then, from those in a registry who have had implants, collect data on whether or not their resulting mental and physical symptoms are improved or not improved.

Those would be some of my final comments. Thank you.

● (1300)

The Chair: Thank you, Dr. Greaves.

I'd like to thank our witnesses for being with us here today. The depth of their experience and expertise is very clear, and the information they provided will undoubtedly be valuable to us as we start to put together some recommendations from here, going forward.

Thank you for taking the time and for being so patient and thorough in your answers.

I have two items before we adjourn.

Colleagues, later today, we will receive documents from witnesses who appeared for the study of the Patented Medicine Prices Review Board. These will need to be translated, so there will be a delay. We will ask the translation bureau to prioritize this request so that we have it back as soon as possible.

On another note, it is with some regret that I have to inform you our illustrious analyst Sarah Dodsworth is going to be leaving us. She's not going far, but she will no longer be attending committee meetings and providing the excellent service we have enjoyed during her tenure. I'm sure you'll join me in wishing her all the best in her new responsibilities within the Library of Parliament.

Voices: Hear, hear!

The Chair: Would you like to give a speech, Sarah?

Voices: Oh, oh!

The Chair: Is it the will of the committee to adjourn the meeting?

Some hon. members: Agreed.

The Chair: We are adjourned.