HOUSE OF COMMONS
CHAMBRE DES COMMUNES
CANADA

44th PARLIAMENT, 1st SESSION

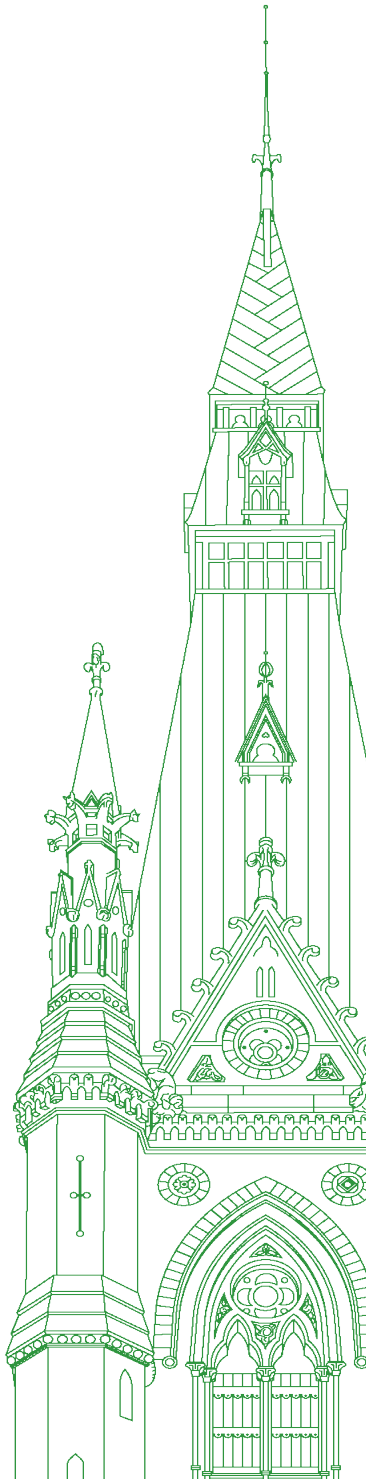
Standing Committee on Health

EVIDENCE

NUMBER 066

PUBLIC PART ONLY - PARTIE PUBLIQUE SEULEMENT

Thursday, May 4, 2023



Chair: Mr. Sean Casey

Standing Committee on Health

Thursday, May 4, 2023

● (1105)

[*English*]

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

Welcome to meeting number 66 of the House of Commons Standing Committee on Health.

Today we will continue our study on the oversight of medical devices and a breast implant registry during the first hour. We're then going to proceed to committee business in camera for the second hour.

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

I'd like to make the following comments for the benefit of witnesses and members.

Both of our witnesses are appearing by video conference today. For those appearing by video conference, click on the microphone icon to activate your mike, and please mute yourself when you are not speaking. For interpretation, you have the choice at the bottom of your screen of either floor, English or French audio.

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

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

I would now like to welcome the witnesses, who have joined us by video conference today. We have with us Dr. Peter Lennox, clinical professor, division of plastic surgery, at the University of British Columbia, and Dr. Stephen Nicolaidis, assistant professor of surgery, Université de Montréal.

Thank you for taking the time to be with us today.

We're going to start with you, Dr. Lennox. You have five minutes for an opening statement.

Welcome to the committee. The floor is yours.

Dr. Peter Lennox (Clinical Professor, Division of Plastic Surgery, The University of British Columbia, As an Individual): Good morning. Thank you very much. I thank the committee for the opportunity to speak before you.

By way of background, I'm a past president of the Canadian Society of Plastic Surgeons and the Canadian Society for Aesthetic Plastic Surgery. My tenure in those roles coincided with the significant increase in the number of breast implant-associated anaplastic large cell lymphoma cases in Canada, which our members were seeing clinically. At that time, there was a significant gap between the numbers that Health Canada had and that our members were seeing in clinical practice.

We started tracking those numbers voluntarily and created a database that our societies still maintain. I started communications with Health Canada at that time to try to get a better sense of—specifically at that time—breast implant ALCL.

I had multiple conversations with them. This was around 2016 or 2017. At that time, it was our societies' recommendation that there be a breast implant registry in Canada so that we would have better information for an event like ALCL. Unfortunately, the communication that was given back to us was that it was not the mandate of Health Canada. It seemed a bit unusual to us that in the organization tasked with improving the safety of medical devices it was not within their mandate to continue to track those devices in the long term.

Certainly, there already exist medical device registries in Canada. The largest one is the orthopaedic joint registry, which is managed by CIHI. Our organizations have approached CIHI in the past—again, without any success.

We're the only G7 country that does not have a breast implant registry, which is concerning.

Subsequently, I think because of the work we did, I've been asked to speak internationally on medical device registries. I've provided you a copy of one of those talks. There's very good, clear evidence about the value of medical device registries, and of breast implant registries in particular, and clear guidelines as to what constitutes an effective registry. That work has been done. It doesn't have to be duplicated. I'm happy to answer questions about what data needs to be collected.

As somebody who treats women both with reconstructive breast implants and with aesthetic breast implants, it's my sincere personal belief that the time is here for a breast implant registry in Canada, and I believe it's the belief of our professional organizations as well. It would allow us to have more accurate information to give to Canadian women regarding the risks and benefits of these devices, and it also would allow the opportunity to track them in the long term if events like anaplastic large cell lymphoma develop in the future. We'd have a way of tracking those patients and providing them accurate information.

Thank you.

The Chair: Thank you, Dr. Lennox.

Next we're going to hear from Dr. Stephen Nicolaidis, assistant professor of surgery at the Université de Montréal.

Dr. Nicolaidis, you have the floor for the next five minutes. Welcome to the committee.

Dr. Stephen Nicolaidis (Assistant Professor of Surgery, Université de Montréal, As an Individual): Thank you for the opportunity to present to you.

As a Greek, I guess my presentation is a bit more emotional—I apologize. I want to point out that you're going to be hearing from some patients, like Julie Elliott and Terri McGregor, who've now spent the better part of their lives as breast implant safety advocates because their lives were turned upside down by breast implants. There are thousands more just like them. Many Canadian women have now died as a direct result of breast implants. Yet, as a physician, despite being a plastic surgeon, my Hippocratic oath is to do no harm.

I'm here because I consider that my speciality of plastic surgery, along with the breast implant companies, have failed patients on a colossal scale by not identifying and addressing the various problems caused by breast implants in a timely manner. Had there been a registry from the beginning, these problems would have been recognized, obliging breast implant companies to be more proactive rather than reactive. Instead, patients have had to pay the price by falling ill, or worse yet, dying.

Breast implants were introduced in 1962. Within a year, there were patients with inflammatory conditions and what is now referred to as breast implant illness, or BII. Dr. Lennox was talking about ALCL, which I'll address a bit, but I'm focusing a bit on breast implant illness.

In the absence of a registry, these individual complaints were brushed aside by both breast implant companies and plastic surgeons, with the claim that breast implants were completely benign. This is way back when, in 1963. Instead, patients were made to feel as though they had mental illness. No studies were performed by the breast implant companies. They were too busy making money.

These patient complaints and no studies continued for 30 years, leading up to the famous Dow Corning lawsuit settlement between 1994 and 1998. The Food and Drug Administration in the U.S. was compelled to withdraw gel implants from the market in 1992, because breast implant companies had failed to ensure and document the safety of their implants. In the following years, a number of small studies suggested the safety of breast implants. The problem is that these studies that appeared were performed by plastic surgeons who were receiving funding from breast implant companies. Conflict of interest is a huge problem when it comes to breast implant safety, and it's easy enough to understand that a plastic surgeon who's being paid by a breast implant company cannot be relied upon to study breast implants in a neutral fashion.

Moreover, with an illness as complex and multifactorial as BII, large studies with thousands of patients have to be performed, something that can only be achieved with a registry. In fact, Fryzek and Watad looked at thousands of patients in the Danish and Israeli registries, respectively, and they found that patients with breast implants did in fact have a higher incidence of rheumatic problems. Nevertheless, these numerous small studies performed by breast implant consultants suggested the safety of breast implants, along with a huge push from a billion-dollar industry, and that convinced the FDA to return gel implants to the market in 2006.

For another 10 years, patients continued to experience BII, but now they were told the studies by reputable American plastic surgeons proved that breast implants were benign. If it weren't for the recognition of that lymphoma in 2016, which Dr. Lennox referred to and which was caused by textured implants, breast implant companies would still be telling patients that their implants were perfectly benign.

Given the absence of a registry, as Dr. Lennox mentioned, this lymphoma was felt to occur very rarely—they said one in a million cases—such that some plastic surgeons even questioned whether they should mention the risk of lymphoma to patients. To give you an idea of just how bad conflict of interest can get, a leading breast implant consultant in the U.S. was so defensive of breast implants that he argued that the lymphoma was caused by poor surgical technique rather than the implant texturing. That issue may have delayed the voluntary recall of Biocell implants, which are now recognized to result in lymphoma in somewhere in the order of one in 400 cases—hardly one in a million.

● (1110)

Here I am, sitting in front of you, 61 years after the introduction of breast implants. I'm taking out breast implants that are making my patients sick and that my colleagues keep putting in.

When patients ask me the simple question of why they're getting sick from their breast implants, I don't have a definitive answer to give them, because we don't have enough data. Why? It is because we don't have a registry.

Thank you for your time.

The Chair: Thank you, Dr. Nicolaidis.

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

Dr. Ellis, you have six minutes.

Mr. Stephen Ellis (Cumberland—Colchester, CPC): Good morning everyone.

Thank you to the two plastic surgeons for being here today. Obviously, this is an important study that we need to get right on behalf of Canadians.

Through you, Mr. Chair, I will start with Dr. Lennox.

You talked about the orthopaedic joint registry, which exists within CIHI. Very simply, the question is this: Could the breast implant registry piggyback on the CIHI registry? I realize these are not orthopaedic devices. That being said, if that style of registry already exists, why do we need to create another one? We need a patient registry.

I'd like your thoughts on that, sir. Thank you.

● (1115)

Dr. Peter Lennox: That's an excellent question.

I don't know all the specific data points of the orthopaedic joint registry, as I've never had to access it, use it or upload patients to it, but I think the format...and, certainly, being housed by CIHI.... One of the criteria for a good registry is that it be independently housed and independently funded, so government or universities are the logical places.

CIHI would be an excellent place. It could certainly piggyback on...in terms of the location of the data and how the data is stored and accessed. The specifics, in terms of the data you collect and how it's identified and everything.... I'm not exactly familiar with the orthopaedic one, but it would certainly be a reasonable model to start with.

Mr. Stephen Ellis: Thank you very much.

Once again, through you, Mr. Chair, to Dr. Lennox, this sounds self-evident to me, but it obviously hasn't been done. Dr. Nicolaidis talked about it being 61 years since implants have been offered.

Is there any downside to having a registry? Obviously, there's cost, but what are the other potential downsides?

Dr. Peter Lennox: There are some criticisms that have been raised about a registry. Specifically, there are some criticisms around consent—in the medical world, if it's a quality registry, you don't actually have to have patient consent—and how you collect the data. An opt-out registry is the one that's most effective, meaning patients have to specifically ask not to be included, as opposed to asking to be included.

One of the other criticisms is on what they do with the data. Any registry or research tool is only as good as the data put into it. You have to maintain a registry, keep track and make sure the data is updated.

The bottom line, I think, is that there is no downside to having a registry. It will hopefully allow us to see these things developing in real time, as opposed to, as Dr. Nicolaidis said, having to react and scramble to provide appropriate care and notify patients. That was one of the hardest things with the ALCL issue—tracking down patients who had textured implants, because there was no repository. Even the implant manufacturer companies, which were supposed to track that data, didn't do it effectively.

Mr. Stephen Ellis: Thank you very much.

Through you, Mr. Chair, to Dr. Nicolaidis, I was a family doctor for a long time. It seems unconscionable that we would put things in people's bodies without knowing whose they were in, what the serial numbers were and those kinds of things. Could you imagine someone putting in a pacemaker, not knowing whether there was a recall on it? It seems absolutely ludicrous. I guess I can't understand why CIHI or any other government agency would hesitate on this.

That being said, my question for you, sir, is this: Do we need more study on implants in general, and would you encourage a study here at the health committee, with a view to making recommendations to Health Canada on the safety of implants? Are we there now, or do we need the registry first to gather more data?

Maybe you could give us an idea about that, Dr. Nicolaidis.

Dr. Stephen Nicolaidis: As I said, they've been around for a long time, and it's easy enough to say, “Let's do some research to prove their safety.” That was done in a half-assed fashion after the withdrawal of gel implants in the U.S.

The bottom line is numbers. To really understand these things, you have to look at huge numbers, not 20 or 30 patients, which has classically been done in the typical studies that were done by the implant companies and their consultants. You need thousands of patients, so that's where the data comes in.

It's not a question of trying to reinvent the wheel. They have a registry in the U.S. that is collecting data. As Dr. Lennox mentioned, the data is okay, but we need to tweak the data to get better information, because it's really with large numbers that we're going to be able to figure things out. The implant companies have pushed these implants forward over the past six years with different variations like texturing, which was meant to decrease contracture rates.

To take that as an example, they figured out that if they texture an implant, it's going to decrease contracture rates. Then we find out, unfortunately, seven or eight years later, that they were introduced in the 1990s, so we ended up not even recognizing it until about 2011, and it took 20 years, give or take, before they started recognizing the lymphoma. Now, the numbers tell us that the lymphoma typically develops around seven or eight years after, so yes, a number of people died unnecessarily because of that lag time, because we didn't have a registry to pick these things up.

● (1120)

The Chair: Thank you, Dr. Nicolaidis.

We're going to go to Dr. Powlowski, please, for six minutes.

Mr. Marcus Powlowski (Thunder Bay—Rainy River, Lib.): Good morning to the witnesses.

I, like Dr. Ellis, was a doctor for a lot of years. I worked in an emergency room, and I'm not familiar with this subject.

I want to really thank my colleague Luc Thériault for bringing this to the committee. It's not a subject I'm familiar with, and I'd like to understand more of the nature of this beast, the nature of the problem, so I have some background questions.

I think it was you, Dr. Nicolaidis, who mentioned that women have died in Canada from ALCL, anaplastic large cell lymphoma. Do you have numbers as to how many women have died, either in Canada or globally? What is the incidence with breast implants, and which breast implants?

Dr. Stephen Nicolaidis: The latest numbers I have are four Canadian women dying from ALCL in Canada, and I think there are 60 around the world.

Dr. Lennox, correct me if you're aware that my numbers are off.

The incidence of the lymphoma, of ALCL, varies depending on the type of texturing. Microtextured implants, such as the ones sold by Mentor, are not very rough. They're just slightly rough on the exterior, and they have an incidence of somewhere in the order of one in 17,000. Unfortunately, with the Allergan Biocell implants, the incidence is approximately one in 400 and might be as high as one in 100.

Mr. Marcus Powlowski: You mentioned that it could be as high as one in 100. What sort of implant is that?

Dr. Stephen Nicolaidis: It's the Biocell implant made by Allergan.

Mr. Marcus Powlowski: How many women have received those implants?

Dr. Stephen Nicolaidis: I don't know if that information is available. I'm not aware of the answer to that question in terms of Canadian or American patients.

Mr. Marcus Powlowski: Are the numbers you've quoted to me based on registry data from other countries or studies, or where do they come from?

Dr. Stephen Nicolaidis: Unfortunately, they're not from registry data.

They have a registry in the U.S., the NBIR, but it's a voluntary registry that's relatively new, and only about 30% of plastic surgeons use it.

If I understood correctly, basically on what happened, since they identified the ALCL, it's been a huge problem getting accurate numbers from the breast implant companies. They were just able to tell us, "Well, this is how many implants we sold."

It's not clear what the numerator and the denominator are. What ended up happening was that one plastic surgeon in particular in New York, Peter Cordeiro, who was doing all his breast reconstructions with textured Allergan implants, collected his own data. He had great follow-up with his patients. Those numbers are coming primarily from him, and he's found that the incidence is as high as one in 100 with his patients.

● (1125)

Dr. Peter Lennox: May I comment?

Mr. Marcus Powlowski: Sure. Go ahead.

Dr. Peter Lennox: Not to disagree with Dr. Nicolaidis, but according to the numbers I'm aware of, which are the current ones in the literature, Health Canada has reported three deaths. It's a bit unclear. As I said, the Canadian Society of Plastic Surgeons and CSAPS have also parallel-tracked data from our surgeons, and our data is really robust. I know exactly all of their scans, their outcomes and things like that.

Health Canada's data is a bit less clear, so I don't know how robust their data is.

There have been 36 deaths globally. The profile registry in the States, as Dr. Nicolaidis has mentioned, is a bit of an outlier. Their estimate is still one in 30,000, which is the least common in the world. The implant manufacturers provided numbers, in terms of the denominator, to us in Canada and also to Australia and New Zealand—not to us directly, but to statisticians, so independent statisticians have those numerators, and the original estimate, based on the Canadian data and the Australia-New Zealand data, was around one in 3,000.

Health Canada's current estimate is one in 1,600. Peter Cordeiro's personal one is one in 385, as Dr. Nicolaidis said. I actually met with Peter recently, and he hasn't had one in 100 yet, in terms of his numbers or anything he's published. That's certainly the highest risk—one in 385.

The current estimate globally for low-textured implants is still about one in 100,000.

I'm sorry to interrupt, but those are the numbers in the literature that I'm aware of.

Mr. Marcus Powlowski: I have only 13 seconds.

It seems that I agree with you. I can't really buy all of the reasons for not having a registry. It seems like something we need.

Thanks.

The Chair: Thank you, Dr. Powlowski.

[*Translation*]

Over to you, Mr. Thériault, for six minutes.

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

Dr. Lennox and Dr. Nicolaidis, welcome to the committee.

For the benefit of our study, I wanted the committee to hear from practitioners who advance different positions in the scientific literature. Today, two of the witnesses we wanted to hear from turned down the committee's invitation.

Dr. Lennox and Dr. Nicolaidis, I don't say this often—I'm not trying to brag—but as a bioethicist, I want to say what a credit you both are to your profession.

On one hand, Dr. Lennox, you told us that you have experience with a registry. I looked through all your material, and I think you have a lot to teach us on how things should be done. The information you provided is fantastic.

On the other hand, Dr. Nicolaidis, in an environment where the industry has been all-knowing and all-powerful for the past 60 years, your position speaks to your incredible courage.

That said, I'd like your opinion on what we heard from Health Canada officials last week. It's a bit of the chicken and egg paradox. They said that there wasn't enough research on the safety or the adverse impacts such as lymphoma to be proactive and introduce a registry. Today, you're telling us that, had there been a registry 20 years ago, we would obviously have more data, and it would be much easier to prove whether or not these devices were safe.

I imagine you agree with that, but you tell me. Dr. Nicolaidis, why does Health Canada not recognize breast implant illness?

Dr. Stephen Nicolaidis: I've heard nothing but negative things about Health Canada from health critics such as Julie Elliott. The department really hasn't been proactive.

The difference between Health Canada and the Food and Drug Administration, or FDA, in the U.S. is that the FDA has been much more proactive. That can partly be explained by the fact that the U.S. has more lawsuits to deal with. It's really important to do things the right way in order to avoid any ambiguity. However, the FDA should be criticized for its 2006 decision to allow the use of breast implants.

I don't have a good answer for you, but my sense is that Health Canada isn't doing its job.

● (1130)

Mr. Luc Thériault: Dr. Lennox, Health Canada is responsible for licensing implants and determining whether they are safe. In the absence of data, shouldn't Health Canada apply the precautionary principle in order to protect women's health? Shouldn't it adopt a much more careful approach and operate on the assumption that there are risks, given that our neighbour to the south has confirmed that BII does exist and that implants do pose a cancer risk?

[*English*]

Dr. Peter Lennox: I think, to be fair to Health Canada, when they approved breast implants—which goes back to the sixties, as you've heard—initially they had no data, but over time they have felt that they had data from a safety perspective.

Just as a point of clarification, BII does not cause cancer. It's ALCL that is the type of cancer.

I think Health Canada has tried to collect data from a safety perspective, and they hopefully continue to do that.

A registry is for long-term data, which you can use to give Canadian women numbers that reflect what's happening in Canada, so we would have a much better idea of the known complications of breast implants as well as of potential unforeseen events such as ALCL. I think there is a huge value in the long-term data of a registry.

[*Translation*]

Mr. Luc Thériault: You are no doubt aware that we've missed an opportunity to collect decades worth of data. As a result, we are missing evidence.

How long do you think it would take to set up a registry?

[*English*]

Dr. Peter Lennox: It should not take too long. All the G7 countries have already done it, so we don't have to reinvent the wheel.

Interestingly, when they were setting up their breast implant registry in Korea, they actually did a meta-analysis and researched the current existing breast implant registries in the world. They published a paper that outlines the key elements of a good breast implant registry and how to build one. Other people have already done the work. We would just have to implement it.

The Chair: Thank you, Dr. Lennox.

Next we will go to Mr. Davies, please, for six minutes.

Mr. Don Davies (Vancouver Kingsway, NDP): Thank you, Mr. Chair, and thank you to both witnesses for being here.

Dr. Lennox, a 2018 article from CTV News quotes you as saying the following with respect to breast implant-associated anaplastic large cell lymphoma. “The numbers that we have seen or that we have identified so far are significantly higher than what Health Canada has as their official data.”

What explains this gap between the data collected by Canadian plastic surgeons and Health Canada's official data?

Dr. Peter Lennox: That's an excellent question.

That quote, or the background to that quote, is what stimulated all this work that I've done. In 2017, Health Canada had five reports of ALCL, and plastic surgeons knew that was far under-reported. The reporting to Health Canada is mandatory from manufacturers and if there's an adverse event, but it requires somebody to do that.

The other problem was that it was very difficult to find out how to do the actual reporting. I had colleagues who notified me of cases. They tried to report them to Health Canada, and that was very challenging in terms of the way you could do that.

I think part of the reason we were very successful in doing it was simply that I reached out to colleagues. If somebody heard of a case, I was able to contact them to get all the details of it, and I was able to keep very accurate information. Had a registry been in place that had easy reporting, I think the numbers would have been much more accurate early on.

● (1135)

It's still unclear. That's the difficulty with the Health Canada data. We asked them to share the data so that we could look at it, compare it with the data we have and see if there was overlap or double counting. They said they were not able to do that, so I have no idea how they get their data or how robust the data is.

Mr. Don Davies: I know there's always a fundamental correlation and causation issue in medical science. How strong is the correlation between breast implants and anaplastic large cell lymphoma? Is there a causation element, do you think? Has that been established?

Dr. Peter Lennox: That's a controversial question in plastic surgery. I personally think, and I think most plastic surgeons think, that there is a causation between aggressively textured devices.... As Dr. Nicolaidis said, the more textured or the more rough the surface of the device, the higher the risk of ALCL. I think most people believe there is a causation there.

Mr. Don Davies: Just so that I can get the basics here, are silicone gel implants still allowed to be sold in Canada?

Dr. Peter Lennox: Yes.

Mr. Don Davies: Are saline-filled implants still allowed to be sold in Canada?

Dr. Peter Lennox: Yes.

Mr. Don Davies: I am also aware that there have been lots of complaints from women who have had breast implants of autoimmune issues as a result of having breast implants. Can you tell us anything about that?

Dr. Peter Lennox: Dr. Nicolaidis, do you want to start with that one?

Dr. Stephen Nicolaidis: Sure.

These are two completely distinctive entities or two problems caused by implants. With BIA-ALCL it's proven, as I alluded to and as Dr. Lennox has just mentioned. It's accepted now that it's the texturing of the implants, as he said, that is leading to the ALCL. Now, the exact details of that are not yet 100% clear, but they're being understood more and more over time.

BII is breast implant illness, which refers to the autoimmune issues that you just mentioned. That's a constellation of symptoms that are very wide-ranging and that patients have been complaining about since, as I said, within a year of the introduction of breast implants. These BII can be caused by any kind of implant. There's a general feeling in the BII community that the gel implants are more problematic, but that has not been proven.

Once again, conflict of interest is a huge problem. We tried to get a good study going recently. Well, it was not “we”; it was the Americans. The study was performed by two breast implant consultants who skewed the data. It's a lousy study. Unfortunately, it's the only well-funded study we have so far on BII. It was done by two consultants who don't believe, frankly, in breast implant illness. It is, nevertheless, recognized by the FDA. As I said, if it weren't for the fact of the recognition of BIA-ALCL, a completely other entity, these patients with BII would still be told now that implants are perfectly benign and that it's all in their heads.

Just to be clear, BIA-ALCL, the lymphoma, is proven, and it's caused by textured implants, with a much higher incidence the more textured the implant is and the more rough it is on the outside. BII autoimmune illnesses are caused by any kind of implant, whether it be gel or saline.

Something we haven't addressed that is even newer is something called “BIA-SCC”, another cancer that was recognized only in September 2022. Just in brief and not to belabour the issue, the difference between it and BIA-ALCL is that this is a more aggressive cancer. It is presenting typically around 20 years after implantation, as opposed to ALCL, which presents about seven or eight years after. It occurs with any kind of implant—saline, gel, textured, smooth—it doesn't matter. It's more aggressive and felt to be very rare.

I'm curious to know what Dr. Lennox thinks, but I'm pretty sure that one will remain rare. We've had implants on the market since the 1960s, and I'm only hearing about this cancer for the first time in September 2022.

● (1140)

The Chair: Thank you, Doctor.

We're going to go now to Mr. Jeneroux, for five minutes.

Mr. Matt Jeneroux (Edmonton Riverbend, CPC): Thank you, Mr. Chair, and thanks to both witnesses for attending here today.

Just for some background for the committee and for the report that I'm hoping we'll eventually write out of this, this was first brought to Parliament in 2004. That is a long time ago. In my opinion, in learning and reading about this, nothing has happened from that first private member's bill until today from the government—Health Canada, in particular—in moving towards a registry.

We had what in my opinion was a disappointing presentation from a representative of Health Canada here last week on what the future of this might look like. I'm learning about some of the work that you've done, Dr. Lennox, or that the Society of Plastic Surgeons has done with your leadership over the years. There is an unofficial database there. I'm curious as to how much of that.... What's captured there? What hurdles have you had to overcome to get that information in creating...essentially going out on your own to do that database?

Dr. Peter Lennox: That database purely captures cases of breast implant-associated anaplastic large cell lymphoma. It wasn't that challenging to set it up in the sense that there are not that many plastic surgeons in Canada. There are probably between 700 and 800. It's a pretty collegial group in general, so any time somebody heard of a case of ALCL, they would contact me and I could reach out to the individual.

I think there was one time when somebody was not comfortable sharing the data. It's de-identified data, so it doesn't have patient information. The downside to that is that I can't do a continuous follow-up and update it, because I have no way of finding out who the patient is. I could identify the surgeon, but not the patient. That's the challenge. However, I certainly wasn't comfortable having an unofficial database that contained patient names or identifiers. It's a fairly small database. There are not that many cases in Canada.

One of the suggestions from Health Canada was that our societies should start a breast implant registry and maintain it. That was absurd. The amount of infrastructure and support that would require was not within the scope of a not-for-profit medical society.

Mr. Matt Jeneroux: I'm glad you shared that, because that was some of the thinking, I think, from a lot of us here in the room too.

Getting back to that database, it doesn't capture patient information; it captures.... Is it then done by serial numbers of implants?

Dr. Peter Lennox: It's done by surgeon, actually. The surgeon and the province they're in are what I've used as the identifier, and then it has all the information about that specific case, the type of implant, when it was put in, when it was taken out, what the symptoms were, any imaging, what the pathology was, what the treatment was and what the outcome was. It's really robust, and that was the challenge.

In the most recent call I had with Health Canada, the challenge was that their data is not as robust. It's unclear how they capture it, and they weren't willing to share it just so that we could look at it and see how it compares to our data.

● (1145)

Mr. Matt Jeneroux: My second question was about that data from Health Canada. From your perspective, I guess talking about your database and what Health Canada has today, is privacy the big...? Is that what they're telling you in terms of data?

Dr. Peter Lennox: It wasn't clear when we last spoke with them why they were not comfortable. I didn't need to know anything about the patients. I just wanted to see the cases and what data they had, to see if it was robust data that was useful or not.

Mr. Matt Jeneroux: On your database, is privacy the reason you don't track patient information in terms of any sort of follow up?

Dr. Peter Lennox: Yes. There are certain things you need if you're going to have a database that tracks patients. You need to give the patient a unique identifier, so that you don't have their name but can go back and track the patient, and it has to be encrypted. There are all kinds of criteria that should exist that I don't have the capacity for, so I wasn't prepared to have patient names in a spreadsheet on my computer.

The Chair: Thank you, Mr. Jeneroux.

Next is Dr. Hanley, please, for five minutes.

Mr. Brendan Hanley (Yukon, Lib.): Thank you very much to both witnesses for their compelling testimony.

Dr. Lennox, I want to continue with you for the time being.

As Mr. Jeneroux pointed out, we had testimony last Tuesday from Health Canada.

First of all, in our testimony from officials last week, I didn't hear anyone say that a registry was a bad idea. I think it was more about the challenges in getting to the point of having an effective registry. Many were pointed out.

Before I get to that, David Boudreau from Health Canada described some steps that Health Canada has taken since 2017. Four main areas were described, including risk assessments, annual reports from manufacturers to discover new or increasing risks, and requiring labelling implant updates from manufacturers, including a patient decision checklist....

My question is on some of these interim measures that Health Canada has introduced since 2017. In your opinion, have they been effective? Are we in a better place than we were six years ago in terms of reporting and getting safety signals associated with breast implants?

Dr. Peter Lennox: Yes, I think we definitely are in a better place.

A big part of that, to be honest, is due to the work that both Canadian plastic surgery societies have done to educate their members about risks associated with implants. At every meeting now, there are talks about ALCL and BII. There's information that people are learning.

I think that increases the reporting back to Health Canada of adverse events. Health Canada has tried to capture data more accurately, I believe.

Mr. Brendan Hanley: That's great. Thanks for the work that plastic surgeons have done on that, and for the advocacy as well. I think it's really important.

We also heard from Ms. Wu from the Canadian Institute for Health Information. She talked about some of the set-up challenges. One would be, of course, establishing clear objectives for the registry. She pointed out the differences between a registry focused on safety versus a registry focused on health service activities and outcomes, such as the existing CIHI joint replacement registry, and that they have different purposes.

Also, more importantly, I think the data flow from private clinics is a challenge. How would we harness that data, when most of these procedures are carried out in private settings? Also, of course, there's provider and patient participation. We don't really have in this country the whole foundational work in data flows. She pointed out that some registries have actually failed. Both the U.S. and the U.K. have had significant challenges in the effectiveness of their registries because of these data flows.

I guess I'm just reflecting that there's a lot to get to with regard to having an effective registry.

In your opinion, how significant are these barriers? Are these barriers that we can overcome? Can we get to an effective registry?

● (1150)

Dr. Peter Lennox: I believe we can.

You're right. There are registries that have had challenges. However, there are also registries that have been successful. Australia has a particularly successful one. The Netherlands has a very successful one. The Korean one was set up to be successful.

One of the data flow workarounds is to make it an opt-out registry. You're mandated to submit the data anytime you put an implant in, whether it's in a private clinic or a public facility, unless the patient specifically, in writing, opts out. That's available to the patient—for the patient to say, “I don't want the government to have my personal information”—but in the absence of that, the provider has to submit the data to the registry. It's the heavy stick of government, but it's effective.

Mr. Brendan Hanley: Before we get there—and it looks like it's a direction we should be heading in—are there other steps in the short term that Health Canada should or could be taking?

Answer very briefly, I guess.

Dr. Peter Lennox: I don't know the inner workings of Health Canada well enough to answer that.

Mr. Brendan Hanley: Okay, thank you.

The Chair: That's fair enough.

Thanks, Dr. Lennox.

[*Translation*]

Go ahead, Mr. Thériault. You have two and a half minutes.

Mr. Luc Thériault: When it comes to informed patient consent, do you think patients in 2023 are fully and adequately informed?

Shouldn't there be a standard form, one that both parties sign, attesting to the fact that all of the risks have been discussed with the health professional?

Dr. Stephen Nicolaidis: That's something they have actually started introducing in the U.S., Arizona for instance.

Breast implant safety advocates have lobbied hard for that, because they found that plastic surgeons tended to minimize the risk of complications associated with breast implants.

It would be easy to establish a checklist. I don't think it's been done in Canada yet, but Dr. Lennox would be better suited to speak to the issue. I know that it's starting to emerge in the U.S. and that Arizona has introduced the measure. Part of the process is to make sure that a checklist is established and that it clearly captures the risk of complications.

My patients tell me all the time that, if all the complication risks had been explained to them, they never would have gotten breast implants.

I want to stress that a breast implant registry has to be mandated by law, as Dr. Lennox mentioned. It has to be mandatory. It shouldn't be something patients can opt out of, because if the data aren't entered in the registry, the guarantee on the implants shouldn't apply.

We haven't talked about this yet, but I think the implant makers should have to assume the cost of setting up the registry. That should be one of their obligations. It hasn't happened yet, but the financial responsibility should fall on them.

[*English*]

The Chair: Thank you, Dr. Nicolaidis.

Next we have Mr. Davies, please, for two and a half minutes.

● (1155)

Mr. Don Davies: Thanks, Dr. Nicolaidis.

I'm going to summarize some of the conclusions that I'm drawing from this testimony.

There have been long-standing reports of illness caused by breast implants. There is now a clear association with at least one form of cancer. All other G7 countries have established a breast implant registry. Dr. Lennox reached out to Health Canada in 2017—over six years ago—yet today, in 2023, Canada has no breast implant registry.

Are you concerned that breast implant manufacturers or other industry forces are lobbying against this registry?

Dr. Peter Lennox: I don't think so. In the interactions I've had with them—

Mr. Don Davies: I'm sorry, Dr. Lennox, but I addressed my question to Dr. Nicolaidis, although I'll give you a chance—

Dr. Peter Lennox: I apologize.

Mr. Don Davies: That's okay.

Dr. Stephen Nicolaidis: I don't feel that.... They've had their chance. They've had 60 years to do something, and they haven't. Unfortunately, at the end of the day, as we all know, money talks. That's been the primary driving force for them.

The conflict of interest has remained. Are they going against the registry? I'm not sure about that, but I think it has to be imposed at this point, whether they like it or not. I don't think they're against the idea.

There are a few criteria—the devil's in the details—to make sure that the registry works, in terms of good data, but it has to be imposed. It can't be an optional thing any longer, and that's where the government stick comes in handy.

Then, as I said—

Mr. Don Davies: Thanks.

If I could just turn to Dr. Lennox—

Dr. Stephen Nicolaidis: As I said, the cost has to be assumed by the companies. It shouldn't be from my taxes or the government.

Mr. Don Davies: Dr. Lennox, I want to give you a quick chance to respond.

If it's not really coming from industry pressure, then that means the torpor is coming from within government. You said, in 2017, after reaching out to Health Canada, “Nothing progressed. We had multiple conference calls and meetings...and there was no resolution.”

Why is there a resistance within Health Canada, do you think, to establishing this registry, which seems so obviously needed?

Dr. Peter Lennox: I'll be blunt. My simple perception was that it was because of bureaucracy. They told me that it wasn't their mandate, that it was possibly CIHI's mandate, and that I should take this idea to CIHI and try to get CIHI to engage. It just seemed absurd that an individual was trying to be the liaison between two government bodies that were responsible for approving the safety of a device and tracking health outcomes in Canadians, and it was my responsibility to coordinate that.

I can't answer the question “Why?”, but it was like hitting my head against a wall.

The Chair: Thank you, Dr. Lennox.

Mr. Aboultaif, you have five minutes, please.

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

Dr. Lennox, what would it take to establish a registry, from the technical perspective and in terms of the cost, including the cost to maintain it on an annual basis?

Dr. Peter Lennox: Those are excellent questions that I don't have the answers to in terms of the specifics, so I apologize. I don't know how expensive it would be to set up a database, or what the annual costs would be. I could probably track that down from comparable ones, like the Australian one, which is for a similar-sized population. I could find that out.

Mr. Ziad Aboultaif: What's the average cost of an implant, excluding labour and doctor charges?

Dr. Peter Lennox: They are around $1,000 per implant, roughly. It's less for saline.

Mr. Ziad Aboultaif: How many implants do we do in Canada on an annual basis, on average?

Dr. Peter Lennox: I don't know. That number is hard to find out.

Mr. Ziad Aboultaif: Health Canada has this data. We must know how many we import, how many we produce and how many we use a year. Is that correct?

Dr. Stephen Nicolaidis: They should be able to know how many are imported. There are none produced in Canada.

Mr. Ziad Aboultaif: Do we know for sure whether they know or whether they don't?

Dr. Stephen Nicolaidis: I don't know.

Mr. Ziad Aboultaif: In order to determine what or who it can be up to, to commit to having a registry, as far as Health Canada.... Also, Dr. Nicolaidis has suggested that this should be paid for by the industry, not the taxpayers, which is something I agree with.

How do we get to that, to basically speed up the process, if a registry is a must?

● (1200)

Dr. Peter Lennox: Some of the databases that are referenced in the presentation I sent are funded by industry. They basically put a surcharge on each implant, and that is used to fund the registry.

There are countries that use that model, for sure.

Mr. Ziad Aboultaif: Dr. Nicolaidis, would you like to weigh in on this too?

Dr. Stephen Nicolaidis: Yes. As I said, the NBIR in the U.S. is an optional one, but I reached out to them to see about it. It's funded there by The Plastic Surgery Foundation, but it's receiving significant funding from the breast implant manufacturers. I think that's a direct one. It's not necessarily per implant, as a tax on the implants themselves, but that's another way of doing it.

Certainly, at the end of the day, it's.... The implant companies were supposed to do this, but they failed to in the past. I think they realize that they have to fund this registry in order to ensure the safety of implants.

Mr. Ziad Aboultaif: Any registry, as such, will require legislation at some point. Do you see a way to avoid going through legislation in order to establish something like that?

Dr. Stephen Nicolaidis: Is that directed to me or Dr. Lennox?

Mr. Ziad Aboultaif: It's to both, please.

Dr. Stephen Nicolaidis: Dr. Lennox, go ahead.

Dr. Peter Lennox: I don't know the machinations of government at that level, so I'm not aware of a way within CIHI to do that outside of legislation. I don't know.

Mr. Ziad Aboultaif: Dr. Lennox, since you're answering this question, you've suggested we need a registry, and then you've mentioned other models out there, such as those in Australia, Korea and the U.S. How can we get from you a clear answer on what shape of a registry we're looking at, and how can that be done in order to make sure the registry is beneficial to Canadians?

Dr. Peter Lennox: I've provided guidelines for what makes an effective registry. I'm happy to go through that. They're pretty straightforward. It's well established what makes an effective registry. It would just be a matter of how you implement that within Canada.

Mr. Ziad Aboultaif: Dr. Nicolaidis, I would like you to weigh in on this, please.

Dr. Stephen Nicolaidis: As I said, there are a few basic premises. I think Dr. Lennox knows more about the details of the registries than I do. There are some basic things to make sure the registry works. One is that it's mandated that basically an implant can't be put in and the guarantee respected unless, for example, the plastic surgeon has gone through a checklist with the patient initially of all the complications, and the patient understands each and every complication. Then it's a question of how to make it so that implantation is not recognized for the guarantee unless it's registered in the Canadian registry, so that it's mandated. Once again, I think it's very practical, and, as I've said and am going to keep saying, it's the breast implant companies who ultimately have to foot that bill.

The Chair: Thank you, Dr. Nicolaidis.

The final round of questions for today's panel will come from Ms. Sudds, please, for five minutes.

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

It's a pleasure to be with you today. I'm not a typical standing member here, but I'm happy to have the opportunity to interact on this important issue.

We have heard in the past, and a bit today, that the safety of medical devices in Canada is a shared responsibility. The federal government is responsible for regulating the sale and importation of medical devices, and then the provinces and territories are responsible for the delivery of health care services, including the licensing of health care professionals and regulating the practice of medicine. Nothing is ever simple, of course.

We heard from Health Canada that any requirement for physicians to provide information to a national registry would need to be supported by the provinces and territories, and that adds a layer of complexity.

I'm wondering from both of you, and perhaps we'll start with Dr. Nicolaidis first, do you see this as an insurmountable barrier? Do you have a perspective on how to bring the provinces and territories, and the regulatory body, really, into this conversation?

● (1205)

Dr. Stephen Nicolaidis: Once again, like Dr. Lennox mentioned, I'm not really familiar with the machinations at that level of the government, but I think the need for a registry is so common sense at this point. Mr. Thériault, from Quebec, brought this forward. I don't see why any physician or organization would be against the idea. As I said, I think the expense has to be picked up by the breast implant companies, so there will be some cost but it won't be something insurmountable at the level of government in terms of cost for anybody.

Ms. Jenna Sudds: Actually, before we go to Dr. Lennox, can I also expand upon that, just to ask you to comment on the complexities of private clinics versus hospitals, and what that dynamic adds to this issue?

Dr. Stephen Nicolaidis: Certainly. It's just one more reason to have a mandatory registry. At the end of the day, in hospitals things tend to get better documented, and that's certainly an issue with plastic surgery. You'll have breast implants being used for both private aesthetic surgery and breast reconstructions. Either way, the registry has to involve all these people, because they're all patients, at the end of the day, who need care.

Ms. Jenna Sudds: That's excellent. Thank you very much.

Dr. Lennox, would you like to comment as well?

Dr. Peter Lennox: Sure. To answer your second question first, I agree. I don't think it would be a barrier if there was a mandatory or opt-out registry in place. You wouldn't have any choice. You would have to do the appropriate upload of data.

That's one of the things that are really important: making that process simple with a good database. Uploading the data into it is an easy thing to do.

On your first question about the relationship between provincial and federal mandates, I'm aware of the division in the delivery of care, but I wasn't aware that if.... It seems that if Health Canada is mandated to ensure the safety of devices...if they put in place a mandatory registry, I can't imagine that provinces would balk at that or interfere in any way.

Ms. Jenna Sudds: Thank you, both.

To me, as I think through this process and many aspects of the work we do here, it's the dynamic of how we interact with a province and how we can ensure that, despite various responsibilities and roles, we are able to bring them onside to work well for the betterment of Canadians.

I'll leave it at that. I think my time is up.

Thank you very much.

The Chair: Thank you, Ms. Sudds.

That concludes the rounds of questions, except that I have one, just by way of clarification for you, Dr. Lennox.

Mr. Aboultaif asked you about the characteristics of a quality registry. You submitted a brief to the committee that has eight criteria in it. I think you referenced criteria in your answer, without enumerating them.

Is that what you were referring to, or is there something else?

Dr. Peter Lennox: I think I also submitted a PDF of a PowerPoint presentation I gave. That has a couple of different summaries collated from different papers, with lots of crossover.

I'll go through some of them very quickly: clear objectives, stable and long-term funding, being independent financially and technically, a simple interface and data upload, an opt-out model, concise data requirements and clean data that can be utilized and reported easily.

That's a perfect registry right there, if you can achieve that. There are well-documented guidelines for a good medical device registry.

● (1210)

The Chair: Thank you, Dr. Lennox, and thank you, Dr. Nicolaidis.

I can only imagine how busy you are, with the very specialized expertise that you have. We certainly appreciate the time you spent with us today. The discussion we've had here will undoubtedly be of great value as we go forward on this study.

With that, colleagues, we're going to suspend while we move over to the in camera portion of our meeting.

Thanks again to our witnesses.

The meeting is suspended.

[*Proceedings continue in camera*]