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Chair

Mr. Rob Merrifield

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● (1535)

[*English*]

The Chair (Mr. Rob Merrifield (Yellowhead, CPC)): I call the meeting to order.

First of all, I want to thank everyone for coming.

Today we have two parts to our meeting. We first of all want to discuss the silicone gel-filled breast implants, and we have with us witnesses from the Department of Health. We have Supriya Sharma and Mary-Jane Bell.

You've been with us before talking about this issue, and we wanted to bring you back, actually, for further questioning. So we want to listen to your presentation.

Then we'll go in camera for the rest of the meeting, where we'll talk about committee business and future business of the committee.

We want to thank you for coming. We'll open up the floor to your presentation, followed quickly by a good round of questioning. The floor is yours.

Dr. Supriya Sharma (Associate Director General, Therapeutic Products Directorate, Department of Health): Thanks very much.

What we'd like to do is give a very short statement at the beginning. We'd really like to use most of the time to give the committee members the opportunity to ask questions. Obviously we're here because of a motion that was passed for us to go over the decision that we made.

Mr. Chair, members of the committee, I wish to thank you for the opportunity to appear before you today to provide information regarding Health Canada's regulatory review and subsequent licensing with conditions of silicone gel-filled breast implants under the medical devices regulations and the Food and Drugs Act.

I have with me today my colleague Mary-Jane Bell, who is the head of the musculoskeletal section of the medical devices bureau of the therapeutic products directorate. She has considerable experience on this file; she has actually been working on it since 1991.

I'd like to begin by briefly outlining both the comprehensive review of these products as well as the significant steps that have been taken to openly share the results of the review with the Canadian public. Following that, we welcome this opportunity to answer any questions committee members may have with respect to the rigorous review that was conducted.

On October 20, 2006, Health Canada announced the decision to grant licences with conditions to Inamed Corporation and Mentor Medical Systems to allow them to sell silicone gel-filled breast implants in Canada. The decision allowed women seeking breast reconstruction following a mastectomy and those seeking breast augmentation open access to silicone gel-filled breast implants.

In order to reach its decision, Health Canada engaged in a four-year-long review, examining more than 65,000 pages of information submitted by the manufacturers. In addition, Health Canada also reviewed the relevant medical and scientific literature, the report of the Expert Advisory Panel on Breast Implants, and submissions from interest groups and interested persons as part of the review. It is significant to note that the directly related scientific and medical literature alone consisted of well over 2,500 articles, with over 6,000 articles in total being examined.

As you are aware, breast implants, both saline and silicone gel-filled, are regulated as medical devices in Canada. The regulatory framework that governs the importation, sale, and advertisement of medical devices has been established by Parliament in the form of the Food and Drugs Act and the medical devices regulations.

The licensing of these products signifies that they have met criteria for safety, effectiveness, and quality, and have undergone an independent, impartial, and objective analysis of scientific evidence. The scientific and regulatory basis for the decisions included assessment of such criteria as manufacturing and quality control; preclinical studies, including chemical, physical, and biocompatibility tests; clinical effectiveness and safety; and labelling of the devices, which includes the patient brochure.

The results of the review have been compiled in the form of the summary basis of decision documents, which describe the type of information provided and what was considered during the licence applications review process. These documents have been made publicly available on the Health Canada website.

In order to ensure that the medical devices licensed continue to meet safety and effectiveness standards, Health Canada, through a combination of conditions and commitments, has required the manufacturers to produce annual reports through to 10 years for clinical studies under way outlining complications and patient/physician satisfaction measures.

We've asked them to conduct at least two patient focus groups in Canada to determine the effectiveness of device labelling. A report on these sessions, along with analysis and recommendations for labelling changes, will be submitted to Health Canada within a year of licensing.

We've required the manufacturers to conduct a large long-term appropriate post-approval study, involving tens of thousands of women. The study will include Canadian women and will be designed to measure any previously undiscovered connection between the use of silicone gel-filled breast implants and any potential rare events. Manufacturers are required to start the study within one year.

We've also required them to survey Canadian plastic surgeons who use the implants, to determine the effectiveness of the labelling and of the decision aids provided with the implants. A report on the survey is to be submitted to Health Canada within one year.

The last condition is that manufacturers continue implant retrieval and analysis studies, from all available sources, for further characterization of potential modes and causes of implant failure.

In addition to the conditions, manufacturers have committed to the following. They have agreed to provide Health Canada with updated marketing histories, including the number of units sold and a summary of any reported problems or recalls concerning the devices, in Canada and internationally.

They have also committed to provide implant registration cards with the devices so that patients receiving these cards from their surgeons can send them voluntarily to the manufacturer. This will allow the manufacturer, in addition to using general methods of dissemination, to distribute any new information directly to the persons affected.

As requested through the motion passed by the committee, we are in the process of providing the information that formed the basis of our decision. As you can well understand, given the volume and the technical nature of the information, this involves considerable human and financial resources.

In announcing the licensing decision, Health Canada continued, and continues, to remind Canadians that no medical device or drug is 100% safe, effective, or without risks. Under the regulations, reasonable measures must be taken to identify the risks associated with the device and to eliminate them or reduce them as much as possible.

● (1540)

The conditions that have been applied to these licences are intended to continually provide information to the patient and health care professional on the risks associated with these devices in order to allow for an informed decision process after the patient has consulted with a physician and has fully explored the risks and the benefits associated with the product.

In conclusion, it should be noted that silicone gel-filled breast implants are some of the most intensively studied medical devices in modern medical history. The decision to grant licences with conditions for these silicone gel-filled breast implants comes at the end of a rigorous scientific and clinical review.

It is also worth noting that more than 130 countries have already licensed these breast implants, including the most recent decision of the United States Food and Drug Administration, which announced the approval of these devices on Friday, November 17.

Finally, I'd like to thank you for inviting us to speak to you today. We welcome the opportunity to answer any questions you may have.

The Chair: Thank you very much for your presentation.

We'll now open it up to questioning. We'll start with Ms. Dhalla.

Ms. Ruby Dhalla (Brampton—Springdale, Lib.): Thank you very much.

I just want to go through this, and perhaps you could advise the committee. You had an expert advisory panel take a look at and review many literature articles and providing Health Canada with information. Can you please comment on the advisory panel? What conflicts of interest were determined in the composition of the advisory panel?

Dr. Supriya Sharma: The advisory panel was actually asked five specific questions. They weren't asked to review the entire submission, nor were they asked to review all the scientific literature. They were also not asked to make a determination about whether or not these products should be licensed. There was conflict of interest declaration by all the panel members, and that was acknowledged. It was discussed at the panel, and we received their report. The report formed only a part of the decision that was made on these implants.

Ms. Ruby Dhalla: Who was involved in the review of the articles and the literature that was examined by Health Canada?

Dr. Supriya Sharma: There was actually a team of people who looked at it. Dr. Bell actually led the review. She has a Ph.D. in chemistry, and that was her area of expertise. We also had people who had expertise in other science elements and medical backgrounds as well. We had a team of people who looked at it.

Ms. Ruby Dhalla: Dr. Bell, could you perhaps provide the committee with information as to the number of people on your particular team and their backgrounds?

Dr. Mary-Jane Bell (Head, Musculoskeletal Devices, Medical Devices Division, Therapeutic Products Directorate, Department of Health): Off and on, there would be up to 10 people. There was a materials specialist, there were mechanical engineers, there were several physicians involved with the review, I was involved as a chemist, and there were toxicologists. There was a whole range of people. We supplemented the expertise we had in-house with the expertise on the expert advisory panel.

Ms. Ruby Dhalla: Were these physicians and toxicologists actually employees of Health Canada or were they people who work at large within the community and were contracted out?

Dr. Mary-Jane Bell: They were all employees of Health Canada.

Ms. Ruby Dhalla: They had no conflict of interest in terms of making any type of decision.

Dr. Mary-Jane Bell: No.

Ms. Ruby Dhalla: The committee had also taken a recommendation in regard to the commitment that would be required on behalf of the manufacturers. It stated that patients would actually be given implant registration cards, and they would be asked to submit them to the manufacturer on a voluntary basis. Was there any consideration that this would be a mandatory reporting requirement or a mandatory submission versus a voluntary submission?

Dr. Supriya Sharma: It is a voluntary program, and it's consistent with a lot of the programs that are happening worldwide.

When we actually had a legal opinion on whether or not we could make it mandatory, it would actually have involved significant issues in terms of privacy and significant issues in terms of mandated legislative change in order to mandate it. There were considerable concerns about the right to information and privacy, so it wasn't recommended that we go forward. We actually couldn't have gone forward with a mandatory measure at this time under the current regulatory framework.

Ms. Ruby Dhalla: Is mandatory reporting required for adverse reactions?

Dr. Supriya Sharma: Mandatory reporting for adverse reactions is required of the manufacturer. But for health care practitioners and the general public, it's voluntary.

Ms. Ruby Dhalla: How would the manufacturer become aware of an adverse reaction if it's voluntary on behalf of the health care practitioners and the patient?

Dr. Supriya Sharma: How would they become aware of it?

● (1545)

Ms. Ruby Dhalla: How would they become aware of it and actually report it to Health Canada?

Dr. Supriya Sharma: Part of the reason we very specifically put in post-market surveillance measures, once these products have been approved, is that you're actually looking for those adverse events in a very controlled way in clinical trials.

Beyond the regular reporting, there are actually tens of thousands of women who would be involved in clinical trials, and those adverse reactions would be reported as part of the commitments. It's actually seen to be a more effective way to gather information on adverse reactions than voluntary reporting.

Ms. Ruby Dhalla: You also have recommendations to have two patient focus groups conducted in Canada and to have a long-term study involving tens of thousands of women. With the patient groups and the study, could you perhaps elaborate on how the focus groups and the women involved in the study would be chosen?

Dr. Supriya Sharma: What happens on a licensing decision is that there's the responsibility of Health Canada as the regulator, and the company is the regulatee. So we put conditions on them. What would happen in the case of the patient focus groups is that they would submit their plans for the patient focus groups to Health Canada—how they were going to do patient recruitment, what questions they would ask, where they would be conducting them, what type of structure it would have—and then we would review that and approve or make changes as appropriate.

The Chair: Don't feel compelled to use all the time. Thank you.

Madam Gagnon.

[*Translation*]

Ms. Christiane Gagnon (Québec, BQ): I will give Ms. Demers the floor because she was responsible for this file during the last session of Parliament.

[*English*]

The Chair: Madam Demers.

[*Translation*]

Ms. Nicole Demers (Laval, BQ): Thank you, Christiane.

Thank you, Mr. Chair.

The FDA authorized breast implants last week on November 17. Health Canada also made its announcement on a Friday. Newspaper reporters were no longer on Parliament Hill, so they could not react immediately to the news.

I have in my possession documents from Inamed, a subsidiary of Allergan in the United States. We are talking about Inamed here, and you approved a license for that company. In a document entitled *Directions for use, Inamed Silicone-Filled Breast Implants*, it clearly states that people who receive breast implants must undergo magnetic resonance imaging at least every two years. Otherwise, the risk of rupture and leakage is very high. It also mentions other health problems. It says that a high number of ruptures are thought to be responsible for serious problems. In the United States, the FDA recommends that women who have had breast implants undergo magnetic resonance imaging at least once every two years.

In addition, Dianne Feinstein, a U.S. Senator, is opposed to the reintroduction of breast implants. Her arguments against them are the same as the arguments we put forward before. Inamed Corporation and Mentor Medical Systems are still facing allegations made by scientists and very credible individuals. Among others, Dr. Sidney Wolfe, Director of Public Citizen's Health Research Group, said that the approval makes a mockery of the legal standard that requires reasonable assurance of safety for drugs and prostheses. He said that, in the case of implants, the risk of rupture and leakage of silicone gel in patients' bodies was high and that they therefore pose health risks.

I have also received emails. For example, a young woman from Manitoba who received breast implants now has to have them removed because they ruptured. But she cannot have the operation because in order to get it quickly, she would have to spend $5,000 out of pocket. Otherwise, the waiting period is two years. The ruptured implants are causing her serious health problems.

You are authorizing companies like Mentor and Inamed to use women in Quebec and Canada as guinea pigs, women who are in good health now but who may not be in the future because of the decision you made. I wonder if you thought about that when you made the decision. In the past, thousands of women have had serious crises because of breast implants. Now, because you made a hasty decision, thousands of women will risk going through that again.

We know that Health Canada receives $42 million a year to approve the devices. Did that factor play into your decision? Can you really be neutral under those circumstances? I would like a list of the people who participated in making that decision, Ms. Bell.

● (1550)

[*English*]

Dr. Supriya Sharma: Mr. Chair, a number of issues were raised, and I'll try to make sure we go through all of them.

I'd like to start with the last comment. With 100% certainty, I can say categorically that this review was independent, impartial, evidence-based, and scientific. If there is an insinuation that in any way, shape, or form there was undue influence on the review, nothing could be further from the truth.

To give you a little bit of context, a normal medical device review in terms of our performance targets takes 90 days on average. That's our maximum. A lot of them will take less than that. These products have been under review for four years. As I mentioned before, these are the most intensively studied medical devices in history, and as I said, none of them are without risks.

The idea of doing a review is to ask if these medical devices, under the regulatory framework under which we are working, made by parliamentarians, meet the safety, effectiveness, and quality standards that are outlined. Do we know what the risks are? If we could have minimized those risks, have we minimized them? Have we quantified those risks? Are we able to provide information to the Canadian public, so they can make informed decisions about their health?

I cannot underscore that more. It really is up to the patient and his or her practitioner to have that dialogue about the risks and benefits of any treatment. It's the same whether you are taking an aspirin or whether you are having silicone gel-filled breast implants. It depends on knowing what those risks and benefits are.

Because these products have been so intensively studied, we know the risks and benefits and we feel they have met the criteria of the Food and Drugs Act and regulations. Having said that, we wanted to make sure they continue to meet those standards, and that's why those post-market conditions were put in place.

In terms of the FDA decision, you'd have to go back to the FDA to decide why they announced it at the time they did. When we made our decision, we made sure we made the announcement in the morning to allow people to comment and for officials to be present on the Hill to brief anybody who wanted to be briefed. We made a conscious decision to make sure we did that early in the day.

On the subject of MRIs, the products are really well labelled for the decisions. We asked our expert advisory panel what their opinion was on the use of MRIs and they gave specific recommendations.

They did not feel MRI follow-up was the best way to follow them up, and that's clearly outlined in the labelling. So if you read the labelling for the products, it goes through the debate and it explains what the FDA opinion was. The FDA had conflicting opinions as well. They had one expert advisory panel recommend it every two years, and they had another expert panel that did not recommend it every two years.

So the recommendations now are to look for clinical signs and symptoms, to go for a mammogram, and to go for ultrasound, and if there is any suspicion, then to sit down with a physician and decide at that point.

If you are going for an MRI, there may be a wait for an MRI, so the decision might be to go and remove them. If not, you can wait for an MRI and do that. But we specifically asked the question on MRI. We've specifically received an expert opinion on it, and the recommendation was not to have an MRI follow-up every two years.

In terms of Public Citizen, that is a consumer advocacy group. In the United States they have a public petition process. Public Citizen has come before the FDA with their concerns and they've had their hearings, and the FDA have cleared all the issues they've had with Public Citizen.

Another part of the question was speaking to wait times for having implants removed. Again, if there is a health risk, if there is a health reason for them to be removed, it's a priority, but individual surgeons will be making their own decisions in terms of their own lists. If it is due to health, then the public health system covers it. If it is not due to health concerns, then it is not covered.

The practice of medicine is regulated at the provincial and territorial level. It's not regulated at the federal level and it's not under the jurisdiction of Health Canada.

● (1555)

The Chair: Thank you very much. We may have another opportunity in another round.

Mr. Fletcher, five minutes.

Mr. Steven Fletcher (Charleswood—St. James—Assiniboia, CPC): Thank you, Mr. Chair.

I'd like to thank the witnesses for their presentations. It's great that your statement on the integrity of the process is so unequivocal, and Canadians appreciate the integrity of the work you've done.

My question is more related to the motion. You may be aware that we have a motion on the floor at the health committee, and it deals with providing the documentation related to the study you have undergone to make your decision.

In question period the Minister of Health indicated that there were 65,000 pages of documentation involved. I understand Ms. Demers would like to have access to that at committee. Of course, certain formats are required for things to be presented in Parliament and at committee. I'm just wondering, how much would that cost?

Dr. Supriya Sharma: That's a good question.

Actually, 65,000 only represents the number of pages submitted by the companies as part of their application. When you look at the total number of pages, all the scientific and technical articles, and the books that were included in that, it numbers in the hundreds of thousands of pages.

As you can imagine, there are a number of things that actually have to proceed before we provide those to committee, including translation, review for proprietary information, and verification. In terms of the papers, we have to get consent from any of the scientific writers. We have to get permission from them to translate.

The total cost of providing all the information that forms the basis of the decision would amount to—and this is a conservative estimate, because it doesn't actually include any delays to other ongoing medical device reviews—$55.9 million.

Mr. Steven Fletcher: I'm sorry, could you repeat that? Did you say $55 million?

Dr. Supriya Sharma: Yes. The licence application translation itself would be $13 million. The scientific article translation would be $41.3 million. There are a number of other purchase costs. But the total, and again it's a conservative estimate, would be $55.9 million.

Just to put it in context, that's more than the budget of my entire directorate, which is responsible for all the pharmaceutical and medical device reviews.

Mr. Steven Fletcher: Wow!

Out of curiosity, then, how much did it cost to come out with the decision?

Dr. Supriya Sharma: This has been going on for four years. We haven't translated those costs to 2007 dollars. But if you look at the reviews, the public forum, and the expert advisory panel, it's around $600,000 that we've already expended on the review itself.

Mr. Steven Fletcher: My last question relates to the announcement made in the United States. I found it interesting that they have approved gel implants as well. Are there any other countries that do not allow silicone gel implants? Maybe you could give us a sense of where we are in the world.

Dr. Supriya Sharma: At this point in time, there are no industrialized countries that limit the sale of silicone gel-filled breast implants. They're openly available in all industrialized countries.

Mr. Steven Fletcher: Those are my questions, Mr. Chair.

The Chair: Ms. Priddy, you have five minutes.

Ms. Penny Priddy (Surrey North, NDP): Thank you, Mr. Chair.

I have read through your comments, and I thank you for them. I would ask if you could just help me figure out one piece. It may not even be a piece that belongs on your plate, but I need help with the answer.

I've learned that being paranoid doesn't make me wrong. Do I read this to be that the responsibility for reporting an implant that has failed rests in the hands of the manufacturer who is doing the focus groups, the reports, the analyses? That's my first question.

I see they're surveying Canadian plastic surgeons who use the implants. But the survey is only on the effectiveness of the aids and brochures, not on the effectiveness of the implants. I am somewhat concerned about how we, as a responsible federal government, would have a true way of knowing if we are in difficulty—as we were last time—if reporting rests only in the hands of the manufacturer.

● (1600)

Dr. Supriya Sharma: As I said, basically the licence is granted to the manufacturer. The only condition—and there's a very rigorous definition of what you can put as a condition in the regulations—is what we called a test. The focus groups are actually testing the patient labelling and the decision aid. The focus of those groups is to look at making sure the labelling adequately reflects the risks and benefits.

Ms. Penny Priddy: Yes, I understand that.

Dr. Supriya Sharma: That's one part of it.

The other part, in terms of looking for adverse events or problems, will actually come primarily from the large-scale studies. Again, because of the way they're constructed, the studies actually have research ethics boards that oversee them. They have data safety monitoring boards that look at it. Because they are clinical studies, they have a number of intrinsic checks and balances to allow us to collect that information in the best possible way. Once a thing is on the market, if it's not in a clinical trial or a formal monitoring system, then we rely on the mandatory reporting. Again, by regulation, the only groups that are mandated to report are the manufacturers.

The way we wanted to make sure we're getting the best information is to put conditions on the manufacturers to conduct these studies, and then have those studies, including all the data, submitted to Health Canada for review.

Ms. Penny Priddy: Did you look at whether it was possible to mandate the manufacturers to report?

Dr. Supriya Sharma: The manufacturers are mandated to report.

Ms. Penny Priddy: By their licensing from us?

Dr. Supriya Sharma: Yes, it's in the regulations.

Ms. Penny Priddy: Somebody went yes and somebody went no.

Dr. Supriya Sharma: It's in the regulations.

Ms. Penny Priddy: Thank you.

The Chair: Mr. Batters, you have five minutes.

Mr. Dave Batters (Palliser, CPC): Thank you very much, Mr. Chair. I have one quick question and then I will yield the rest of my time to Madam Demers, who has spent a great deal of time on this issue. I know she's very passionate about this and I want to give her an ample amount of time to ask her questions.

First of all, thank you to the witnesses for appearing today.

My comment is, at least we have a decision. My frustration the last time this issue came before this committee was the fact that there really was no decision. We seemed to be in limbo.

I wonder if there could be some consideration given to developing some literature for patient education that could be distributed to family physicians nationwide. We talked in our study of childhood obesity about how GPs could be given information for their patients. The same thing could apply here.

Perhaps there could be a piece of literature put together that GPs could distribute to their patients, because the number of Canadian women who will actually see a label and read through all of the information will reflect a very low percentage. I think if we make it easier for Canadian physicians to pass on this scientific-based, non-biased information to their patients, then it would help Canadian women make that decision. I do think this is significantly different from the aspirin example. There's significant post-surveillance requirements here, much more so than any other device or drug that I'm aware of.

Since it's been studied for four years, I think it's a reasonable request. I wonder if you'd give it some consideration and take that back to Health Canada.

That's my question. The rest of my time will go to Madam Demers following the response.

Thank you, Mr. Chair.

Dr. Supriya Sharma: It's a really good point, and we feel the same way. That's why in 1992 we actually put out a document. It's in the format called "It's Your Health" in Health Canada. It's written in lay language for people and it's on specific issues. It can be anything from an issue like breast implants to other safety issues. That continues to be updated, and we've updated it recently. So since 1992 we've had publicly available information for GPs, for the public, giving them information on breast implants.

In addition to that, we were talking about the specific decision, and we posted all the documentation that went into the review in terms of the summary basis of decisions. We actually published and publicly put on the website all of the patient information that went along with these products. We thought it was really important to do that because we didn't want patients and GPs to have to order a product in order to get the labeling information that often comes back with it. You can actually go onto the Health Canada website and you can access publicly all of the patient brochures, all of the decision needs, all the documents that help Canadians through the decisions they have to make before they actually go and have that discussion with their physician.

● (1605)

The Chair: Thank you.

You'll have two minutes, Madam Demers. I actually went gracious on you as well; you had nine plus two.

[*Translation*]

Ms. Nicole Demers: Come on, Mr. Chair.

[*English*]

The Chair: That's all right. Go ahead. You're passionate about this issue.

[*Translation*]

Ms. Nicole Demers: Thank you for being so generous, Mr. Chair.

Thank you too, Mr. Batters.

You said that you took into consideration the 65,000 pages provided by the industry, by Inamed Corporation and Mentor Medical Systems, before approving silicone gel-filled breast implants, also known as gummy bear implants. However, you also said that you consulted another expert to determine that magnetic resonance imaging was not necessary after two years.

Do you mean to say that the information contained in the 65,000 pages provided by Mentor Medical Systems and Inamed Corporation is unfounded? What I have here comes from those documents. In their own words, they say:

[*English*]

Therefore, you should advise your patient that she will need to have regular MRIs over her lifetime to screen for silent rupture, even if she is having no problems. The first MRI should be performed at three years post-operatively, then every two years thereafter.

[*Translation*]

We know that young women who have had MRIs within the past two years are not supposed to have access to silicone gel-filled implants for breast augmentation.

Will they still have access through the special access program for medical devices?

[*English*]

Dr. Supriya Sharma: I have just one correction. The breast implants you were referring to, in terms of the gummy bear implants, are not currently licensed in Canada, nor have we received any submissions. So those are the fourth-generation implants. Those were not part of this decision, just to clarify that point.

In terms of the MRI, and again it's very clearly laid out in the labelling, there is still a debate about how best to monitor the patients in terms of whether MRI is actually the best way to monitor them. We specifically asked our expert advisory committee, and they came back with the recommendation that they felt that MRI was not the best way to do it.

[*Translation*]

Ms. Nicole Demers: [*ed. note: inaudible*] —conflict of interest.

[*English*]

Dr. Supriya Sharma: Again, the FDA did the same thing. They had two panels that considered it. The two panels actually gave conflicting information. It's still up for debate in terms of the best way to monitor the patients.

In terms of the special access program, the special access program for medical devices is available for patients and practitioners to have access to medical devices that are otherwise not licensed in Canada. So these products are now licensed. If there is another product, for whatever reason, that a practitioner would like to access that is not licensed, he or she would have to put in an application and provide us with information as to why they would want them authorized. So at the time of licensure, when we license these silicone gel-filled breast implants–To date there have not been any silicone gel-filled breast implants that have gone through the special access program, because we now have a licensed alternative.

The Chair: Okay. Thank you, Madam Demers.

Madam Fry.

Hon. Hedy Fry (Vancouver Centre, Lib.): Thank you very much, and thanks for your report, Dr. Sharma and Dr. Bell.

I note that on page 3 you talk about your scientific and regulatory basis for decision-making in allowing these back on the market. Manufacturing and quality control—that's a good one. Preclinical studies—that's a good one. Biocompatibility tests, effectiveness and safety, and labelling are good ways of informing the patient about what is currently the status.

But given that this product is a product that has had very severe side effects in the past, I would see it not just as any other device on the market; I would see it as a red-flag device. I would have hoped—and I wonder why you didn't consider doing it—that for this particular product, there would be mandatory reporting by physicians of any new adverse effects, not at the end of the year but immediately, rather than on the voluntary basis by which they would be reporting those things. I just think, purely because this is a red-flag device and not just any old one, that we need to be able to do that, because I think we should still be putting this product on sort of a trial basis, so to speak, because it has to re-prove itself now.

I mean, it's about the fact that this is not merely something you wear on your arm. It's something that if it causes problems becomes an absolute horror to remove, and therefore the ability to look at the patient's long-term results, if something goes wrong, is extremely important. So you would need to know sooner rather than later, and at the early stages, that something is going wrong. So for that reason, I wondered why you did not decide to have mandatory reporting by physicians of any adverse effects.

As a physician, I don't believe in mandatory reporting. It's too much like hard work. If you had to do it on everything, you'd never practise medicine. But at the same time, because this is a specific red-flag device, I would have thought that it would be an important thing to do.

● (1610)

Dr. Supriya Sharma: Starting at the end, the point you raised is really important in that, as a physician, I don't know if mandatory reporting works. There's a lot of debate about whether or not mandating physicians to report would work, because you would actually not just mandate it. How would you enforce it? And if you actually put it into legislation, it would actually go into criminal legislation. So on the enforcement side of it, you would actually have inspectors, in this case from our health products and food branch inspectorate, going into physicians' offices trying to enforce the suspicion of an adverse event being associated with the product. And then if they failed to report it, there would be criminal complications.

So just in terms of mandatory reporting, those are the concerns we would have.

Hon. Hedy Fry: I'm not speaking in general now. I made my point about “in general”. I'm speaking of this specific product. For instance, you know that one of the first things you try to do is this: first do no harm.

Right now, in Vancouver, we have turbidity in the water. There has been no one sick yet, but they're still continuing to advise you to boil water, because that is a precautionary principle.

Given that this product had shown itself to be a dangerous product at the beginning, and given that some of the repercussions of it were very damaging to women particularly, I just think that in this instance the mandatory reporting of any adverse effects, on a regular basis, as soon as they occur, should have been there. And I believe that if the physician doesn't do it when he or she was asked in this instance to do mandatory reporting, then that's going to be the physician's problem to deal with. But I think Health Canada has a duty, with a product that has been shown to be harmful, to take that precautionary principle in this instance.

Dr. Supriya Sharma: The precautionary principle was taken in that–for instance, one of the conditions. There are two studies already ongoing, and one very large study will be undertaken by the companies that monitor these patients. In that context, there is mandatory reporting because it's a clinical trial. Not only is there mandatory reporting, but there's all the patient information that goes along with mandatory reporting.

What we find when we're doing even active surveillance, which encourages reporting, is that it's not the number of reports you get, it's not just the quantity; it's the quality of reports. So mandatory reporting may give you a piece of paper that says this was the adverse event, but to put that in context you really need the rest of the information around the patient. The best way to get that is through a clinical trial.

We had that discussion internally about the best way to monitor these products, given the context, the history, and the concerns that have been expressed by the Canadian public. The best way we found was to continue the mandatory reporting by the manufacturers and then put in very stringent conditions so we're not just getting the adverse reaction reports; we're getting all the clinical information associated with these patients so we can interpret the reports. It happens all the time that we get adverse reaction reports and we can't interpret them because there's not enough information in them.

Hon. Hedy Fry: I understand all of that. I'm just saying that in this case there should be mandatory reporting of adverse effects, because before any product goes for public use and is okayed by Health Canada, it has to go through clinical trials and be proven safe. We thought this was a safe product when it first came out, and it has proven not to be. So knowing that, I think we should be doing really careful monitoring of it, and that doesn't mean to have people after a year....

I understand that quality is not the same as quantity, but if you get enough people saying something might be related to it, we need to red-flag it.

The Chair: Your time is gone. The time for answering is gone as well, but I'll allow a quick answer if you want.

Dr. Supriya Sharma: Again, it's the quality of the reports. Whether it's a medical device or an adverse reaction related to a drug, it hasn't been determined whether or not mandatory reporting gives you good-quality information to be able to make those determinations.

A number of countries in the world have instituted mandatory reporting, and they did not feel it actually gave them any additional information. There have been no safety signals picked up as a result of mandatory reporting in any of the countries that instituted mandatory reporting worldwide.

● (1615)

Hon. Hedy Fry: It's not convincing.

The Chair: Madame Demers, do you have any more questions? I'll allow you to continue with some questions.

Then we'll have one more from Ms. Dhalla.

[*Translation*]

Ms. Nicole Demers: Thank you, Mr. Chair.

Through the special access program for medical devices, you have allowed surgeons to obtain 24,000 silicone gel-filled breast implants. Do you have any information about the results of those implants? You have been allowing silicone gel-filled implants through the program since 1993, so you had a whole group of people to do a long-term study on. Did you do one?

One more thing: if you did not approve gummy-bear implants, you should let that surgeon in Burlington, Ontario, know because he is publishing ads offering patients exactly what was just approved by

[*English*]

Health Canada:

> Saline or cohesive gel-filled breast implants — which are better?
> - Both are safe and approved for use in Canada...
> - Saline "mini-waterbeds"
> - Gel — "gummy bears"

[*Translation*]

Comparing breast implants to aspirin downplays their importance, and that is exactly what you did earlier. I found that very petty on your part. We are not talking about taking an aspirin to make a headache go away. We are talking about something carried inside the body that can cause much more serious problems than an aspirin. Can you explain this kind of ad, Ms. Sharma? It downplays the risks even more. It does not mention the risks associated with silicone gel-filled breast implants; instead, it says they are much safer than saline breast implants—

[*English*]

The Chair: Let's ask for the answer to that.

[*Translation*]

Ms. Nicole Demers: How do you explain that?

● (1620)

[*English*]

Dr. Supriya Sharma: In the first instance—I'm just getting corrections by Dr. Bell here—the gummy bear implants are licensed for sale in Canada, but they are not licensed for sale in the United States. Is that correct?

Dr. Mary-Jane Bell: Yes.

Dr. Supriya Sharma: Okay.

Second of all, in terms of the special access program, the special access program is very much an exception program. The reason we prefer to have products that have gone through the rigorous review is that we do have the ability to put conditions on them in terms of the licensure to be able to regulate them. For the special access program, there's limited monitoring because it's an exception program. But as a result of the special access program, we have not received any complaint reports submitted from the cohort of patients who have been examined.

In terms of the comparison, the comparison was not being made between risks associated with aspirin and risks associated with breast implants. What I'm saying is that something on a very low level of risk, such as an aspirin, still carries risk, as well as something on a high level of risk.

This is a surgically implanted device. There are risks to surgery. There are risks to putting a foreign body into your body. We know the risk. We've studied the risk. We've informed people of the risk. We've labelled the products. We've done an intensive review. So what I'm saying is that everything we do has a certain amount of risk associated with it, and we have to consider both the risks and benefits of anything we do in terms of our health care.

What we're doing is saying that these devices have passed the bar in terms of safety, effectiveness, and quality, and just to remind everyone again, that's mandated by the Food and Drugs Act and regulations, the medical devices regulations, put in place by Parliament, which forms the basis of our regulatory decisions. They've made that submission. Those submissions have been reviewed and they've met those criteria.

To continue to meet those criteria, there are conditions that are put on their sale. But all medical devices have risks associated with them. They are not 100% safe, they are not 100% effective, and we need to continue to monitor them. We need to know about the risks. We need to know about the benefits. Practitioners need to inform their patients. Patients need to inform themselves, and people need to make educated, informed decisions about their health.

The Chair: Just as a correction—and correct me if I'm wrong—I understand that the regulations are not set by Parliament; they're set by the department. Is that accurate?

Dr. Supriya Sharma: Well, they're passed in Parliament.

The Chair: The research team are saying they're not passed in Parliament, they're set by the department. I'm not sure. I'm not going to debate it.

Maybe just for the committee, from our research team, we'll allow this.

Mrs. Nancy Miller Chenier (Committee Researcher): I'd like to go on the record on this, because you have scolded the committee a couple of times.

The Food and Drugs Act is a piece of legislation that was passed by Parliament. The regulations are gazetted through a special gazetting process that Parliament sees as any member of the public would see. The only regulations that the health committee sees are the tobacco regulations and the assisted human reproduction regulations.

Dr. Supriya Sharma: Right. I was referring to the Food and Drugs Act, and the act is actually an act of Parliament, right?

Mrs. Nancy Miller Chenier: Just drop the regulations part of it.

The Chair: The act we see; the regulations we don't. Fair enough. That's just for the information of the committee.

Ms. Dhalla.

Ms. Ruby Dhalla: I just want to build upon something that you were saying at the end, about the responsibility for physicians to be able to educate their patients and for patients to make an informed decision. In your particular decision that has been made by Health Canada, what types of initiatives or steps have you taken to ensure that patients do receive the right information? Building, I think, upon what Mr. Batters was saying earlier on, what type of educational tools and resources are going to be provided to these women to make an informed choice?

I know you talked a number of times, both in your report and in your discussion, about there being a mandatory reporting requirement. But from everything that you've told the committee, it's the manufacturers that are required to report adverse reactions. First, there are no restrictions on patients reporting those reactions to their surgeons or physicians; and second, there is no mechanism there for the surgeons and physicians to actually go out and report those to the manufacturer. So if a woman out there is experiencing an adverse reaction, the manufacturer may never, ever know about it, and the physician and surgeon may be very hesitant, as this is their bread and butter, to go out and actually report that.

So I would like to know what initiatives Health Canada has taken, in light of all the information available, over a period of four years, to ensure that women in Canada are going to be able to make an informed choice?

Dr. Supriya Sharma: In terms of the informed consent process, the process by which a physician or a practitioner actually exchanges information to make those decisions, that's regulated at the provincial and territorial level. So the actions of the physicians are actually governed by the Colleges of Physicians and Surgeons—

Ms. Ruby Dhalla: I know that, but what has Health Canada done?

Dr. Supriya Sharma: So that's that.

So the role of Health Canada is to provide information to inform that decision, and it's done in a number of ways. I mentioned the "It's Your Health" document, which is written in lay language, and the background on the file in terms of all the decisions that have gone up into this point on the file. The decisions are actually posted publicly. So for each breast implant that has been licensed, there's a summary basis of decisions that summarizes all the information that went into the review, and that's actually listed on the website for every single product.

Ms. Ruby Dhalla: Not everyone has a computer, and not everyone is literate in medical language to be able to actually disseminate the information. So has there been any initiative by Health Canada to make a—

Dr. Supriya Sharma: I'm getting to that.

Just to go back to before I was interrupted, all that information is there. In addition, what's also there is all the patient labelling and all the patient information that goes along with the product. The patient labelling and decision aids are included. There are actually booklets that go to the patients, which they can go through and which have all the questions for them to ask themselves. There are also questions provided that you can ask the surgeons: How many surgeries have they performed? What are the side effects? What are the adverse events? There's a whole decision-making aid that goes along with the product for the patient. Then there's information for the practitioner to be able to make this decision.

All that information is mandated. It's part of the patient labelling. It's been reviewed. It was part of the rigorous review. It's available not only publicly on the website, but with the product. If anybody writes in at any point in time to Health Canada and says they don't have a computer, we copy it all off and send it out to them. We've made all of that information available.

All that information is just part of the information that's out there. There's a wealth of information out on breast implants, from a variety of different sources, with a variety of different opinions. It is then up to the patient and the practitioner to sit down and go through the information. All patients and all practitioners view risks and benefits in different ways. So you really have to cater that discussion to the person you have in front of you.

Ms. Ruby Dhalla: Can you just, for the sake of this committee, submit that information, those tools that are made available to patients, please?

Dr. Supriya Sharma: Actually, they've already been submitted. As part of the notice that went out to parliamentarians, there was a package that went out when we made the decision. It identified all of the links. Those links have also been provided to the committee, so the committee actually has all that information.

Ms. Ruby Dhalla: I actually never received it. So if you can forward it to the committee, that would be great.

The Chair: I just want to remind the committee that we have a considerable amount of business to do. We had scheduled the first hour for this. There is limited time. But I see a couple of hands going up now. We'll allow that.

Madam Gagnon, did your hand go up?

[*Translation*]

Ms. Christiane Gagnon: I just wanted to say that Ms. Sharma is talking too fast and that the interpreters are having a hard time following her. She should slow down.

[*English*]

The Chair: Okay, thank you.

Ms. Priddy, do you have a quick question?

● (1625)

Ms. Penny Priddy: Yes, thank you. I wasn't sure if we were going in order. It seemed as though we were just all of a sudden asking.

The Chair: No, I was hoping to start it.

Ms. Penny Priddy: I was trying to be polite. So much for that.

I just have a comment that if we'd had at some stage an agreement to have a national breast implant registry, a number of the questions we are dealing with today would have been dealt with in a national registry, and though some of our discussion today would still have been necessary, some of it would not have been. So at some stage, I expect that I and others I work with will still go back to the national registry, because it gets at a number of the issues around reporting, confidentiality, and our ability to see a trend when there's something happening, without necessarily relying on a manufacturer or a physician who may—I say "may"—have a vested interest.

Thank you.

Dr. Supriya Sharma: Just to address the implantation registry, it's something that we did consider in the review. Specifically, the panel recommended that Health Canada consult with the Canadian Institute for Health Information on the subject of a registry. We did that. We actually went back to CIHI because they're the national experts in terms of data collection and database and registries, and they went through all the information that we have with breast implants. Their opinion—and we actually have that in writing—would be that a national registry would not be the best way to follow these patients.

There were a number of different reasons that they actually signified that it wasn't. One was that for a registry you actually a priori usually identify the events that you're looking for, and that for a registry to work we would have to mandate reporting. As an interesting point, the U.K. breast implant registry was operable for a number of years. They closed it down for two reasons. One was that they didn't actually get a very high level of participation, and the second was that they didn't actually get any meaningful clinical data out of the registry.

So we did consult with CIHI on the issue, and they went through all of the reasons why it wouldn't be the best way to monitor the patients, which is why then we began to think of what would be the best way to monitor these patients. What conditions could we put on? The way we structured the clinical trials not only met the outcomes of what people were looking for in a registry, but it surpassed them.

The Chair: Thank you very much.

I'm a little reluctant to do this, but Ms. Bennett has asked for a very quick question. I've got to see this, so we'll try.

Hon. Carolyn Bennett (St. Paul's, Lib.): Just following up on Dr. Dhalla's question, the whole issue of informed consent, I think, is what people are concerned about. Do people actually know enough to give informed consent? Certainly I think the medical-legal community has been interested in maybe a new innovative, creative thing. Maybe this would be the perfect area to look at it, because it's so controversial.

There was a CD that showed you three patients who loved it and three patients who hated it. You had to have seen the CD in order to sign and say that you actually knew enough to give informed consent. This comes out of the highly litigious American milieu.

I wonder if the department would be interested in looking into maybe a special kind of informed consent for something that's been so controversial.

Dr. Supriya Sharma: In terms of sharing information, once we've done the licensing, part of the reason that we have the focus groups is to see if the information we've provided adequately reflects the risks. Does it meet the requirements? The last time these were on the market was back in the early 1990s. As you mentioned, times have changed since then. Really, the idea is what would be the best way to share that risk information.

When we're talking about things in terms of the CDs and sharing of consent, that primarily comes from the practice community. It's the same way as clinical practice guidelines come about. It doesn't usually come from a federal regulator because of the nature of informed consent. We have no authority over informed consent and we have no authority over the practice of medicine.

So I think it's an interesting concept. I think it's an innovative approach. It will be interesting to see what comes up from the focus groups, but it isn't something we would be able to put in in terms of a condition of licensure.

The Chair: Just for the committee's information, Ms. Dhalla wants to make a point quickly.

Ms. Ruby Dhalla: On behalf of all committee members, I just want to clarify something for the sake of Dr. Sharma, Dr. Bell, and Health Canada.

You mentioned that when the decision was released, we received information and website links in regard to the educational materials provided to patients and provided in addition to what's within the package inserts. I believe the day the decision was released was a Friday. I just want to clarify for the committee that the information was not received on that particular day. The information was received yesterday at about 4:30, at which time our gracious clerk here forwarded us the information at 5:30.

● (1630)

Dr. Supriya Sharma: Actually, on the press release that went through, it went out with a link to the Health Canada website and the decision, and then on that—

Ms. Ruby Dhalla: We all received the decision, but the information with regard to the educational materials—

Dr. Supriya Sharma: All the educational materials were linked to that decision, so we went through it. It's still on the Health Canada website. If you go on the Health Canada website, there's a big icon that says "Licensing Decision: Silicone Breast Implants", and all of the links are then provided. We provided the major link, and then all the links with all the information.

Just to give you an idea, we have the hard copies here just to show you, but when you print it out it's this much information that has been publicly available. So that original link was actually provided.

Ms. Ruby Dhalla: Just out of curiosity—and I'll end here—are patients actually going to read that link with that information?

The Chair: Let's move on.

We have your information. We appreciate your coming. We've had a fairly fulsome debate, and now we're going to go to the motion.

Madame Demers.

[*Translation*]

Ms. Nicole Demers: I promised victims of complications due to breast implants that I would ask the following question:

These people would like to know if you and your Health Canada colleagues who participated in making this decision would be prepared to be test subjects. You would receive next-generation breast implants. For the purpose of advancing science, of course, we would be sure to find out everything there is to know about them. We would monitor you very closely.

Would you be prepared to do this in order to advance science?

[*English*]

The Chair: All right. The question was asked. Let's move on.

We want to thank you very much for coming and presenting before the committee again.

I thank the committee for their very good questions. They were very probing and informative. Now we'd like to move on.

Madame Demers, you have a notice of motion that you have presented to committee. It's on our agenda. We need an indication from you as to whether you want to proceed with that or not.

[*Translation*]

Ms. Nicole Demers: Mr. Chair, I wish to introduce my motion.

[*English*]

The Chair: Do you want to speak to it? I'll allow you to introduce it very quickly.

[*Translation*]

Ms. Nicole Demers: Mr. Chair, I think enough has been said about breast implants. I am sure you understand why I want to introduce my motion. I am still very offended by the way Health Canada dealt with this issue. We are talking about a level 4 medical device, which means very high risk.

Health Canada's role is to protect the health of Canadians and Quebeckers, not to expose them to risk by approving a product that has not yet been proven safe. We absolutely have to report this to the House of Commons and have a debate on this issue.

[*English*]

The Chair: On the floor, we have the motion that is before us. We have it introduced by Madame Demers. We'll open the floor for debate on the motion.

Mr. Fletcher.

Mr. Steven Fletcher: I shall let the Liberal—

The Chair: Okay. Well, we'll close down the debate. I don't see any other hands. It's to be concurred in the House, so if there's—

Mr. Steven Fletcher: Well, I have a few comments, then, Mr. Chair.

With the preamble of Madame Demers' comment, there is certainly a problem. To suggest that proper diligence has not occurred is not correct. Due diligence has occurred. We have seen that Health Canada has proceeded through all the appropriate rules and regulations as outlined in the act.

We've also heard that the cost of bringing forward all the material to the committee is $55.9 million. I actually asked the member to repeat that, because that is an astronomical sum of money—$55.9 million—and I believe the taxpayers of Canada would prefer that kind of money spent on real issues, real things that can definitely improve the quality of life of Canadians.

● (1635)

Hon. Hedy Fry: On a point of order, please, Mr. Chair, this motion has already been passed and debated as a substantive motion by this committee, and it was adopted. We are now discussing whether this should go to the House—

The Chair: That's right.

Hon. Hedy Fry: —so any debate should be about the propriety of taking it to the House and not about the substance of the motion anymore. It's already been passed.

Mr. Steven Fletcher: And that's a fair point, so we'd like to do a consenting report.

Can you explain it to us?

The Chair: Fair enough. You mean a dissenting report.

So I think we're ready for the question.

Madame Gagnon.

[*Translation*]

Ms. Christiane Gagnon: I only want to ask a question about what the parliamentary secretary just said.

What will cost $55 million? Translating all of those reports?

[*English*]

The Chair: No, I believe that question was asked to Ms. Sharma, and she said the documentation that was encompassed in this first motion would cost $55.9 million—to get the consent and the information. I believe that's what she said.

[*Translation*]

Ms. Christiane Gagnon: So he is repeating the same thing.

[*English*]

The Chair: Yes, I think that is the point he was making.

[*Translation*]

Ms. Christiane Gagnon: I have a hard time believing that will cost $55 million.

[*English*]

Mr. Steven Fletcher: Mr. Chair, I'd just like a recorded vote as well.

The Chair: Okay, so we have a recorded vote requested—

[*Translation*]

Ms. Christiane Gagnon: He said the same thing Health Canada said.

[*English*]

The Chair: —and a dissenting report.

Ms. Priddy.

Ms. Penny Priddy: This is really perhaps a newcomer question, but perhaps you could be so good as to guide me.

The Chair: I will give you my best information.

Ms. Penny Priddy: Thank you so much. I knew you would.

Given the motion, we're really simply saying this work that was done, other than perhaps the list, has come to the health committee, and the motion simply says to the House, we want you to know that this happened.

Is this in any way precedential? Do we do this on other items? Just help me with the motions. It's just a lack of experience, on my part.

The Chair: Essentially my experience, serving in both a majority government and a minority government, is that it's more prevalent in a minority government, but it does happen from time to time.

I'm just calling a spade a spade. Madame Demers has the opportunity, then, to bring it forward in the House and ask for a three-hour debate on it, and we've seen that before. So that gives you —

Ms. Penny Priddy: Yes, I understand that. I just wondered how frequently it happened and so on. Thank you.

The Chair: Yes, from time to time.

Okay? So everyone is clear on the motion. We would ask the clerk to continue now with the vote.

The Clerk of the Committee (Mrs. Carmen DePape): Do you want a recorded vote?

The Chair: We want a recorded vote. That is what the request was.

Mr. Steven Fletcher: A recorded vote, and I would like a dissenting report.

The Clerk: Okay. We have to have a motion on the dissenting report, also.

Mr. Steven Fletcher: Okay. At what point do I do that? After this?

The Clerk: We can do it afterwards.

The Chair: Fair enough. We can do it afterwards.

(Motion agreed to: yeas 7; nays 4 [See *Minutes of Proceedings*])

The Chair: We now have, I would imagine, a motion.

Mr. Steven Fletcher: Yes, I would like to bring forward a motion for a dissenting report.

The Clerk: I need to know when he will give me the dissenting opinion. I need to have it so we can decide when to table the report.

Mr. Steven Fletcher: I will give it to you in a timely manner.

The Chair: Does he have to name a date, such as the next meeting or whatever? What do you need?

● (1640)

The Clerk: It's usually a day.

Mr. Steven Fletcher: It will probably be at the next health committee meeting. Is that all right?

The Clerk: Will it be by the end of the day on Thursday?

Mr. Steven Fletcher: Is a week all right?

Hon. Carolyn Bennett: Aren't the four of you voting against a dissenting report?

Mr. Steven Fletcher: No, we're asking for a dissenting report. We're only setting the timeline.

The Chair: You're saying it will be next Tuesday.

[*Translation*]

Ms. Nicole Demers: Mr. Chair, I think this is both very funny and very bizarre. The vote was not on the three points presented. We already voted on that during another meeting. The Conservative Party members voted for it. The purpose of the vote was just to inform the House that we adopted the motion. Health Canada representatives have already come to give their testimony. We still have to get the list and the studies, but our colleagues voted for that too.

Now we are talking about costs amounting to $53 million and I do not understand anymore. Reporting the motion to the House will not cost $53 million. We already voted on that part of the motion.

[*English*]

The Chair: No. I think we're becoming confused on two things.

[*Translation*]

Ms. Nicole Demers: But that has nothing to do with this motion.

[*English*]

The Chair: The information we received today is that the documentation requested in the original motion was going to cost $55.9 million. The motion on the floor is to report to the House. I understand the dissenting report would be opposing that it be reported to the House.

It's the issue that's on the table, and you've given notice of motion to the report. Do we vote on it now?

We have a motion on the floor that there be a dissenting report by next Tuesday.

[*Translation*]

Ms. Nicole Demers: Can someone explain this?

[*English*]

The Chair: The motion is for Mr. Fletcher's dissenting report saying he does not agree with this being concurred on in the House. Is that right?

Mr. Steven Fletcher: Mr. Chair, can we not do that? Do we need to vote on a dissenting report?

[*Translation*]

Ms. Christiane Gagnon: He was fine with it before.

[*English*]

The Chair: Give me a minute. I'll confer with the clerk.

Ms. Ruby Dhalla: Mr. Chair, I have a question.

The Chair: Let me clarify this. This is what the clerk is suggesting to us.

We'll have Carmen explain it, and it won't have to go through me.

The Clerk: This motion will become a report of the committee to the House. In order for there to be a dissenting opinion, the committee has to agree that the committee append to its report a dissenting opinion. We did it, for example, when we did the report on fetal alcohol syndrome. But the committee has to agree to append a dissenting opinion to its report. The report is the motion.

The Chair: Is there a problem with that? I see concurrence over here, so if there's no problem, then we've—

Ms. Tina Keeper (Churchill, Lib.): No, we don't want a dissenting report.

[*Translation*]

Ms. Christiane Gagnon: You are asking that a dissenting report be attached to the report and that it be accepted by committee members. I see no reason why not.

[*English*]

The Chair: It's similar to what you did. I see concurrence there. The motion that allows the dissenting opinion is on the floor.

(Motion agreed to)

● (1645)

The Chair: We will get that opinion later.

We will now move in camera. We'll have a brief recess while we clear the room and move in camera to future business.

[*Proceedings continue in camera*]

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