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Chair

Mr. Rob Merrifield

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● (1130)

[*English*]

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

First of all, we have a very interesting meeting ahead of us. I believe we've been anticipating this meeting for some time. I want to thank the Department of Health for being here, also the Public Health Agency of Canada. I will be asking them to present initially.

We have Neil Yeates, assistant deputy minister from the health products and food branch; Ms. Sharma, associate director general, therapeutic product directorate, health products and food branch; and we have the Public Health Agency as well. We have Dr. Stachenko—thank you for being here—and Dr. Mao.

We appreciate your coming forward and being able to share your insight on this issue. We're talking about the study on silicone gel-filled breast implants.

We are going to ask the department, who are at the table right now, to do their quick presentation, then we're going to go to the rest of the witness panels, and we'll ask them to retreat from the table so there's room at the table for the rest.

This is a rather special meeting, and I also want to acknowledge and thank Dr. Mitchell Brown. Dr. Brown, can you hear us and see us?

Dr. Mitchell Brown (Plastic, Reconstructive and Cosmetic Surgeon and Associate Professor, Department of Surgery, University of Toronto): Yes, I can, Mr. Chair. Thank you.

The Chair: Thank you, and you're looking fine. I'm glad this technology is working for us, and I appreciate your giving us your time.

After we listen to the department, we'll have you come forward in the second part, as part of the presenters in the second half of the panel, if that's all right.

Without any more delay, we'll ask Health Canada to start, and then we'll go to the Public Health Agency.

Mr. Neil Yeates (Assistant Deputy Minister, Health Products and Food Branch, Department of Health): Thank you very much, Mr. Chair and members of the committee. I'd like to thank you for the invitation to appear before you to provide an update on Health Canada's regulatory review of the six pending medical device licence applications for silicone gel-filled breast implants.

As you know, medical devices are regulated under the medical devices regulations and the Food and Drugs Act, which fall under the responsibility of the health products and food branch, for which I am the assistant deputy minister.

My colleague Dr. Supriya Sharma, the associate director general of the therapeutic products directorate, is joining me today.

We welcome this opportunity to come before the committee to discuss the issues raised over the last few weeks and to answer any questions that you may have.

I would like to begin by addressing the two fundamental issues raised recently, first by outlining briefly how medical devices are regulated and reviewed by Health Canada, and second, by outlining the role of external advisory bodies in this regulatory review process, and I will then conclude by providing you with an update on the status of the review of the six pending applications for breast implants.

As you are aware, breast implants—including saline and silicone gel-filled breast implants intended for reconstruction following mastectomy, primary augmentation, or for replacement—are regulated as medical devices in Canada. The importation, sale, and advertisement of medical devices in Canada are governed by the Food and Drugs Act and the medical devices regulations. Through the act, Parliament has created a legislative regime to govern the approval of medical devices for sale in Canada. This regime is given full effect through the medical devices regulations, created pursuant to the act.

Under this regime, the minister has the legal responsibility for approval of licences to permit the sale of these medical devices in Canada. In turn, the minister relies on Health Canada's scientific and regulatory expertise and its processes to execute this responsibility. Decisions are made following an independent, impartial, and objective analysis of the scientific evidence related to the safety, quality, and effectiveness of a medical device included in a licence application. Such decisions are taken in consideration of sound scientific expertise, in an environment that encourages collaboration among a team of experts skilled in a variety of fields and disciplines.

This process reflects the key principles that underpin both the integrity and quality of Health Canada's regulatory decision-making framework and the public's confidence in Health Canada's ability to fulfill its mandate and to make objective, evidence-based regulatory decisions. Health Canada's decision-making framework outlines the key principles that guide such evidence-based decision-making. These include a recognition of the need for comprehensive information; the value of team work and expert opinions, given that sound evidence-based decisions can only come from a collaborative process where varying opinions are encouraged and considered in all phases of an evaluation; and the value of the multiple disciplines of the experts whom we consult and of the Health Canada employees who contribute to our decision-making teams. Such disciplines include microbiology, material sciences, medicine, chemistry, physiology, toxicology, engineering, and ethics.

The medical devices regulations are based on a current, internationally consistent, risk-based approach. I note this point in addition to our recognition of the need for comprehensive information to support decision-making, as they are, together, the core determinants of Health Canada's regulatory approach with respect to higher-risk—or class IV—medical devices such as breast implants. The medical devices regulations and Health Canada's publicly available guidance documents outline that manufacturers of class IV medical devices must submit certain specific information in support of each medical device licence application. This information alone, in addition to any information obtained from external experts and the public, represents a very significant amount of scientific, manufacturing, and quality data, which Health Canada reviews in order to reach a regulatory decision.

I'll also note that the panel was requested to provide its advice in response to very specific questions posed by Health Canada, related to the safety and effectiveness of the silicone gel-filled breast implants described in the device licence applications—advice to inform Health Canada's assessment of those specific medical device licence applications.

● (1135)

The panel was not asked to make a decision on behalf of the minister or Health Canada, nor was it asked to recommend whether any of the specific products should or should not be licensed for sale in Canada. That decision is the responsibility of Health Canada alone, to make on behalf of the minister. As this committee is aware, the advice resulting from the expert advisory panel's deliberations was presented in the panel's final report to Health Canada on December 2, 2005, and, following a review for confidential information and translation, was made publicly available by the previous Minister of Health on January 12, 2006.

The panel's work is now concluded, and its report speaks for itself with regard to the various viewpoints represented on the panel. It is now being taken into consideration by Health Canada as one important piece of information, among others, in the regulatory review of the six pending medical device licence applications for silicone gel-filled breast implants.

Health Canada's decision will be based on a solid, evidence-based, scientific assessment of all the information before it. It is public knowledge that Mentor Corporation and Inamed Corporation each have separate medical device licence applications currently under review by Health Canada. The first of six licence applications was received almost five years ago. The Health Canada review team is led by two scientists, one with a degree in chemistry and the other with a degree in material sciences, and input is received from medical officers and biomedical engineers as required. Together, these individuals have more than 20 years of experience in the regulatory review of medical device issues.

Health Canada has examined more than 65,000 pages of evidence submitted by the manufacturers. Health Canada has reviewed the scientific literature, the report of the expert advisory panel on breast implants, documentation from the American Food and Drug Administration, and submissions from interest groups and interested persons. The scientific literature alone consists of over 2,500 articles, including over 300 review articles dating from the 1960s. In the interest of obtaining comprehensive information to inform the review of each of these applications, Health Canada has most recently in January 2006, during the course of these separate reviews and consistent with the advice received from the expert advisory panel on breast implants, requested that each manufacturer clarify existing information, or provide additional information. Health Canada is continuing with its reviews of these applications, and once these assessments are completed, regulatory decisions will be made in accordance with the responsibilities conferred upon it via the minister's role under the Food and Drugs Act and the medical devices regulations.

The potential decision for each application is one of the following: a licence for general sale in Canada, a licence with post-approval conditions, or a refusal to licence. Once the regulatory decisions have been made, Health Canada commits to reporting publicly to Canadians, through the publication of a summary basis-of-decision document for each application, outlining the nature of the evidence considered and the conclusions reached.

In conclusion, I would like to reiterate that the legislative regime created by Parliament and given full effect through the medical devices regulations to govern the approval of medical devices for sale in Canada and the execution of the responsibilities Parliament conferred upon the Minister of Health through Health Canada's scientific and regulatory expertise and processes is strong. It's built upon the independent, impartial, and objective analysis of evidence that is supportable and is driven by the key principles. These principles support the use of a collaborative process in which comprehensive information and varying opinions from multiple disciplines and consideration of all of the best scientific evidence are integral to regulatory decision-making.

Thank you very much, Mr. Chair. Those are our opening remarks. I do need to advise the committee that, regrettably, I have to leave after the first portion of this hearing, but my colleague Dr. Sharma is available throughout.

● (1140)

The Chair: Thank you very much.

We'll now hear from the Public Health Agency.

[*Translation*]

Dr. Sylvie Stachenko (Deputy Chief Public Health Officer, Health Promotion and Chronic Disease Prevention, Public Health Agency of Canada): Mr. Chairman, members of the committee, I wish to thank you for your invitation to speak to you about the Breast Implant Cohort Study. I am Dr. Stachenko. I am Deputy Chief Public Health Officer responsible for the Health Promotion and Chronic Disease Prevention Branch of the Public Health Agency of Canada. I am happy that Dr. Yang Mao has been able to join us. He is Director of Health Promotion and Disease Prevention at the Centre for Chronic Disease Prevention and Control. He also takes part in the cohort study as a researcher.

The Breast Implant Cohort Study is the largest study ever designed to investigate the risk of cancer and other health outcomes in women with cosmetic breast implants. The first scientific results of this study are now available. As you are aware, an article on cancer incidence was published in English in December 2005 by the *International Journal of Cancer*. In response to the request of the clerk on May 11, 2005, we at the Public Health Agency have secured permission from the journal's publisher to translate the article and provide it to the committee in French. I understand that the French translation has been provided to her yesterday.

As well, a second article based on the study has been developed. It concerns the relative risk of mortality from breast cancer and from other causes. This article has been accepted by the *American Journal of Epidemiology* and is expected to be published within the month.

The Breast Implant Cohort Study involved identifying women in Ontario and Quebec who received implants for cosmetic purposes during the years 1974-1989, inclusively, as well as gaining access to their patient records. The study includes information from over 40,000 women aged 18 years and older. It brought together plastic surgery patients records from Quebec and Ontario and linked them to the National Cancer Registry Database maintained by Statistics Canada.

The women and physicians who participated in the study were assured that the study had passed rigorous scientific and ethical reviews.

● (1145)

[*English*]

Since the study was first announced, the frameworks for privacy, information protection, and information access have evolved significantly, both within the Government of Canada and in the provinces of Ontario and Quebec, from which the cohorts were drawn. This has considerably lengthened the time it took to gain access to patients' records and to link them to cancer data, beyond what had been originally foreseen. The study data set was completed in June 2003.

Starting in 2003, our epidemiologists and their colleagues in Quebec, Ontario, and academia have been able to undertake the epidemiological analysis and the development of scientific articles more rapidly than was anticipated.

The first article on cancer incidence found that women undergoing cosmetic breast augmentation do not appear to be at an increased long-term risk of developing cancer. Overall cancer incidence rates among women who received breast implants were similar to those of the other plastic surgery patients. In fact, women who received breast implants had lower breast cancer rates than other plastic surgery patients. As well, no increased risks were observed among the implant population at the other cancer sites examined.

As well, I can very briefly outline some of the key findings of the second article on mortality, which will soon be published. Overall, women who received breast implants for cosmetic purposes had lower mortality rates than those of the general population. A lower than expected number of deaths, mainly from cancer and cardiovascular diseases, accounted for most of this reduction. The article acknowledges that self-selection is a likely explanation for lower mortality rates; women who choose to undergo an invasive cosmetic procedure are, on average, likely to be in better health than the general population.

However, it is of note, and consistent with previous work, that increased rates of suicide were observed among women who received breast implants relative to the general population, but there were no statistical differences relative to other plastic surgery patients. The authors suggest that further studies that collect detailed risk factor data for suicides among both implant and other cosmetic surgery populations may be needed.

In closing, I would like to thank you for the opportunity to share these results with you. The Public Health Agency will be providing an information circular to practitioner organizations and the women's groups who participated in the development of the study.

I'd also like to thank the committee for its interest in the agency's ongoing risk assessment and analysis efforts for cancer and other chronic diseases.

Merci.

The Chair: I want to thank you for your presentations.

I'd just let the committee know that in the briefing you received, there is one page missing—actually the best page—and we will get that to you.

Thank you very much for your presentations. After the other presenters have presented, we'll open the floor to questioning.

We would ask Dr. Chidwick if he would come forward, and Dr. Zuckerman.

We have, through video conferencing, Dr. Brown.

Dr. Brown, I appreciate your taking the time to be able to teleconference on this important issue. The floor is yours.

● (1150)

Dr. Mitchell Brown: Thank you very much for accommodating me and allowing me to be a part of this committee meeting today from my hospital here in Toronto.

Mr. Chairman, members of the Standing Committee on Health, thank you very much for inviting me today to address the committee and respond to your questions.

Let me begin by introducing myself. I am a plastic reconstructive and cosmetic surgeon on active staff at Women's College Hospital. I am a full-time academic surgeon and associate professor in the department of surgery at the University of Toronto.

My clinical practice is focused primarily on esthetic and reconstructive plastic surgery of the breast. I have had the honour and privilege of treating thousands of women for problems ranging from congenital abnormal development of the breast, to required reconstruction after breast cancer surgery, to desired aesthetic changes.

Last year I was invited by Health Canada to sit as a volunteer member of both the scientific advisory panel and the expert advisory panel on silicone gel-filled breast implants. I was honoured that Health Canada felt that my clinical experience in using both saline and silicone gel-filled breast implants would be beneficial in helping to answer specific targeted questions relating to applications made by implant manufacturers for their gel-filled devices.

I would like to congratulate Health Canada on the work they have done to put together the scientific and expert advisory panels, as well as the open public forum. I believe that all Canadians should be very proud of and confident in the group of individuals who were asked to form these panels.

In contrast to what we have seen in some other parts of the world, these panels included a diverse selection of individuals, each highly skilled and respected in their particular areas of excellence. Virtually all stakeholders were well represented, and the panel included a balanced mix of expertise, gender, age, and geographic regions.

The panel's report was formed through intense, unencumbered debate, following a thorough review of all provided materials, manufacturers' presentations, and public forum hearings. The panel was asked to answer specific questions based upon the information available to us and our clinical experiences.

I firmly believe that the report submitted to the Minister of Health is a balanced, thoughtful, and complete response to the questions posed. The report has synthesized the views of all members present, and when any dissenting opinion arose, the report clearly states the number of members in agreement or opposition to any statements made. I am proud of my participation in this process, and as a Canadian consumer, I am comforted in knowing that this template exists for the approval of devices in Canada.

Mr. Chairman, I have come here today in support of my patients and their right to make an informed decision about their esthetic and reconstructive breast implant options.

No material has been studied, analyzed, and researched more than silicone. Silicone is presently one of the most commonly used implanted devices in medicine. It is a component of cataract lenses, ventricular peritoneal shunts used in neurosurgery, artificial finger and wrist joints, testicular and penile prostheses, stents, and saline breast implants, just to name a few. Every day in Canada, hundreds of implants are inserted that contain silicone in one form or another. Silicone is used in the processing of medical supplies, in intravenous bags, and is used to coat injection needles. It is estimated that the average diabetic receives 200 milligrams per year of silicone directly injected into their bodies as a result of insulin injections. Silicone is also used in the processing of bottles, glassware, and rubber, and is found in many store-bought food products. Did you know, for example, that measured levels of elemental silicone are substantially higher in store-bought baby formula than levels detected in the breast milk of women with silicone gel-filled breast implants?

There have been many well-conducted research studies evaluating the potential negative health effects of gel-filled implants, and the overwhelming majority of information has failed to demonstrate a connection between the use of these implants and disease in women.

No device is perfect; all implants fail at some point. If you were to ask me today, would I like to know more about the lifespan, failure rates, and long-term risks of any device that I presently use, the answer would most certainly be an emphatic yes. Information is good, and more information is even better. If you ask me, however, when is enough, enough—when do we have enough information so that a reasonable person can make a properly informed decision about the benefits and risks associated with silicone gel breast implants—I would say that time is now.

● (1155)

Silicone gel breast implants are used extensively throughout the world. In almost every country outside of North America, silicone implants comprise 99% of implants used. In the United States, the FDA has provided conditional approval letters to both manufacturers. Once those conditions are met, it is expected that these implants will be available for routine use.

Not all patients are candidates for silicone gel-filled implants. There are advantages with saline implants, and many women achieve excellent results with these devices. In many cases, however, gel-filled implants offer significant benefits. Gel-filled implants are soft, they feel more like natural breast tissue, and they move more naturally under the breast—all important considerations for women undergoing breast implant surgery. As well, they are less likely to produce rippling, a common problem with saline implants, which results in a palpable, unnatural edge at the periphery of the breast margin.

I have been using cohesive silicone gel breast implants in my practice since 2001 and I can emphatically state that no new device or technology has had such a positive impact on what I am able to provide for my patients. They are ideal for treating young women with congenital abnormal development of the breast, and the consistency and shape options produce excellent outcomes for women who have concerns about their breast esthetics following pregnancy and breastfeeding. Results have been far superior to that seen with saline implants, and patient satisfaction has been uniformly high.

In reconstructive surgery, new cohesive gel implants have completely changed what we are able to offer our patients. During the years from 1995 to 2000, 70% of all post-mastectomy breast reconstruction that I performed was large surgical procedures using the patient's own natural tissue, commonly from the tummy. Although these procedures produce excellent results, they are major operations that require scars elsewhere on the body and prolonged recovery times. This is often an unacceptable option, especially for young women with small children, or women who were not prepared to accept that degree of downtime.

The saline implants available at that time produced very unsatisfactory results, with almost 100% of patients developing rippling, an unnatural feel of the breast, and an exaggerated round shape to the breast, often looking very different from the natural, non-operated side.

Women were left with few options but to undergo bigger reconstructive procedures. Since 2001, 75% of all reconstructions are being performed with the new cohesive gel-filled implants—a complete reversal from what I was doing previously. These new gel implants, the ones we are talking about today, are very different from previously developed implants. They are made of a far more viscous, thicker gel, so that if you cut into one, it is very much like cutting into a gummi bear.

These implants come in a wide selection of sizes and shapes, allowing us as reconstructive surgeons to provide outcomes that more closely match the shape of a natural breast and provide for a much more natural-feeling breast. As well, if a device was to break, the gel filler is much less likely to escape from the implant shell in comparison to older-style implants from the 1970s and 1980s.

Since 2001, I have used these implants in over 100 patients for post-mastectomy reconstruction. Results have been excellent, patient satisfaction has been high, complications and re-operation rates have been low, and patients have had a viable alternative to more invasive reconstructive options.

I have concerns about the direction this committee has chosen to pursue. A detailed and thorough report has been submitted to the Minister of Health from a panel of experts who are well qualified to answer the questions put before them. Canadians were invited to, and provided with, a forum to make their views known directly to the panel. Presentations were thoughtful and considerate, whether they were in support of, or in opposition to, the applications.

In fact, Dr. Zuckerman, who is here as a witness, was listed as speaker number 40 on that day, but she did not attend the forum, nor did she present her views to the panel. She is, however, receiving an opportunity to address the committee today without a panel of experts present, a position that I feel is hard to justify to the many Canadian women who support the applications for these devices. Where is their voice? Why are they not invited to speak to this committee today? What is new since the public forum that justifies Dr. Zuckerman's invitation to address the members today?

● (1200)

I would like to read a letter by a woman that I know personally. In fact, she is the wife of a clergy member at my synagogue. She is not my patient, but when she heard about the direction the committee was taking, she asked that I find a way to have her views heard.

> I am a 35-year-old woman who was diagnosed with breast cancer two years ago while pregnant with twins. Although I had to make many decisions quickly, I feel that I made very informed ones. As a critical psychologist, I have been well trained in the art of scientific research. I have a lot at stake: my two-year-old twin daughters and their three-year-old brother. As a BRCA1 carrier, I felt that I had no choice but to have a double mastectomy. I spoke with several other BRCA1 carriers to discuss their decisions regarding implants. After consulting with plastic surgeons, doctors specializing in lupus, general surgeons, medical consultants, researchers and oncologists from several top teaching hospitals in Canada and the US, I decided to proceed with reconstruction using tissue expansion and silicone gel filled breast implants. I was well informed of the risks of silicone implants, but felt that the benefits far outweighed the risks. After all of these consultations, my own readings and testimonials, I feel that I made the right decision.
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> As a young professional woman, it is very important for me to look and feel as good as I possibly can. First, I want my girls to develop a healthy body image; and second, for my own body image and self-esteem. In my busy schedule, I wanted life to go on as normal as possible. The implants I have chosen are very realistic and comfortable for me, and I have thus far had no problems with them. I am very happy with my decision, and I would not have done anything differently if I had the chance. I often advise other women like myself to seriously consider cohesive gel implants as an option for reconstruction. It is comforting to know that as a woman, I have the right to decide what goes into my body.
>
> Thank you,
>
> Melissa Lieberman-Moses

Mr. Chairman, I thank you for the opportunity to be here today, and I look forward to addressing any questions from the committee.

The Chair: Thank you very much, Dr. Brown.

We'll continue with the witness list. We have Dr. Chidwick.

The floor is yours.

Dr. Paula Chidwick (Director of Clinical and Corporate Ethics, and Ethicist, William Osler Health Centre, Brampton Memorial Hospital Campus): Thank you for this opportunity to present a few brief remarks on the process I experienced, witnessed, and participated in as a panel member; on my role as an ethicist; and on some key ethical considerations related to breast implants.

I was a member of both the scientific advisory panel and the expert advisory panel on breast implants convened by Health Canada. This was the first time I have been asked to be a panel member for such a topic, so I had no preconceived ideas or expectations on what would happen.

First, I'll say a few words on the process. Let me begin with a quote: “There does not have to be agreement about the answers to all moral questions, but we do have to accept that everyone must agree on the procedure to be used in deciding moral questions”. This quote emphasizes nicely how important process is in determining answers to questions.

I can say with confidence that the process I participated in was open, transparent, and rigorous. Panel participants came from diverse backgrounds, with diverse experiences and knowledge. Few of us knew each other when we began, and we spent many hours rigorously deliberating on the issues and facts. All views offered in these discussions were treated with respect and all views were equally respected; in other words, there was not, in my experience, a preconceived right perspective that dominated or directed discussion. I witnessed what I call unity in diversity, where diverse views were offered by panel members contributing together to an emerging consensus.

Our task or role was clearly delineated by Health Canada and is available on their website. We were charged with responding to specific questions for feedback. Health Canada clearly outlined that our task was neither to make recommendations to approve breast implants nor to decide what was good for Canadian women.

The chair, Dr. Wells, did a remarkable job in facilitating the diverse views and in creating an environment for frank and honest discussion of the relevant facts and values. I felt free to express all of my views on this matter and felt free to ask any questions about any aspect of the scientific detail. In the public forum, we likewise heard from diverse views, ranging from strong support and enthusiasm to concern, reservations, and warnings. All views were listened to, respected, and incorporated into all the subsequent discussions.

And now I'll say a few words on my role. The context and field in which I work is called bioethics. Bioethics generally involves critical reflection on moral and ethical problems faced in the health care setting, with a view towards deciding what we should do, explaining why we should do it, and describing how we should do it. Ethicists, therefore, attend to the moral question, what should we do, as opposed to what can we do? We support answers with moral reasoning and invoke moral principles, many of which you are no doubt familiar with, such as autonomy, beneficence, and justice.

There are many myths about what ethicists do, and it's worth saying that we are not moral experts or the arbiters of right and wrong, or legal experts, or risk managers, or the moral police, or the decision-makers, or the all-knowing. Instead, ethicists are resources for health care professionals, patients, the public, and others to access when they need facilitation, negotiation of conflicts, case consultation, policy development, research, and education in ethics.

Key ethical considerations. Within the parameters set out by the questions posed by Health Canada, a key ethical consideration included informed consent. For example, questions arose around who should make decisions about breast implants and whether they were decisions that women patients should make, and around who should define risk, benefit, and harm.

● (1205)

It is generally acknowledged that what is a benefit to one person may not be shared by another. The circumstances in which we can impose what we believe are benefits on another person are very rare.

If we believe that we ought to practise patient-centred care, which is “an approach that consciously adopts the patient's perspective about what matters”, then what the patient thinks will affect the coordination and integration of care. In other words, we need to take our cues from the patient and what the patient believes is meaningful in terms of harm, benefit, and risk. This raises questions about what patients need to know to be informed.

In summary, some key ethical considerations include the following:

One, individuals need to determine what constitutes a risk, benefit, or harm. This would occur in a context of safe and effective devices.

Two, informed consent is a process, not an event. It occurs over time, and people can change their minds.

Three, there are risks, benefits, and harms to every treatment decision, and it is incumbent on those involved to make sure treatments are as safe and effective as possible and patients are informed of all relevant information.

Four, there are always known unknowns. That's data that will be revealed for example in time but that we do not have right now. There are also always unknown unknowns, and these might be unanticipated outcomes that may be risky or they might be beneficial. Both need to be expressed to the patient. Patients need to be informed of this information.

Five, finally, ongoing examination of this issue is important. Getting feedback on the process is crucial in understanding how to improve it for the future.

To close, I understand this process embarked upon for breast implants was the first of its kind for Health Canada. I believe it has proven to be open, transparent, and rigorous, and the results it has revealed can be considered with confidence.

Thank you very much. I'm happy to provide further information and answer any questions.

● (1210)

The Chair: Thank you very much, Doctor.

We will now move on to Dr. Diana Zuckerman, the president of National Research Center for Women & Families.

Dr. Diana Zuckerman (President, National Research Centre for Women & Families): All right, thank you.

I'm Dr. Diana Zuckerman, and I am honoured to be here. Our research centre uses research to improve the health of women, children, and families. I personally come from the perspective of being trained in psychology, epidemiology, and public health, and I was a faculty member and researcher at Harvard and Yale. I then worked on health issues in the U.S. Congress and the U.S. House of Representatives and Senate, the Department of Health and Human Services, the White House, and I worked for non-profit organizations. I'm also currently a fellow at the Center for Bioethics at the University of Pennsylvania.

My current work focuses on breast cancer. I've read every published epidemiological study of breast implants, and I'll briefly discuss what is known and not known. I will also tell you about a criminal investigation of one of the implant companies that has been started by the FDA. I will also mention in my testimony the many calls and e-mails we've received from women in Canada who tell us that they're having a great deal of problems getting leaking silicone breast implants removed in a timely manner.

I'll just start off by saying we've made a lot of mistakes about breast implants in the United States, and I think and hope that Canada can show more wisdom than we have.

Clinical trials are a major source of information on the short-term risks of breast implants. Breast implants have been on the market for more than 40 years, but the clinical trials have studied women for only two or three years. That's a big shortcoming. The clinical trials have been conducted by implant manufacturers as part of their efforts to get approval in the United States and Canada, so for that reason there's some bias in those studies.

In contrast, epidemiological studies are a great way to find out what really happens to women in the real world when they do get breast implants, and have them for more than five years, but almost every epidemiological study that's been published has been funded by implant makers or silicone makers. In fact, Dow Corning has spent many millions of dollars giving money to one particular company in the United States that has published almost every epidemiological study of breast implants. Perhaps it is not a coincidence that all of those studies funded by Dow Corning have concluded that breast implants are safe.

However, if you scrutinize those studies carefully and look in the results section, not just in the conclusions, you'll find that there is some clear evidence of problems even in the studies funded by Dow. For example, one study found that women with breast implants for a long period of time were significantly more likely to report chronic breast pain. Their breasts hurt all the time. They were also more likely to take anti-depressants, but despite that, this study still concluded that breast implants were safe.

Fortunately, there are a small number of studies conducted by independent researchers funded by the Canadian government and the U.S. government, and those are the studies that I'm going to focus on today.

The first study I want to mention was done by FDA scientists to look at rupture and leakage. The FDA scientists found, when they looked at women who had breast implants for at least seven years, that most of those women had at least one ruptured implant, one implant that was broken, but they didn't know it. These were women who were happy, who hadn't sought medical help. When they got MRIs, it was discovered that they had at least one broken implant, and 21% of the women had an implant that was leaking outside the scar tissue into their bodies.

The women who had leaking implants were significantly more likely to report fibromyalgia or several other painful and debilitating diseases. So what this study shows is that it matters how long women have had implants. You really have to focus on women who have had implants for a longer period of time, and if you want to know if an implant has broken, you have to do MRIs. The clinical exams didn't show it.

What happened for these women, and what we found in talking to women, is that most of them are happy with their implants for several years, sometimes for many years, but slowly and surely the implants break. They leak. The women don't know it, and usually, after much longer than seven or ten years, they find out too late that the implants have leaked into their lymph nodes under the arm, and from there can go to their lungs and their liver.

● (1215)

I want to start out by talking about the cosmetic problems with breast implants, since the information about rupture and leakage is important, but it's not conclusive. Here's a 29-year-old woman who had her implants removed after seven years. Her capsular contracture was so painful she would rather look like this than have breast implants. This photograph, by the way, is from the FDA's website.

Obviously this is not a good outcome. This is not how a young woman would like to look. But here's a woman who wasn't so lucky. Her name is Sharyn Noakes. Her ruptured implants had leaked into her healthy breasts and when those ruptured implants were removed, so was some of her breast tissue, resulting in deformed breasts. You can see they're puckered, and they don't look anything like a normal breast.

This is Kathy Nye, a breast cancer survivor who suffered from necrosis. Many of you know that when the skin or the tissue dies, it does not grow back. When that happens, the implant comes out of the breast, and that's what that red orb is. It is the implant, the blood around the implant coming out of the hole in her breast. lnamed, one of the implant manufacturers, found that 6% of their breast cancer reconstruction patients had necrosis. It's a very serious problem.

Now I'm going to talk a little bit about what are called the symptoms of autoimmune disease. This was presented at the FDA meeting, but it is not published anywhere or available widely, so I wanted to share it with you. The implant makers were asked to ask the women what kind of symptoms they had, and they found a statistically significant increase in pain and other autoimmune symptoms after only two years. These are just two of them. I didn't want to give you a complicated slide. But you can see the percentage of women who had these problems at the beginning, at the baseline, and at one year, but by two years and then again it's just statistically significantly going up.

So the question was this. They're getting a couple of years older, and they're only about 30 to begin with, so you don't expect these women to have joint pain or chronic fatigue, but what happens if you control for age? So a statistician controlled for age, and you can see, although it's not as steep in terms of how it increases over time, it is still significantly increasing. These symptoms are increasing over time. The other thing that's not in these slides is that when a study was done they found that for women who had these kinds of rheumatalogical symptoms, when their implants were removed and not replaced, more than 90% of the women got better.

Aleina Tweed, who's an epidemiologist at the British Columbia Centre of Excellence for Women's Health, conducted a study of breast augmentation patients in Canada. Most of those women had implants for at least 10 years. She found the women who had breast implants for augmentation had more doctors' visits, more visits with specialists, and were four times as likely to be hospitalized. So the question is, why hasn't this very important Canadian study been quoted more? For a simple reason: no PR firm was hired to talk about it. When the Dow Corning studies are released and show that implants are safe, a whole PR firm and a whole spin control machine goes into place and talks about those studies. You hear about those studies. They're reported. I'm sure they were reported at the Health Canada meeting. They were certainly reported at the FDA meeting.

The problem with the Dow Corning studies is they tend to include women who've had implants for as short a period of time as one month, sometimes one day. Now, any epidemiologist will tell you the diseases they're looking at, whether it's autoimmune diseases or cancer, take time to develop. You can't study women who've had implants for a month or even a year if you want to look at autoimmune diseases. The Dow Corning studies have reduced the statistical power of the studies by including women who have implants for a very short period of time, rather than focusing on those who had implants for a longer period of time. That's why the Dow-funded studies seem to always have results that look very different from the studies funded by independent—particularly government—researchers.

● (1220)

So although we can't conclude, on the basis of the studies that have been done, that breast implants cause autoimmune diseases, we can't conclude that they don't. It's my understanding that the standard for Canada, as it is for the United States, is supposed to be proof that a product is safe; it is not up to anybody to prove that the product is not safe.

I'm going to talk briefly about the National Cancer Institute study, which is similar to the mortality study you heard about today. I had not heard about this Canadian mortality study because it wasn't published, but it's a similar study. The results are a little bit different.

The National Cancer Institute study included women who had breast implants for at least 12 years, so that's a longer period of time than in the Canadian study, which I believe was nine or ten years. The women in the National Cancer Institute study also had implants for an average of 20 years. For cancer that's very important, because cancer takes 15 to 20 years to develop, usually. It's hard to do these studies, and you really have to study women for a long period of time.

The National Cancer Institute found that those women were twice as likely to have brain cancer, twice as likely to have lung cancer, and twice as likely to kill themselves. So the suicide data were similar to the Canadian data. The data on brain cancer and lung cancer were apparently different.

Like the Canadian study—this excellent research design—they compared them to other plastic surgery patients. That's very important. I don't really know why there is a difference between the Canadian study and the U.S. study, because I haven't seen the Canadian study, but based on what I've heard about the Canadian study, the women had implants for a somewhat shorter period of time.

Last, I want to talk about the quality and integrity of the data. Both Inamed and Mentor started making breast implants years ago and started studying women with breast implants in 1990. If they had continued those studies in 1990, we'd have more than 15 years of data and we'd really be able to say what the long-term risks of these implants are. Unfortunately, the company started the studies, lost track of all their patients, and we have no idea what happened to them.

Just last year, several Mentor employees called me personally, because of the work we've done on this issue, and expressed concern about the accuracy of the data that had been presented at the FDA. It was in American newspapers and they had seen it. After talking to these Mentor employees, I put them in touch with the FDA, and the FDA started a criminal investigation in December, which is still ongoing. It's my understanding that part of the reason the FDA has not made a decision yet on breast implants—it's been over a year, which is very long for them—is that this criminal investigation is under way. One of the engineers at Mentor, for example, said that the implants leaked more than was reported.

Finally, I want to mention that just recently a study came out in analytical chemistry showing a very high level of toxic platinum in the breast milk of women with breast implants, as well as in their blood and urine. This is very important because platinum can cause neurological damage. It's very toxic.

The implant makers have claimed that the platinum used in breast implants is not a toxic form, but these researchers found that while it may not be toxic when it's used in the implant, when the implant is in the body it may change. This is also very important for breast cancer patients. As some as you know, chemotherapy agents often have platinum in them, so if a women is getting chemo with platinum for breast cancer and then gets breast implants, she's getting an especially high dosage of platinum, which could be dangerous.

● (1225)

Finally, I just want to say that we have heard from many women in Canada. Particularly, we've heard from women who tell us that once they find out their implants are leaking and that they need to get them taken out, they have trouble finding plastic surgeons who will do this.

I think Dr. Brown probably can speak to this as well, because he's a very well-respected plastic surgeon. We have heard from several women who have gone to him, and his staff have told them if they want to get their leaking silicone breast implants taken out through the Canadian health care system, they'll have to wait about a year and a half. We think that's a very long time to wait.

In conclusion, if Health Canada does decide to license silicone gel breast implants, we expect more women will get them, and more women will need to have them taken out. It's not clear to me that there are currently enough plastic surgeons in Canada who are very experienced in taking out leaking silicone breast implants so that it can be done in a timely manner.

I'd be happy to answer any questions.

The Chair: Thank you.

And thank you to the entire panel of witnesses.

We have the departments here—both Health Canada and the Public Health Agency of Canada—and because of time restraints, we'd ask you to come back to the table.

Just to let the committee know, two of our witnesses need to leave a little bit early. They are Dr. Yeates and Dr. Stachenko.

We'll now open the floor to questioning, and you can question whomever you wish.

Madam Brown.

Ms. Bonnie Brown (Oakville, Lib.): Thank you very much, Mr. Chair.

My first question is to Dr. Chidwick, and I want to thank you for serving on Health Canada's expert panel.

I am looking at the report that has been submitted from your panel to the minister, and the first recommendation says, “The panel felt that questions regarding the potential health effects of any exposure to low molecular weight silicones had not been sufficiently addressed”.

Seeing that this is the first recommendation, and it seems to me to be very strong, do you understand that to mean that the panel is suggesting to the minister he not approve these applications at this time?

Dr. Paula Chidwick: What page is that on?

Ms. Bonnie Brown: It's on page 6: “...the potential health effects of any exposure to low molecular weight silicones had not been sufficiently addressed”.

Dr. Paula Chidwick: So your question to me is whether, based on that, we would not recommend that they approve it?

Ms. Bonnie Brown: Yes. If the safety issues have not been sufficiently addressed, isn't the logical conclusion that approval not be granted?

● (1230)

Dr. Paula Chidwick: My understanding of the task that we were charged with was not that we were to recommend that they be approved or not. The answer to that question would come from the consultative process for those people in positions to make the decisions.

Ms. Bonnie Brown: Then you go on further in your panel's recommendations to say, “the manufacturers must demonstrate that migrated silicone provides acceptable risks of hypersensitivity and autoimmunity by a critical review of company and literature data and, if necessary, by undertaking studies in animal models”.

So once again, recommendation ii suggests there is not enough data to conclude safety.

You're saying that none of your recommendations about the process or none of the findings of your panel are to make any recommendation to the minister as to what he should do or not do, but these two recommendations look pretty clear to me.

The Chair: Dr. Brown is here. He was on the panel as well, if he's interested in commenting. If you're not getting answers, we'll ask Dr. Brown.

Dr. Paula Chidwick: If I can just add—and then maybe Dr. Brown can add as well—that again, I understood my role was not to draw the conclusions of what that might mean. We were to assess what was in front of us, answer very specific questions, and the decision as to what that meant would be determined by the decision-makers.

Ms. Bonnie Brown: On page 8 you suggest: “Due to the limited laboratory fatigue data, there is uncertainty associated with the predicted lifetime of the device”, and on page 11, “The data is sufficient to establish how the devices perform *in vivo*. However they do not address all aspects of long-term safety”.

Dr. Paula Chidwick: I was a panel member, and I would stand by these comments. But again, what they mean, what that means related to risk, and what it means related to harm and benefit needs to be determined perhaps by others. Every device will have uncertainties around it, questions that aren't fully understood. That's readily acknowledged by the panel, and what it means will be determined through another process.

Ms. Bonnie Brown: Thank you.

The Chair: Because of the complexity of the technology, Dr. Brown, do you have anything to add to that? If you do, just raise your hand or something and I'll get you to answer.

Dr. Mitchell Brown: Yes, I would like to make a few comments.

I think one of the outstanding features of the expert advisory panel was its diversity of membership. You could ask Dr. Chidwick or me to comment specifically about the panel's recommendations as they relate to fatigue testing, rupture rates, toxicology, etc. Dr. Chidwick mentioned immunology in one of the points that she raised. The beauty of our panel is that we had experts from each of these different areas who helped us, as a group, to put together a response to the questions put forth to us by Health Canada.

I do not put myself out as a biomaterials expert or an expert in immunology. I was part of the consultation process to put together this report. There was certainly debate about what safety is and when enough information is enough, and it's reasonable to request further information that is helpful and useful. The question becomes a determination of when there is enough information for a person to make a reasonable, informed decision based on the risks laid out in front of them.

Ms. Bonnie Brown: My next question is for Sylvie Stachenko.

The Chair: Did you want further comment on that, Mr. Yeates?

Ms. Bonnie Brown: No. I don't want to hear any more about that. I want to ask Sylvie Stachenko—

Mr. Neil Yeates: No, I can leave it. That's fine.

The Chair: Okay.

Go ahead, Madame Brown.

Ms. Bonnie Brown: Sylvie Stachenko, thankfully, brought forward a summary of the epidemiological study that we have been trying to get to this committee for about the last three years.

Looking at your notes, you said that the suicide rates for silicone gel breast implant patients were about the same as for all plastic surgery patients, but even so, greater than for the general population. What about the cancer rates? The cancer rates in silicone gel breast implant patients were the same as for regular plastic surgery patients, but were they greater than those of the general population? No?

● (1235)

Dr. Sylvie Stachenko: No. The answer is no.

Ms. Bonnie Brown: Okay. So the only aberration you found was....

Dr. Sylvie Stachenko: It was mortality.

Ms. Bonnie Brown: Mortality? Death, and it was usually by suicide?

Dr. Sylvie Stachenko: By suicide. Correct.

Ms. Bonnie Brown: Okay.

Thanks very much, Mr. Chair.

The Chair: Okay. Thank you.

Madame Demers.

[*Translation*]

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

I will address my first questions to Mr. Brown.

[*English*]

Can you hear me?

Dr. Mitchell Brown: Yes, I can, thank you.

Ms. Nicole Demers: I can see that I'll have to pose my questions in English.

I also have some letters from some of your patients. They are not so encouraging, though. One of them tells us that before she could get a meeting with you in order to get her breast implants extracted there was a nine-month wait, and then after that it would take 12 more months to get them extracted because you have too much work doing implants and reconstruction.

The same person tells us that if she was ready to pay $4,800 to get ahead of the list of patients covered by the Ontario health insurance program, you would be ready to operate on her before the other patients, who were covered by the Ontario health insurance program. On top of that, she had to give you an $800 deposit, which was not refundable if she decided not to have the operation with you.

Can you explain why you have such a practice with people who are desperate to get their implants extracted?

Dr. Mitchell Brown: Thank you, Madame Demers.

I must start by saying that you are quite incorrect in the information you have just requested of me. Those are absolutely not the facts as they exist, so let me please explain.

I see patients on a very regular basis who come to me with concerns about their breast implants, or just to have them checked because their surgeon may not presently be around—is deceased, etc. If a woman comes to me with a problem with a breast implant and she requires, through informed consent, to have something done —to replace, reposition, remove her implant, etc.—I like to operate on her immediately if it's at all possible. There is no incentive for me to have a patient wait.

In Canada, at least in Ontario at the present time, women who come to my office who have concerns with medical problems related to their implants are offered surgery under the Ontario health insurance program. It is a medically insured service. In those instances, I must provide surgery in the publicly funded hospital where I work, Women's College Hospital.

I am only provided a certain amount of operating time. Every bit of operating time that I am provided is directed at reconstructive patients, such as the patients you have described. All of the esthetic surgical work I do that is not covered by the Ministry of Health is done outside of the hospital, so as not to impact on the time I have available in the hospital.

I can only use the time that is provided to me. I have had four days removed from me for surgery during the summer because of the hospital slowdown. I have days removed from me because there are not enough nurses to staff the operating facility. I have days removed from me because there are not enough anesthetists. So I do the work I can—

Ms. Nicole Demers: Excuse me, Dr. Brown. Can I tell those women that they'll get their deposits refunded to them?

Dr. Mitchell Brown: Excuse me. I will finish my remarks.

Ms. Nicole Demers: No, I'm sorry, you have a very short time and that was not my question. My question was, do you charge those women $4,800 to pass ahead of the others? That was my question.

Dr. Mitchell Brown: The answer is a very clear no. Patients who come to see me—

● (1240)

Ms. Nicole Demers: So they can get a refund?

Dr. Mitchell Brown: I will now complete my answer.

Patients who come to see me with a concern that is medically related, where there is a medical problem, are only offered service in the publicly funded hospital, without a penny being charged to them by my office.

If a patient comes to my office because she has implants that have been in through her choice for many years, there is no medical indication for their removal, and she wishes to have them removed, that is her choice. That is not a medical indication. That is something that is not an insured service in our province, and patients are charged a fee that is appropriate for that type of procedure.

Thank you.

Ms. Nicole Demers: Thank you, Dr. Brown.

Dr. Brown, how many MRI machines would you say are available in Canada?

Dr. Mitchell Brown: I do not know the answer to that.

Ms. Nicole Demers: Don't you suggest to your patients, once they've had the surgery with the implants, that every year or every other year they be tested with an MRI machine to make sure there aren't leaks? Isn't that proper procedure?

Dr. Mitchell Brown: It is not, Madame Demers. There is no consensus to suggest that routine screening by MRI is appropriate. That is not the standard of practice in Canada, and that was not the recommendation of the radiologist who sat on our expert advisory panel.

Ms. Nicole Demers: Does that apply to women who have to get their breasts examined every year after they're 50 years old?

Dr. Mitchell Brown: Yes. The present standard in Canada is regular monthly self-examination, and mammograms and ultrasound as required. MRI is used as a secondary or tertiary screening if a potential problem is noted to exist.

The Chair: Madame Demers, your time has gone.

Mr. Fletcher, you have five minutes.

Mr. Steven Fletcher (Charleswood—St. James—Assiniboia, CPC): My interest is in the process. Did women with breast implants have any input on the breast implant cohort study?

Dr. Sylvie Stachenko: Yes, they did. There was a consultation process in 1992 and 1995. The women actually participated in these consultations in terms of the protocol and design of the whole study. So they were involved at the inception.

Mr. Steven Fletcher: Was this study ethical?

Dr. Sylvie Stachenko: This study underwent rigorous ethical reviews. As you know, the women came from two provinces, Ontario and Quebec, and the investigators in these provinces came from Laval University in Quebec and from Cancer Care Ontario. Reviews were done by the University of Toronto ethics review as well as l'Hôpital du Saint-Sacrement ethical review process in those two provinces.

Other review processes were done during the time of the record linkage, which happened later, as I mentioned. That also required extensive ethical review processes.

So the answer to that is that this study met all the rigorous ethical reviews that are necessary.

Mr. Steven Fletcher: Who funded this study?

Dr. Sylvie Stachenko: The funding came initially from Treasury Board, but the provinces also contributed, particularly in kind, and the total amount for this study from 1995 right to this time is about $2.5 million. A good deal of it is also in-kind resources in terms of the researchers, the epidemiologists, and the analysis.

Mr. Steven Fletcher: You mentioned the researchers. How did they get the patient's records, the health records?

Dr. Sylvie Stachenko: As you know, epidemiological cohort studies require rigorous approaches, one of which is access to information. In Quebec there's a body I don't know the name of—perhaps Dr. Yang Mao could tell me—but there's a body there that was required to be consulted in terms of release of information.

Also, in Ontario there's a regulation of the...I think the Ontario Medical Act, that we also need to go to so physicians can release patient information. Those two bodies were certainly consulted and agreed to the release, but there definitely was a strong provision for making sure the individuals were anonymous.

Perhaps Dr. Yang Mao, being part of the methodology, might want to add some further answers to that.

● (1245)

Dr. Yang Mao (Director, Health Promotion and Disease Prevention, Public Health Agency of Canada): The record in Quebec comes from Med-Echo's surgery record and from the plastic surgeon's office. We announce these records publicly and send them to the patient. We tell them that if they don't want to participate, they can call a number or respond with the card we provide. But the data has come from Med-Echo's surgery office and from the plastic surgeon's office.

The Chair: Thank you.

Ms.Priddy, you have five minutes.

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

My first question is to Dr. Zuckerman. I didn't realize until I did some recent reading about platinum and breast implants.... Could you tell me, if you look at what I would call generation one, generation two, and generation three breast implants, whether the level of platinum is the same or has significantly decreased?

The second part to that question would be—I think it was partly on the screen—what the two or three most common or perhaps most serious results you would see with women who've had significant amounts of platinum in their body, which stays and reacts in their body? I think some of these other examples are not platinum.

Dr. Diana Zuckerman: One of the common complications that women who have problems that seem to be related to their implants complain about has to do with concentration and memory loss. They get better when the implants are removed. The women are often in their thirties and they feel like they're in their seventies. They're having trouble concentrating, they can't remember things, they can't speak coherently. It's these kinds of neurological problems that could be related to the platinum

There is no data that compares the different generations. The platinum seems to come from the shell, not from the gel. Platinum is used to thicken silicone to make the elastomer that makes the shell. That's not the natural form of silicone. That's why it's used. Some research is under way to see whether these new gummi bear implants have more platinum; thickening the gel so much may require that you use platinum.

The amount of platinum used to make breast implants is supposed to be really microscopic—very tiny amounts. What we don't know is whether some end up having more platinum in manufacturing than they're supposed to. Perhaps that would explain why some women get very sick from breast implants and other women don't.

Ms. Penny Priddy: I think this is to Health Canada, but I'm not sure. Breast implants are a medical device. Could you tell me the percentage of "medical devices" that are applied for that are breast implants?

Mr. Neil Yeates: Sorry, I'm not sure I understand the question.

Ms. Penny Priddy: For the sake of the discussion, let's say 100 people apply for a medical device—

Mr. Neil Yeates: That's the special access program. Okay.

Ms. Penny Priddy: Yes. What percentage of those 100, or however it goes, would be for breast implants?

Mr. Neil Yeates: Thanks for that clarification.

I can give you some numbers from last year, to give you a sense of this. We had approximately 11,000 requests for all medical devices, and about 8,500 were for silicone gel implants. I should add, though, that some of those requests that we get for other types of things, for other drugs and devices and so on, might be in lots of several hundred.

● (1250)

Ms. Penny Priddy: Thanks. That's helpful.

Do I have some more time?

The Chair: For a short one.

Ms. Penny Priddy: All right.

I have a point about the expert panel. Maybe it's just a comment, but I will waste my time on the comment.

Three people were listed as patient experts and they were all nurses. Do I assume that they were also patients who had breast implants? Was there a real patient as a patient expert on the panel? When somebody said "patient expert", I expected that they had been a patient of that particular procedure.

Dr. Paula Chidwick: Nobody on the panel openly discussed their medical status. The people who I—

Ms. Penny Priddy: The people who were listed as patient experts were actually nurses with additional training who worked with patients.

Dr. Paula Chidwick: They were people who worked with patients. Whether they had personal experience as a patient was not discussed at the panel.

Ms. Penny Priddy: So there may very well not have been a patient as part of this patient-centred study.

Thank you.

The Chair: Thank you very much.

Ms. Davidson, you have five minutes.

Mrs. Patricia Davidson (Sarnia—Lambton, CPC): I wanted to ask Dr. Brown a question.

In order to obtain the silicone gel-filled breast implants, physicians are required to seek authorization through special access. Special access is defined as "access to a medical device for emergency use, or if conventional therapies have failed, are unavailable, or are unsuitable".

With respect to the silicone gel breast implants, could you explain the meaning of "emergency use" and "conventional therapies"? Further, do you apply for special access for breast implants? Could you provide the committee with some estimate of how often your special access requests are for replacement of a failed implant, for reconstruction, or for cosmetic augmentation?

Dr. Mitchell Brown: Thank you.

Yes, through the special access program, I do apply for silicone gel-filled breast implants. I would estimate that approximately 40% to 50% are for reconstructive breast surgery for women who have undergone mastectomies or lumpectomies, and that the remaining 50% to 60% are divided between women undergoing implant replacement, who have likely had silicone gel breast implants in the past, and women undergoing primary breast augmentation with specific indications, such as an abnormal tuberous shape to the breast where defined devices that are presently available—i.e., saline breast implants—would likely cause significant problems and elevate the re-operation rate in those particular patients.

Examples would be patients who have very minimal tissue in certain areas, such as in a tuberous breast patient or in a patient who has undergone mastectomy, where there is little tissue to cover an implant in a certain area or where a salient implant would be extremely palpable, and so unnatural to the feel and look. Those are circumstances where conventional devices that are presently available would not be suitable.

Mrs. Patricia Davidson: Thank you.

In your experience, how long are these implants lasting? When you see your patients, how long is it before some of them are experiencing a problem, and what seems to be the percentage of people who do experience that problem?

Dr. Mitchell Brown: We've just finished looking at our data in the first five years since I started using these devices in 2001. Of course, I would like and hope to have longer data as the years go by.

At the present time, my re-operation rate for any indication—which would be for any patient, whether for reconstruction because a patient had changes to the breast because of breast feeding or for replacement on an implant—is 5.7% over the period of the study, and that could be for a variety of reasons. It could be for mal-positioning, such as turning or changing in the position of the implant. It could be for asymmetry, which is a common potential problem, especially when you're reconstructing a single breast and trying to match it to a natural breast on the opposite side. It could be for issues related to scar tissue or contracture around the implant.

I have not identified a ruptured gel implant that I've used in my practice. There may be some I have not identified, which would only be identified through longer follow-up or MRIs of every single patient, but I have not seen a ruptured device yet.

● (1255)

Mrs. Patricia Davidson: Thank you.

Do I still have some time?

The Chair: You can have a very short one, if you want.

Mrs. Patricia Davidson: Okay, very quickly, I'd like to please ask Dr. Zuckerman about testicular implants made of similar substances, which are also on the market. Could you comment on those from the FDA? How do they assess the clinical data regarding their safety?

Dr. Diana Zuckerman: Much less is known about them, but I believe that the testicular one is a harder silicone. I don't believe it's gel, but if it were, the amount of gel would be much less.

One of the problems with breast implants is that there is so much silicone. If it breaks and leaks, there is an enormous amount of silicone that can get into the body, whereas if you have a very small implant, like a testicular one, even if it were gel and did break, the amount of silicone the body would be exposed to is much less. Therefore the chances for problems would be fewer.

Also, the number of men who get testicular implants is very small compared to the number of women who get breast implants, so we know much less about them. When you have millions of women getting a product in the United States, you see a lot more problems. Even if the proportion is the same, it's easier to keep track.

Also, for women with breast implants, it's taken 40 or 30 years to start talking openly about it. I don't think men with testicular implants are speaking very openly about it yet.

The Chair: Thank you. This is getting to be a very sensitive area.

Ruby Dhalla. You have five minutes.

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

Thank you to all of the people who have taken the time to come today. It's an extremely important issue to a number of my constituents in Brampton—Springdale, along with many of the colleagues around this table, and to women in general across this country.

There a couple of concerns I have on how Canada could best address them. They took a look at establishing a panel to consider scientific, medical, and clinical evidence, and put the panel together. Perhaps answering with a yes or no, in light of the time, were the individuals appointed to this panel required to declare a conflict of interest?

Mr. Neil Yeates: They were required to identify any conflict of interest, yes.

Ms. Ruby Dhalla: Thank you.

I find it quite alarming, then, in light of the fact that we know that they were required to declare a conflict of interest, that three of the nine members did identify a conflict of interest, and a couple of the individuals actually acted as paid advisers to companies that actually produce these medial devices. Why was no action taken by Health Canada to ensure that this panel would provide objective and unbiased advice?

Mr. Neil Yeates: We felt that it was very important that we have access to people who are involved in the field. So some of these interests and affiliations are unavoidable if we're going to get people who have real-world experience. We feel that we need that. The expert panel report actually was delivered with a very high degree of consensus and represented a very wide spectrum of views. So given the nature of what we were dealing with here, we think it was very important to have people who had that real-world experience.

Ms. Ruby Dhalla: With all due respect, though, when we look at the number of plastic surgeons that exist in this country and in the U. S., if we had to go there, which I wouldn't imagine we would, could Health Canada not go beyond the individuals they had on that panel to find other individuals who did not have a conflict of interest?

You can imagine that for colleagues around this table, it's very difficult for us to have recommendations put forward by an advisory panel that had a declared conflict of interest, which Health Canada did nothing to address. When individuals are paid by a company that has been producing those silicone implants, many women around this country are going to question the validity of the recommendations they put forward.

Mr. Neil Yeates: We felt that these people who served on the panel served the panel well. They had affiliations, but we didn't feel that they had a conflict of interest. To some extent this is unavoidable, given the nature of what we're dealing with. We feel that the experience of experts such as Dr. Brown, who is also presenting today, is very important, and we need to hear from them about what is used here in Canada. I think we need to know that.

Ms. Ruby Dhalla: With all due respect to Dr. Brown and the great work he's done for women, I'm sure there are many other plastic surgeons around this country who did not have that conflict of interest. Were any efforts made by Health Canada to look to individuals who perhaps didn't have a conflict of interest? If so, what types of efforts were made by Health Canada?

● (1300)

Mr. Neil Yeates: I'll ask Dr. Sharma to speak a little further about what went into the selection of panel members.

Dr. Supriya Sharma (Associate Director General, Therapeutic Product Directorate, Health Products and Food Branch, Department of Health): Just to speak about conflict of interest, and I'm sure Dr. Brown can speak to this as well, a lot of the concerns the committee has raised in the past about conflict of interest have focused on the plastic surgeons on the panel, that they somehow received some sort of remuneration based on their recommendations. I'm sure Dr. Brown will reiterate that. But we do have saline implants on the market, so there's no incremental advantage, in terms of monetary funds, for doing the surgery.

In picking the panel, there were equally patients, representatives, and other people who had opinions that were different from those of the plastic surgeons. It's important to remember that these panel members are volunteers. We actually do have a slate of plastic surgeons we go to, but there are always challenges in terms of finding people who are available and who are able to come and represent themselves.

With regard to some of the other conflicts of interest that have been raised, Dr. Brandon, I think, was another name that was mentioned. He is the North American expert on rupture data. To find someone who is the North American expert who has never given advice, for example, to other governments or to industry is definitely a challenge.

The Chair: Thank you.

Mr. Batters.

Mr. Dave Batters (Palliser, CPC): Thank you very much, Mr. Chair.

I appreciate all of you being here—and Mr. Brown by video conference.

As a new member of the health committee, I'm going to start by making a few observations from 35,000 feet, and then I'll ask representatives from Health Canada to comment, perhaps Dr. Zuckerman as well, on this first observation.

First of all, this is obviously a heated debate and there are some very passionate viewpoints on both sides. Being a new member of the committee, I think everybody could gain by dialling it back a little bit and looking at what's truly in the best interests of patients, and going from that perspective.

I'd say to Health Canada, looking at this issue and doing the reading, the entire process seems very arduous and awkward. Health Canada asked that these implants be pulled from sale in 1992—that's 14 years ago—and we're talking about 19,000-plus requests per year under the special access program. This looks like an absolute nightmare.

You've conducted multiple studies, and you've had more than one expert group look at this issue. There are studies on the issue. I'm anxious to hear Dr. Zuckerman's take on the experience in the United States. At what point do you make a decision and make some recommendations to the minister?

I tend to agree with Dr. Brown in that enough is enough. When you believe you have enough information...perhaps you're not at that point, maybe that's your argument, but we've gone 14 years. At what point do you say, “Here's the information, Minister, make the decision”?

Minister Clement is a very busy man, I'm sure he doesn't have time.... Maybe you can explain the process for this apparent minister's permit for the special access program. There are thousands of requests for this. Maybe you can tell me what I'm missing here. Multiple studies conducted, at what point do we make a decision and put this before the minister?

Mr. Neil Yeates: The member's quite right, the process has been extensive to date. We are nearing the end of the process in terms of our analysis of the studies that have been done and looking at the literature. As I say, we're approaching the end of that.

I should clarify that it will not be the minister making this decision; it's made by the department. That authority is delegated to Health Canada.

Mr. Dave Batters: HPB?

Mr. Neil Yeates: Yes, to our branch.

We are nearing the end of what has been, yes, a long process, but as you've noted, there has been a lot of interest in this issue, a lot of concern regarding the products in question. So we want to make sure we do a very thorough job reviewing all the safety data, the efficacy data, the quality data, to make sure we have all the information we need to make a decision one way or another. And yes, we are reaching the end of that process.

● (1305)

Mr. Dave Batters: Definitely, Dr. Yeates, but we talk about the backlog in drug approvals. This looks absolutely ridiculous to me. If I were a woman in Canada, whether I were seeking an implant for cosmetic reasons or, God forbid, for reconstructive procedure following surgery, this would be an absolute nightmare, and I don't know how I'd make this decision. It must be a nightmare for physicians as well, but I really commiserate with the patients.

If I have a little bit more time, Mr. Chair, I'd like to ask Dr. Brown a couple of questions. How much time do I have? One and a half minutes?

Dr. Brown, I just want to cover a few areas, if you could touch on a couple of things for me. In terms of esthetic procedures for breast augmentation, my initial concern was waiting to hear how that would affect wait times in our hospitals. You seem to indicate those procedures are done in your private clinic. Is that true, sir, that all these are done in private clinics? A primary—

Dr. Mitchell Brown: I can only speak for—

Mr. Dave Batters: Sorry, I'm talking about primary surgery for augmentation.

Dr. Mitchell Brown: I understand. I can only speak for my personal practice. I use every bit of time that's provided to me at Women's College Hospital for my reconstructive practice. Any time on top....

Thank you.

Mr. Dave Batters: Thank you, sir. I just want to keep going, because my time is very limited.

Maybe you'd agree with me that there's desperate need for it. Maybe there are firm guidelines in place.

Take this in the spirit in which it's intended, sir. I'm not trying to trip you up at all.

For a woman who is having problems with her implants, whether they were implanted under the publicly funded system or in your private clinic, if they're having problems with them, can these implants be removed if they pay to do so, if they decide they can't afford the wait for their scheduled surgery time in the public hospital?

Dr. Mitchell Brown: My understanding is that if a procedure is to be covered as a medically necessary procedure, it would contravene the Canada Health Act for a person to be able to provide payment and have that procedure done quicker in a different method. That's my understanding.

The Chair: Thank you, Mr. Batters.

I'm informed that Mr. Yeates and Ms. Stachenko have to leave at this time. I thank them for coming forward. I appreciate that very much.

We'll continue the questioning with the remaining panel.

Ms. Keeper.

Ms. Tina Keeper (Churchill, Lib.): Thank you.

I had a question for the Public Health Agency, so I'm wondering if Ms. Sharma would be able to answer that question, as she works for Health Canada.

Dr. Sylvie Stachenko: I'll answer.

● (1310)

Ms. Tina Keeper: Thank you, Doctor.

The results of the cancer incidence in a cohort of Ontario and Quebec women study have found that there was, as you mentioned, no correlation between increased rates of cancer and women who had received breast implants. Is that a position or a statement that is going to be made by the Public Health Agency of Canada? Will that affect how you promote safety or risk around breast implants for women in Canada?

Dr. Sylvie Stachenko: We will simply state what the study says, that is, there is no increased rate of cancer, from the study. Obviously if you're looking at safety and other issues, which is really with the regulations, we're only one input. This is a population study that is one input among others in terms of the very complex decision-making process.

There's more than just the issue of the long-term impact; there are other issues that we've discussed here. Basically, our position is from the population-based study, which is consistent, by the way, with other cohort studies. One of the things that are very important to note is that this one allows more statistical power because we have more women than in any other cohort study. In practice, it is important to say that in terms of looking at specific categories and subgroups it has more power to make some assertions.

Secondly, and it was mentioned by Dr. Zuckerman, when you're looking at long-term impact you have to have follow-up periods that are more than five years, particularly when you're talking about cancer. This study actually has a mean follow-up time of 15 years, some of which is even 25 years. In terms of this specific study versus other international cohort studies, we had more power and a fair follow-up period to be able to validate the other studies. What we're finding is very consistent.

When we discuss population health impact, it is going in the same direction. We are adding to that base of knowledge and we're adding it from a point of a view that has actually got more statistical significance, given the statistical power of the study.

Ms. Tina Keeper: You also mentioned you found there is an increase in the suicide rate among these patients. From a public health perspective, have you looked at other factors in terms of maybe fibromyalgia, immune system disorders, or others?

Dr. Sylvie Stachenko: One of the issues around these studies is that we are looking at mortality. Obviously from that perspective we weren't able to look at morbidity, and that's a bit like the question you're asking.

Ms. Tina Keeper: Does the Public Health Agency or the federal government plan to seek additional studies to examine these other issues?

Dr. Sylvie Stachenko: Given those results, we will be discussing the next steps with our provincial, academic, and federal government partners. Obviously this is a cohort study. As you know, there are many databases in this country. There are risk factor databases through the community health survey. What we can do is perhaps see if there are any opportunities to link and do further linkage, to understand some of these questions that you're raising.

So it's in discussion, no firm decision, and we are just now looking into opportunities for further research.

Ms. Tina Keeper: Dr. Zuckerman, you found that there were, indeed, increased rates of cancers. Could you explain a little bit about that study and how you came to those conclusions?

Dr. Diana Zuckerman: Sure.

It's not my study; it's a study by the National Cancer Institute. It's comparable, but perhaps not quite as large as the Canadian study that was just described. It involved women who had implants for an average of 20 years rather than 15 years. So it was a little longer.

I put the slide up. They had a doubling of brain cancer deaths, a doubling of lung cancer deaths, and a doubling of suicides. This was compared to women with other plastic surgery. Women who have plastic surgery are more likely to smoke. So it's important to look at them compared to each other, and not to the general population.

When they looked more carefully at lung cancer, for example, they found that the women who smoked and had breast implants were more likely to die from lung cancer than women who smoked but did not have breast implants. Perhaps it was that double vulnerability of smoke and leaking silicone that made the difference, but who knows?

It's possible that if they study these women for longer periods of time, things will look different. If you look at people who have smoked for an average of 10 or 15 years, most of those people will not die of lung cancer yet. But if you study them for 25 years, many of them will. It takes time.

The Chair: Thank you.

Mr. Dykstra is yielding his round to Mr. Batters.

Mr. Batters, you have five minutes.

Mr. Dave Batters: Thank you again, Mr. Chair.

I want to follow up on my earlier line of questioning with Dr. Sharma and then with Dr. Zuckerman.

Regarding the process that's in place, Dr. Sharma, what can we expect to see as the next step in all this? How does Health Canada move from its consideration of scientific and other evidence to a regulatory policy decision on this device? Where are we, and what are the next steps? Can you give us a timeframe?

Dr. Supriya Sharma: I'm assuming that when you're asking about a regulatory policy decision, you're talking about a decision on licensure of these products.

● (1315)

Mr. Dave Batters: Right. Exactly.

Dr. Supriya Sharma: We're actually in the final stages of the scientific review, and as you've mentioned, it's been going on, for some of the applications, for approximately five years. Just to put that into context, normal review times for class III and class IV medical devices are either 75 or 90 days. So this examination is definitely more extensive and much more indepth than those for other medical devices.

We are coming to the end of that process. At the end of that process, there's a recommendation. The recommendation can take one of three forms. There's a recommendation to license. In that case, the implants would be available for general sale. It can be a recommendation to license with conditions, so there may be conditions placed on that licensure. Or the decision would be to not license. I said that we're in the final stages of that, but information that prolongs the process can come up in those final stages.

Mr. Dave Batters: Absolutely.

I have one more question for Dr. Sharma.

Right now, when we talk about the special access program—again, we're talking about thousands of applications here, many of which are granted—how extensively are the decision-makers looking at these applications? To my reading, that's the minister. We're talking thousands of applications.

I can't believe—maybe it's just my personal bias—that every time Dr. Brown or one of his professional colleagues makes an application, there's a detailed study done patient by patient. Or maybe that's the case. Can you tell me what kind of process this involves, every time one of these special access program requests is granted or denied?

Dr. Supriya Sharma: Absolutely, and here is a clarification on an earlier point.

We were talking about numbers. For breast implants, in the last fiscal year it was approximately 8,000. Although the number of requests for other medical devices is smaller, as Mr. Yeates said, sometimes they come through in batches. For instance, for a drug-eluding stent that goes into your heart, we would release about 8,000, so it's comparable to breast implants.

Every application that comes in through the special access program is from an individual physician making a request for an individual patient for breast implants. Each application is looked at, screened, and analyzed against four sets of criteria that must be fulfilled before the minister—and that's delegated down to the department—can authorize that request. Every application is like that.

Mr. Dave Batters: Thank you.

Dr. Brown, is this an absolute nightmare in terms of getting patients approved? Is it a long, arduous process to get patients approved?

Dr. Mitchell Brown: No, it's not particularly long and arduous. I try to apply for special access only when I feel that it's very appropriate and when there's a specific indication for it. In those instances, when I've essentially pre-screened the process by not applying when there's not an appropriate indication, I have generally received approval.

Mr. Dave Batters: Thank you, sir.

Dr. Zuckerman, what's the experience in the United States regarding the process for patients to get silicone gel implants?

Dr. Diana Zuckerman: The process is somewhat similar. Silicone is supposed to be restricted to women who need reconstruction after breast cancer or need an implant replaced. However, their idea of reconstruction in the United States includes women whose breasts don't look as young as they used to because they breastfed. I was surprised to find out that this was a deformity, but apparently it is. So a very large percentage of women in the United States are getting silicone gel breast implants because their breasts look like they're 35 years old instead of looking like they're 20 years old. It's very easy for those women to get breast implants, because all they need is a doctor to say this is reconstruction. And as I said, their definition of reconstruction is not what I think the women here would probably think of as reconstruction.

It is a problem in the sense that these women are supposed to be studied. In the United States, if they get implants through special access, they're supposed to be studied over a long period of time, and they are not. They're not studied at all, actually.

The Chair: I'm sorry, your time is gone.

Madame Barbot, you have five minutes.

[*Translation*]

Mrs. Vivian Barbot (Papineau, BQ): Thank you.

How can you say that Dr. Brown, who has been using these implants since 2001, does not benefit directly from the decision that will be made? In fact, these breast implants are not covered by insurance.

[*English*]

Dr. Supriya Sharma: What I was saying is that because saline-filled implants are licensed for sale in Canada—and they have been basically since 1971—if somebody is seeking a breast implant and there's a fee charged for that service, there's no difference in remuneration, whether it is a saline implant or a gel-filled implant.

[*Translation*]

Mrs. Vivian Barbot: I would like to know whether, at the present time, any class action have been launched against Health Canada and, if so, for what reason.

● (1320)

[*English*]

Dr. Supriya Sharma: There are a number of issues before the courts. Some of them have actually been dismissed and settled. There was no money paid by the Government of Canada in the settlement of those, and those were the ones that were happening in British Columbia. I can't comment on the rest of them because they're before the courts, but we maintain that the regulatory and scientific decisions that were made with those issues were scientifically sound.

Mrs. Vivian Barbot: I have a question for Dr. Brown.

What would you say about the fact that cancer survivors with implant experience have more complications and are more likely to need additional surgery to correct those problems compared to augmentation patients?

Dr. Mitchell Brown: Thank you.

That fact is not the least bit surprising. Breast reconstructive surgery is very complex and very difficult and very challenging surgery for the plastic surgeon, whether it is with the use of an implant or whether it is with the use of tissue taken from other areas of the body. Breast augmentation surgery is generally a fairly straightforward procedure, where we're dealing with a natural and normal part of anatomy and changing its feature. If done properly, it can be done with a very low complication rate.

Reconstructive surgery is trying to reconstruct, build, or create a new breast, essentially from nothing. It is a much more difficult and complex procedure, not to mention that it's often a unilateral procedure. Many of the re-operations that are quoted in these studies are re-operations to fine-tune balancing and symmetry issues, for example, lifting or reducing an opposite breast to try to make it look more like the breast that's been reconstructed.

So that data does not surprise me in the least.

The Chair: Thank you very much.

Madam Brown.

Ms. Bonnie Brown: Thanks very much.

Dr. Sharma, of the over 8,000 applications for these devices, how many Health Canada employees are reviewing those applications, and what are their qualifications?

Dr. Supriya Sharma: You're referring to the special access program.

Ms. Bonnie Brown: Special access, 8,000 silicone gel....

Dr. Supriya Sharma: At any given time, there's usually two or three people who are reviewing those. The special access program for medical devices is actually led by a physician, a health care practitioner, and the people who are reviewing them are chemists and people who have expertise in materials, primarily.

Ms. Bonnie Brown: Okay. So they're not all reviewed by physicians, but by chemists.

Dr. Supriya Sharma: No. They're all ultimately reviewed by the physician, because that's the person in charge of that program.

Ms. Bonnie Brown: He's in charge of those staffers. They make a recommendation to him and he has to approve or not approve—or can they say yes on their own?

Dr. Supriya Sharma: No. He has to approve or not approve, and he actually reads every single special access form.

Ms. Bonnie Brown: Of the more than 8,000 requests, how many were turned down last year?

Dr. Supriya Sharma: I actually don't have the statistics, but it's a very small number. Less than 100 would have been turned down.

Ms. Bonnie Brown: Considering the expert panel and its report, it seems to me that, at least in those discussions that I'm sure you monitored, there was a lot of negativity about saline implants. Certainly at the public hearing I attended I heard a lot about the negative effects of using saline. That's why the plastic surgeons want to get approval for this newer silicone.

Because of all the negative conversation about saline, is Health Canada considering removing saline from the marketplace?

Dr. Supriya Sharma: There are probably two separate points in that.

Most of the commentary around saline implants was in comparison to gel-filled implants for specific indications. As a result, the conversations were fairly negative. For instance, patients with very thin chest walls don't do very well with saline implants. Patients have a higher risk of contracture, for example. So it didn't really reflect the body of knowledge we have on saline implants in general.

Saline implants have been available since 1971 and they are continuously monitored, as are other class-4 medical devices. So there's a program by which we look at risk and adverse events that have been associated with it. There is a re-review. So that is continuing, and at this moment there hasn't been enough evidence to warrant the withdrawal of saline implants from the market.

Ms. Bonnie Brown: Dr. Sharma, do you know how many plastic surgeons there are in Canada?

● (1325)

Dr. Supriya Sharma: I do not.

Ms. Bonnie Brown: But however many there are, you're saying that in trying to select two or three for your panel, your choice was so limited that you had to pick two who already had a monetary connection to the two companies applying for the device to be approved, to be licensed.

Dr. Supriya Sharma: A number of plastic surgeons were approached and they declined, either because of availability or because of lack of availability for an honorarium to be provided. But we did look extensively for plastic surgeons to sit on the panel.

Ms. Bonnie Brown: How many did you invite before you settled on these few?

Dr. Supriya Sharma: I would have to go back and look at that.

Ms. Bonnie Brown: Could you get that information to us?

Dr. Supriya Sharma: Sure.

Ms. Bonnie Brown: Thanks very much.

The Chair: Thank you very much.

We have two more questioners, and I ask that we split the time. We have five minutes left, so each can have two and a half minutes.

Mr. Dykstra is next, and then Madam Demers.

Mr. Rick Dykstra (St. Catharines, CPC): Thanks, Mr. Chair. I'll be specific. I have a couple of questions and I'll try to get to them as quickly as possible.

One is on the process, and I'm not sure who to direct this to. If a leak is found in a woman's breast, what is the process to deal with it? How does it work through? The indication is that there are extensive wait times that are damaging to the health of women. What specific guidelines do we use to deal with it, from either an Ontario perspective or, better yet, from a federal perspective? Are there guidelines?

Dr. Supriya Sharma: I can just speak to the special access program if we're talking about gel-filled implants. If a gel-filled implant is accessed through the special access program, there's a requirement to report any adverse event associated with it to Health Canada within 72 hours. So there is a requirement to get that information on the device.

In terms of how it's dealt with at the practitional level for removal, that's actually a practice of medicine issue, so I would probably direct that to Dr. Brown.

The Chair: Dr. Brown, do you have any comments on that?

Dr. Mitchell Brown: The issue is to have a discussion with your patient about what you've found and lay out the options for them. There is not general consensus that even in the presence of a known leaking implant it is necessarily an indication for removal. So options are presented to women about observation; the likelihood of there really being a leak, even if it's been identified potentially on a mammogram, MRI, or ultrasound; and the options for removal and replacement. They are laid out, and then the procedure is scheduled for the patient if it's required.

I try to triage my patients as best as I can. If a woman has a very noticeable leak of an implant and it looks like it may have come out from the capsule that forms around the implant, I try to move surgery and get that woman in as quickly as possible to deal with it. It's essentially done on a case-by-case basis.

The Chair: Dr. Zuckerman.

Dr. Diana Zuckerman: At the FDA meeting the decision was clear that leaking implants should be removed as soon as possible, and that almost always it isn't obvious that an implant is leaking. That's why the MRIs are so important. I guess that's one difference between the Health Canada panel and the FDA panel. They felt very strongly that once it starts leaking...well, even if it's broken, it's going to start leaking and it should be removed right away.

The Chair: Thank you.

Madame Demers.

[*Translation*]

Ms. Nicole Demers: Thank you very much, Mr. Chairman.

Dr. Sharma, I would like to know, first of all, whether in your view Health Canada has some responsibility regarding the health and well-being of Canadians and Quebeckers in general.

Also, among the requirements in order to make a special access application for breast implants, the physician and the patient must both sign the application form. Such being the case, how is it that there is no particular space on the form for the patient's signature?

Moreover, we have seen in a news story broadcast by Radio-Canada that physicians do not advise the patient that she must sign an application to obtain breast implants. How do you explain this?

[*English*]

Dr. Supriya Sharma: To the first part of the question, I'll speak specifically to the mandate of the health products and food branch and how it relates to health products.

We absolutely have a mandate. Our mandate is to maximize the safety of the products we regulate while minimizing those risks. That contributes to the health and safety of Canadians, so that is absolutely our raison d'être.

On the signing, the requirement is that the practitioner, the requester, sign the form. It's a declaration that the practitioner has actually discussed the risks and benefits of the device with the patient, but there is no requirement for the patient to sign the actual form.

● (1330)

[*Translation*]

Ms. Nicole Demers: Yes, but there is a requirement that the patient must sign the application form. I am sorry, Ms. Sharma, but it says so in the documents issued by the Department of Health, more particularly in the special access program's guidelines. In the case of breast implants, both the patient and the physician must sign the form. It is on page 3 of your own document. These are the guidelines for the industry.

[*English*]

Dr. Supriya Sharma: I'm actually referring to the regulations that govern the special access program for medical devices. In section 22 of the Medical Devices Regulations, it stipulates only that the practitioner sign a declaration that says he or she has discussed the risks and benefits to the patient. I can take a look at the document you're referring to, but that's not in the regulations.

The Chair: Thank you. Our time is gone.

I want to thank the panel for being here and presenting this information to the committee. I thank the committee for their questions, particularly Dr. Brown for the technology and for taking time out of his practice.

Dr. Mitchell Brown: Thank you.

The Chair: We will be discussing on Tuesday whether we want any further action on this, as we go into the report on fetal alcohol spectrum disorder.

[*Translation*]

Ms. Nicole Demers: I would like to table a motion before the end of the meeting.

[*English*]

The Chair: You can table a motion at any time.

This meeting is adjourned.

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