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Chair

Mr. Rob Merrifield

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● (1535)

[*English*]

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

I want to first of all thank our panellists for coming.

We have two sets of panellists today. We're going to be talking about FASD, the fetal alcohol spectrum disorder, and looking at the report to us on where we're going with the FASD and how we're going to be able to do as much as possible to prevent it. That's in the first hour.

In the second hour we're going to talk about the report on breast implants, and we'll have a subsequent panel that will come before us at that time.

Without any delay, I would like to thank the witnesses for being here. I would ask that you introduce yourselves and start with your presentation; then we'll follow it with questions.

Dr. Sylvie Stachenko (Deputy Chief Public Health Officer, Health Promotion and Chronic Disease Prevention Branch, Public Health Agency of Canada): Thank you, Mr. Chair.

[*Translation*]

Mr. Chair and Members of the Committee, I am pleased to be here to discuss the Government's Response on FASD.

I would like to introduce my colleagues. Kelly Stone is the Director of the Division of Childhood and Adolescence, and is responsible for the FASD work within the Public Health Agency. Beth Pieterson is Director General of Drug Strategy and Controlled Substances and leads the National Alcohol Strategy work. Kathy Langlois, Director General of the Community Programs Directorate in First Nations and Inuit Health Branch, is responsible for the First Nations and Inuit FASD Program. And from the Canadian Institutes of Health Research, we have Dr. Barbara Beckett, Assistant Director of the Institute of Neurosciences, Mental Health and Addiction.

[*English*]

Mr. Chair, I'd like to thank the members of this committee for your thoughtful analysis of the challenges confronting all of us in addressing the issue of fetal alcohol spectrum disorder.

We're here to address issues raised in the Standing Committee on Health report on FASD and to speak to the government response to this report that was tabled on January 17, 2007.

The first recommendation calls on the Government of Canada, and the health portfolio specifically, to develop a comprehensive action plan for FASD with clear goals, objectives, and timelines. The Government of Canada recognizes the importance of this recommendation. In fact, since 2003, *Fetal Alcohol Spectrum Disorder (FASD): A Framework for Action* has guided the efforts to address FASD in a comprehensive way.

Both the framework and its companion document, *It Takes A Community*, developed in 2000 with first nations and Inuit experts, focus on two key pillars: the prevention of future births affected by alcohol and the improvement of outcomes for those individuals and families already affected.

These foundation documents resulted from a series of consultations with provincial and territorial representatives and key stakeholders. They provide agreement on the common vision, goals, and objectives across a range of jurisdictions and sectors. The government affirms the federal role by providing consistent access to culturally appropriate evidence and knowledge for decision-making, as well as tools, resources, and expertise across the country.

As to the question of leadership and coordination for the FASD initiative, that issue is presently under consideration by the Minister of Health. The minister has the lead with respect to FASD within the government and takes an integrated approach to the issue by deploying resources or calling on expertise from across departments and agencies. However, the government and key stakeholders recognize that FASD is more than an alcohol and addiction issue. It has impacts related to a range of aspects of public health, including women's health, disabilities, family violence, child welfare, and criminal justice, to name just a few.

As such, FASD is a public health issue, but also a social and economic issue, in which there is an important role for health promotion and disease prevention in government's efforts on FASD.

The second recommendation also deals with a need for public and professional awareness. The health portfolio's commitment to preventing and managing the health impacts of FASD is evident through its support for new and better information. The government supports publications, websites, tools, and shared awareness efforts spanning multiple jurisdictions.

As a result, public opinion surveys reveal that general awareness of FASD and the harm alcohol can cause to a baby have increased significantly over the past decade. Tangible results include new resources for use at the community level, such as parenting guidelines for families of children with FASD or the Canadian diagnostic guidelines.

Many federally supported tools and training programs are being used in the government's community-based programs, such as the Canada prenatal nutrition program and the community action program for children, to help address FASD among the vulnerable populations they serve.

The health portfolio has a website that provides good information on healthy pregnancy to women of child-bearing age. We are currently looking at additional ways to promote this information to the target audience, including women who are pregnant or planning to become pregnant and aboriginal women.

We will soon be releasing the new solicitation for the FASD national strategic projects fund to seek proposals on training to implement the diagnostic guidelines. As well, the national alcohol strategy, developed by a multi-disciplinary and multi-jurisdictional working group, is almost ready for release.

● (1540)

The Government of Canada provides health programming in first nations and Inuit communities. In fulfilling these responsibilities, we work in partnership with many stakeholders to reduce the number of newborns affected by FASD, through prevention programs to reduce drinking during pregnancy.

The FASD program has played a key role in raising FASD awareness on reserve.

The report's third recommendation calls for more robust data collection and reporting for FASD. As FASD is difficult to diagnose accurately, particularly early in life, the development of a surveillance system will be a long-term effort. The government continues to work in partnerships that span jurisdictions to standardize approaches to identify, screen, and diagnose those with FASD, and to collect and report the data in a common manner.

Along with the provinces, territories, and national aboriginal organizations, the government recognizes that health data must be distinct for each aboriginal group, including first nations, Inuit, and Métis.

Correctional Service Canada is working to establish accurate estimates of the numbers of individuals in federal institutions who may be affected by prenatal alcohol exposure, as no such data exists at this time. A reliable screening tool is also being developed to identify possible FASD-affected offenders so they can be referred for full assessment.

An important part of the government's response to FASD involves supporting research. Since 2000, the Canadian Institutes of Health Research have invested nearly $4 million into FASD-related research. This funding is helping to support researchers such as Dr. James Reynolds from Queen's University. His team has developed a fast, simple, and portable eye-tracking tool to determine if a child has a brain injury indicative of FASD.

The government recognizes the need to build the evidence base in our country, and in this regard, work has begun to develop a Canadian economic impact model so that all potential costs for FASD are part of these calculations, including costs for those who are within the justice, correctional, or homeless systems.

Within the range of FASD work we undertake, the health portfolio is a world leader through its constructive collaborations with the World Health Organization, the Centers for Disease Control and Prevention, and the Indian Health Service in the United States.

The report's fourth recommendation also notes the importance of value-for-money evaluation to frame FASD activities and the importance of ensuring that this is undertaken in partnership across the country. The health portfolio's FASD initiative is part of two major results-based management and accountability frameworks. Value for money is one of the major aspects of the associated evaluation plans.

Reporting mechanisms such as the report on plans and priorities and departmental performance reports will continue to provide Parliament the means to review the government's FASD programs and activities.

The Government of Canada has carefully considered all of the recommendations in the Standing Committee on Health's report and is addressing them through its wide range of current and planned activities.

Thank you.

● (1545)

The Chair: Thank you very much for being here and presenting, and for bringing so many experts with you.

We'll now open the floor up to questions.

We'll start with Mr. Owen.

Hon. Stephen Owen (Vancouver Quadra, Lib.): Thank you very much for your presentation, and for being here today.

You've talked a lot about this committee's recommendations for more data and the different efforts that have been made to improve data in the country. Do we have a sense that on one hand there are fewer cases and fewer incidents of cases because of the educational or other preventative actions? Is this a declining problem? Is it something that is out of our control at the moment?

And on the treatment side, are we finding that while there may not be cures, there are effective opportunities to treat the condition in a way that assists people to have a higher quality of life?

I ask both of these questions bearing in mind the wide range of concerns this raises at all levels of government and in different sectors of society. But are we effectively collecting data from the various sectors you mentioned—the homeless, the prison population, and kids in school? It seems to me that based on the numbers we were seeing a few years ago, if it's not plateauing or indeed the incidence is not being reduced, there's a ticking time bomb here in terms of costs, but more importantly, in the deterioration of people's lives.

I'd like to get from you a little better sense of what kind of grip we have on this issue.

Dr. Sylvie Stachenko: Thank you very much for the question.

In terms of whether or not there are fewer incidences, fewer cases, we do not have currently a national incidence system for FASD. However, we do have indirect measures in terms of alcohol awareness during pregnancy. So we know that at least at the first stage there are more people who are aware of the impact of alcohol during pregnancy.

What is absolutely needed...and that's why the development of an incidence system for FASD is a key piece in terms of all program planning in the future. We have basically two vehicles right now. The first one is that we have in this country a perinatal surveillance system, and already in that perinatal surveillance system there are 27 health indicators that are being collected, one of which is alcohol ingestion during pregnancy.

Secondly, we have a very important platform, which is the congenital anomalies surveillance. In Canada we are extremely privileged to have opportunities for data linkage. Basically, this surveillance system allows us to link various anomalies over a period of time from the birth registry. So in the future, what we're looking at with our colleagues in the provinces, the academic centres, the diagnostic centres is how we could register FASD in those various, I would say, administrative databases. The problem is—and that again is another very important step—accurate diagnosis. We need standardized procedures to say that this is a case of FASD.

I think the major step has been reached for Canada right now. We have these diagnostic guidelines that are key in terms of setting up any system with accurate diagnosis in the future.

So that's basically what your question is, and I'm answering in a very long-winded way.

● (1550)

Hon. Stephen Owen: Do the congenital abnormalities identify particular predispositions of different sectors of society?

Dr. Sylvie Stachenko: You could do some further analysis on that database. It just describes what some of the prevalences of various congenital anomalies are. What I'm saying is that we could, in the future, work to add FASD as a component of the anomalies surveillance system we already have.

However, one of our biggest challenges right now is the diagnosis, because the recording of diagnosis needs to be accurate, standardized across the country, and at this point we're not there.

I would like to say that with respect to what we know from other countries, Canada has the greatest chance and greatest opportunity to do record linkage than many other countries. So that opportunity exists, and basically that is work that is ongoing with our partners, with our players, in the surveillance arena, and it is a possibility that we can do that.

Hon. Stephen Owen: Thank you.

Chair, if I have a moment left, the question of treatment—

Dr. Sylvie Stachenko: Yes, in terms of treatment aspects, at this point, as you know, the impact of FASD is very much in terms of learning disabilities and various other neurological disorders. Basically, it's more to optimize the societal integration of these individuals.

So, yes, there are a number of efforts, not just from the health sector but also from other sectors. It's how you best integrate and what are the good practices that we have learned over time in being able to afford these individuals—

Hon. Stephen Owen: Thank you.

The Chair: Thank you very much.

Now we'll move on to Monsieur Malo.

[*Translation*]

Mr. Luc Malo (Verchères—Les Patriotes, BQ): Thank you, Mr. Chairman.

I welcome the witnesses. Thank you for being here this afternoon.

I believe that we are unanimous around this table in saying that the Fetal Alcohol Spectrum Disorder is a significant problem and that we must act and put in place the best practices in order to deal with some of the aspects of this disease.

In this context, the Bloc Québécois issued a dissenting opinion vis-à-vis the recommendations made in the committee report, in order to underline the fact that we believe that it is up to the provinces, to Quebec and each and every province, to establish the best practices and the best models in order to eradicate this problem within their respective jurisdiction.

Let me quote from the government response to this report. I will then ask for some clarifications.

It says:

> The GoC agrees that strong federal leadership around FASD is important and that accountability and governance structures are essential for program effectiveness and concrete improvements in outcomes.

I am simply asking who will be accountable. Will the provinces be accountable to the federal government on this issue?

● (1555)

Dr. Sylvie Stachenko: That is an excellent question. I will first deal with good practices.

It is indeed up to each province to offer the programs. However, as far as best practices are concerned, it is important to know the full range of good practices, be it in other provinces, in France or anywhere else. There is a need to synthesize; we have to see the big picture. This allows provinces to decide what they want to do. Our role is not one of service delivery, but it is rather a complementary role, a supporting role.

Regarding your question on accountability, you know that the framework was developed by the provinces, by all actors, because at the end of the day, it is not only about the government, but it includes a whole range of actors. The federal component is where the accountability lies in terms of what we are doing, be it in the area of Aboriginals, in surveillance or tools and resources. There will be accountability on that for which we have received money. However, the federal is not the only actor, it is really a shared jurisdiction.

What I was saying about accountability is that as far as federal money is concerned, there should be accountability because it is part of our mandate.

Mr. Luc Malo: So it only concerns the federal government's share of the funding?

Dr. Sylvie Stachenko: Yes.

Mr. Luc Malo: If I understand correctly, to come back to the first element of your answer, you do not consider that provinces are able to find out about best practices everywhere in the world, to collect this information and to put in place a structure that could be their own.

Dr. Sylvie Stachenko: Every province can do so, but we have precisely done a sort of sampling of the provinces' capacity to proceed in this way. Capacities are quite different from one end of Canada to the other. One simply needs to have the capacity to disseminate the information in all provinces. This does not prevent provinces to do their own work as well.

However, there is a difference in the capacity of provinces throughout Canada to do that kind of work themselves, and that difference has been confirmed by a survey that we have done on this matter.

Mr. Luc Malo: Thank you very much.

Further on in the report, you indicated that:

> Key partners work together to address sectoral and jurisdictional barriers to implement a well-coordinated system of services.

If I understand correctly, there are obstacles between jurisdictions. Could you tell us more about this?

Dr. Sylvie Stachenko: In fact, I was saying that the approach must be multisectoral. This does not only concern the health sector. There are many sectors committed to this exercise and we must try and facilitate the integration of the work being done. Within the framework of this initiative, especially at the federal level, we have many joint projects, which enables us to do some pooling of resources to meet the needs of the situation.

So it is between sectors that there are definitely some silos and we often need to facilitate exchanges because the health sector is not the only participant. There are impacts in all areas, even at the level of identification. We can identify some cases in prisons or other places.

Mr. Luc Malo: I also see that there is an enquiry—

[*English*]

The Chair: I'm sorry, your time is gone. You can come back for another round if there's time.

Mr. Dykstra, you have five minutes.

Mr. Rick Dykstra (St. Catharines, CPC): Thank you, Mr. Chair.

My questions follow along the same lines. One of the things I listened to with interest in your comments was about the number of times we've come trying to determine when we could actually achieve some statistics so we can actually do some analysis, actually do a review, and begin to focus a little more clearly. You mentioned in your remarks, Sylvie, the long-term goal, and I've read about it in the report that was prepared for us here. I'm wondering if you might be able to be a bit more specific. In terms of a timeframe, what do you think “long term” might represent?

● (1600)

Dr. Sylvie Stachenko: If you look at other surveillance systems that we've established—and basically you have to go through the step of getting common definitions, right through to getting all the provinces on board—I would say it usually takes a period of five to 10 years, from our experience in other areas.

I can't tell you. I think we're really at a very important stage right now, because of the diagnostic guidelines and the fact that all professionals in this country have something in common. It's a very specific tool, and our efforts are going to be to try to disseminate it and implement it throughout the country. That will be the first step.

Potentially we can accelerate some other steps, because we have the platforms. If we can get better dissemination of these guidelines and work very closely with all the professional organizations, as well as institutions, I think we'll be well on our way to accelerating the process. On average, if we look at others—we've got cancer surveillance systems for children in this country, and we've got a number of others—it takes about five to 10 years, just because of all these processes and standardization. As I said, that first step—getting a common definition agreed to—is crucially important, and I think we're well on our way. I would even say that we are international leaders currently.

Mr. Rick Dykstra: Yes, I noticed that in your comments. I actually bridge that a little bit, because the research portion of your presentation mentions that since 2000 the Canadian Institutes of Health Research has invested nearly $4 million into FASD research, and I am a little bit hopeful that it will correlate to levels of awareness.

What do you think of the results of that research? Could you come up with a couple of specific examples of how it has assisted in terms of awareness?

Dr. Sylvie Stachenko: I'm going to let others speak to this, but I can say that in terms of some screening tools, Canadians are leaders. We have some work around the meconium, which is the first stool of babies when they're just born. It is important because it gives you an important indicator of whether or not the mother drank alcohol during the whole pregnancy. That came out of research, and it's a Canadian researcher. I don't remember the name, but it's somewhere in Ontario. There is hair analysis. There are all these new tools that will be extremely important, because they will validate the diagnosis in the future.

Maybe you could say a little bit more, Barbara.

Ms. Barbara Beckett (Assistant Director, Institute of Neurosciences, Mental Health and Addiction, Canadian Institutes of Health Research): The researcher who did the meconium studies is Dr. Gideon Koren from the Hospital for Sick Children. He did a fairly extensive study in Grey-Bruce County in Ontario. Obviously, that's something that would need to be extended to other parts of the country if you wanted to have a really good snapshot of what's happening nationally. I would have cited that as one of the examples of research with practical impact that CIHR has funded.

Another one is the eye movement study that Sylvie referred to that is coming out of Queen's University. James Reynolds has done that. If it pans out, that would represent a simple and easy-to-use diagnostic tool that could certainly help get the statistical data you were talking about.

Another important piece of research is by Dr. Caroline Tait, at the University of Saskatchewan, who has done some research with first nations women, accepting the reality, I guess, that there are women who are alcohol dependent and working with them to try to minimize the impact on their children.

Those are three practical examples.

● (1605)

The Chair: Thank you very much.

Mr. Fletcher, you have five minutes.

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

I wonder, Sylvie, if you could describe the leadership on the FASD file. That was probably the key recommendation the committee had in the previous report—who would be taking the lead?

Also, could you expand on the role of the Public Health Agency in dealing with fetal alcohol syndrome. And what more needs to be done in a timely manner? I think the committee is frustrated that not a lot seems to have happened in the time the committee has been looking at it.

Dr. Sylvie Stachenko: The first question I think you mentioned is around the lead. Basically, the lead is something that will defer to the minister. At this stage, the Public Health Agency, whatever the lead will be, has a key role to play. Public health has a number of essential functions, one of which is health promotion, and another one, surveillance. I think those two functions are clearly important in advancing the FASD agenda. So in that context I would say that the Public Health Agency will remain a key player.

When we say health promotion, it's not about campaigns. It's also about a definition that means, how do you facilitate healthy public policy? How do you work with your other sectors to advance issues? It's very much like tobacco, which uses a health promotion approach. You have to take a number of measures that span policy interventions, community interventions, and health care interventions, and have a number of players and partnerships.

So you need, somewhere, a broker to bring all this together, and I think that is an area where public health has had a fair amount of experience over time, that brokering role, that stewardship role of bringing all the players.

We're working in complexity. All these issues are no longer the issue of one jurisdiction. It's basically an issue that requires a breadth of players and partners. As I said, one of the first important measures in the future, if we want to better plan and evaluate our programs, is really to develop robust surveillance systems, and that is a key function for public health. So those two dimensions, for me, mean that we will continue to work in a very important way to advance this agenda.

With respect to what the Public Health Agency does, we—and not just the agency, I would say, but the entire portfolio—have structured the entire activities around this framework for action.

There were five goals in that framework for action, and for each one of those areas or themes, we have a number of activities. For example, we have had a number of efforts in the area of professional and public education. The latest one has been the diagnostic guidelines with the professional organizations. As I said, this is a very important step for the future.

What we're going to be doing now is working on the implementation of this. So we have the guidelines, and now we'll work on the implementation, not just for physicians but also all allied health professionals and other front-line workers, because they're not only in the health sector, they're in other sectors, as I mentioned. So that's one aspect of professional education.

The other aspect is that we completed a survey around all health professionals to really understand what are their attitudes and their levels of awareness of the FASD issue. That will be extremely important in orienting any future work with the professional organizations.

On the public side, we have, obviously, a website. We have a number of tools. If you go into our FAQ website, you'll see quite a number of tools and, basically, pamphlets. But we are also working with this healthy pregnancy website to look at how we can advance and look at new activities around specific vulnerable groups, and this is part of some future direction.

So, again, on public and professional education, we've done things. We've done things in terms of surveillance, which I've mentioned to you and I'm not going to go more into it. We've done things in terms of building capacity. We have the national strategic projects fund, which is an extremely important tool for us to support organizations and communities across the country to develop resources and tools.

● (1610)

We work for the Canadian Centre on Substance Abuse, in terms of looking at and collating best practices.

We organized our work very clearly around some of those themes, and the issue of coordination is one we took very seriously. Since we've had this framework for action, we led an interdepartmental group, which included Justice, and obviously HRSDC, INAC, and quite a few federal departments.

We are also leading the health portfolio efforts internally, and this helps us have a coherent response.

It's not just about saying it's good to partner. We actually have mechanisms and joint funding, joint projects, and a lot of in-kind leverage through these various partnerships.

The Chair: Thank you very much.

Ms. Davidson, you have a few minutes.

Mrs. Patricia Davidson (Sarnia—Lambton, CPC): Thank you, Mr. Chairman.

Thank you very much for your presentation this afternoon.

Certainly we undertook an extremely interesting study, and there were many heart-wrenching aspects.

I appreciate what you've had to say here this afternoon, regarding the leadership that was developed and is further developing and regarding the cross-departmental cooperations, the identification and data collection, and all of those processes that are in place, are increasing, and are trying to resolve this issue.

But given the role that the alcohol industry could play in the prevention of FASD, I was wondering, what does the health portfolio do with them? Do they collaborate with the alcohol industry on this issue? Is there a coordinated effort with them?

Dr. Sylvie Stachenko: I would say yes, we do collaborate, but I'll let Beth respond more specifically as to how we do that.

Ms. Beth Pieterson (Director General, Drug Strategy and Controlled Substances Programme, Healthy Environments and Consumer Safety Branch, Department of Health): The most recent collaboration is the development of a national alcohol strategy. As Sylvie noted in her opening presentation, the strategy is being printed and about to be released. We collaborated with the alcohol industry—with the vintners, spirits, and brewery industries —as well as with academics, provincial governments, and a wide range of stakeholders on the development of that strategy.

It has 41 recommendations. They are targeted at the federal and provincial governments—at all the stakeholders, including the industry.

The industry is very much willing to work with us on preventing alcohol use during pregnancy, as well as preventing alcohol use that creates harm right across the board.

So they are collaborating with us.

● (1615)

Mrs. Patricia Davidson: Do you know when that strategy will be released?

Ms. Beth Pieterson: It's being printed now. That will depend somewhat on the Minister of Health's willingness. It's not just a Health Canada publication. It was co-chaired and led by three organizations: Health Canada, the Canadian Centre on Substance Abuse, and the Alberta Alcohol and Drug Addiction Commission. So it was sort of tri-government, organization-led, and it should be released in the spring.

Mrs. Patricia Davidson: Thank you.

The Chair: Thank you.

Ms. Bennett.

Hon. Carolyn Bennett (St. Paul's, Lib.): Thank you, all of you.

I scanned the presentation quickly and was thrilled to see partnerships across government departments and in the whole sector.

My concern was where you said that with the provinces, territories, and partnerships, you collect and report the data in a common manner. Do you think you now have the tools to do the surveillance? If not, how do we do better on this, in understanding the incidence and gravity, but also in evaluating best practices?

Dr. Sylvie Stachenko: Thank you for your question.

Yes, we have the mechanisms right now. I mentioned that we have the perinatal surveillance system, which includes the provinces and a number of academic centres in the country. We also have the congenital anomalies surveillance network. Basically those platforms exist.

What we really don't have is the diagnosis and how we could standardize it. So, yes, we have the tools. As opposed to other areas, this surveillance network has been in place for the last 10 years and consists of a fairly robust group of provincial representatives and academic centres across the country.

Canada is in the lead in this area, and basically we can accelerate the development of a good surveillance system, given the fact that we have these platforms in existence now with the provinces.

Hon. Carolyn Bennett: Is FASD now considered something that would be included in a congenital screening program? How far have we moved in being able to do the knowledge translation from Dr. Koren's study on meconium screening to a universal screening program?

Dr. Sylvie Stachenko: I think we're not there yet. My understanding is that this is not generalized yet, so—

Hon. Carolyn Bennett: Because on this side, when Dr. Beckett presented, there's a.... From what I understand when I was in Owen Sound, they turned up four, five times more than they had expected in that study. What that means is that probably across this country we're looking at much greater incidents than we had thought. What would be the impact of having universal meconium screening across Canada?

Ms. Barbara Beckett: Well, that study did turn up a high rate of alcohol exposure to the newborns. But if you estimate that 40% of those infants would actually be affected by FASD—which I think is the figure that's used, and I'm not sure where it comes from—you end up with perhaps 1%, which is in line with some data that's come from the United States. I don't think it indicates that there's a huge increase in cases over what we would expect.

Hon. Carolyn Bennett: In what we learned from some of the communities, the earlier you identify a child, the more likely you'll be able to do an intervention with the mom and prevent four or five more children who might be affected being born to that same mom. Do you see that we're starting to turn some of this around? Is there hope?

Other than data and whatever, when we say we're the leader, on the contrary, we're a leader in being able to wring our hands and say how bad it is. Or are we actually turning this around?

● (1620)

Dr. Sylvie Stachenko: I think we've made some progress. That's what's important. There has been progress on a number of fronts. There has been progress on awareness of the issue, that's for sure. There has been progress in terms of professional awareness, and that came out of our survey. We now have guidelines in terms of professionals having some tools to use.

I'm going to ask Kelly to talk a little bit more about this, but in terms of community interventions, we have been able to develop some and look at some good practices that we implemented in terms of how well they are working. My understanding is we're into the evaluation stage of this, because it's only been a few years.

On the aboriginal front I think there's a lot of examples and there's very good progress. So I'm going to let both Kelly and—

Hon. Carolyn Bennett: Maybe Kathy and Kelly could tell us something, but in telling us, could you tell us a little bit about the importance of aboriginal head start and prenatal nutrition programs in your surveillance?

The Chair: We have another questioner or two, and her time is actually up. So keep it tight. Go ahead.

Ms. Kelly Stone (Director, Division of Childhood and Adolescence, Public Health Agency of Canada): I would just comment, then, that we do have a national strategic projects fund, a grants and contributions fund that allows us to develop tools out in communities with communities, which then, with the help of the federal government, can be disseminated into other communities. Certainly we use our national children's programs, such as the Canada prenatal nutrition program, the aboriginal head start program, and Canada's action program for children, all three of them, as a way to disseminate to high-risk populations. We use those tools and the opportunity to have those at-risk moms there with their children to share as much of the practical information as we possibly can about the risks of alcohol, either when you're thinking about becoming pregnant or when you are pregnant. And we also use interventions that help the child who may already have been exposed to alcohol to perhaps get screening or diagnosis, as is appropriate through the program.

Kathy, can I turn to you?

Ms. Kathy Langlois (Director General, Community Programs Directorate, First Nations and Inuit Health Branch, Department of Health): I believe the programs you're talking about, in terms of interventions of mums who've already had one baby and then preventing further ones, describes very well the mentoring programs we've been implementing with our FASD funding in first nations and Inuit communities. In this coming fiscal year we'll have 30 communities that have mentoring projects.

There are some results that are coming out of the Stop FAS program in Manitoba, on which we have modelled our programming. That program is starting to get preliminary evaluation data, and some of the results are indicating that 60% of the women in that program were no longer at risk of delivering a child with FASD because they've been abstinent from alcohol and drugs for six months or more and were using a family planning method regularly. Sixty-five percent in that program had completed an addictions treatment program. So the model of mentoring—particularly among aboriginal women—is starting to show some results, that it's an effective strategy.

In terms of the aboriginal head start and CPNP youths in our surveillance, the new element we've introduced this year is our maternal child health program, which is introducing home visitors on reserve who will come in pre/post pregnancy. It will be able to make linkages to support programs such as the mentoring program, should that be needed.

So the maternal child health program is building off the head start and the CPNP in that we're starting to look more at operating those programs in a clustered approach, so the programs are all linked and effectively supporting each other.

The Chair: Okay, thank you very much.

Mr. McKay, you have a quick question.

Hon. John McKay (Scarborough—Guildwood, Lib.): Thank you, Mr. Chair.

Thank you for your presentations here. I'm not a regular member of this committee, but I have followed the issue through our colleague, Paul Szabo, in his books and private members' bills on the subject, and a constituent of mine named Bonnie Buxton, who has also written on the subject. What has puzzled me over the years—and possibly the agency or the department has a position on this—is that a certain percentage of pregnant mums either can't or won't get it, won't make the linkage between their behaviour, their ingestion of alcohol, and the damage that happens to their fetus. Does the department or the agency have a position with respect to mandatory restriction of alcohol ingestion by pregnant mothers?

● (1625)

Dr. Sylvie Stachenko: By what?

Hon. John McKay: By pregnant mothers?

Dr. Sylvie Stachenko: Maybe I could leave that question to Beth.

The Chair: This does sound like a lawyer's question.

Ms. Beth Pieterson: We don't have a position on that. I think certainly in the alcohol strategy we're trying to develop—it's called "Toward a Culture of Moderation"—through education, awareness, a range of activities, we're trying to change alcohol consumption, especially in the high-risk groups, recognizing, though, that saying they can't drink is not within the scope of Health Canada's usual policies.

Do you mean to say like putting a restriction on bars serving pregnant women?

Hon. John McKay: That's one suggestion. It's not one I'd thought of, but I'm not sure I'd go quite as far as incarcerating, but certainly you are in effect giving a life sentence to a child because mum is either unable or unwilling to appreciate the nature and consequences of her behaviour. I wondered whether the department or the agency had arrived at a decision as to whether it would recommend that kind of restrictive behaviour. There seems to be a fair bit of buck-passing here.

The Chair: That's probably one that will be left to the courts eventually, if it were ever challenged in a court of law. It's similar to what we've seen with HIV/AIDS patients having unprotected sex being challenged in the courts, and you're suggesting a similar thing here.

I'm not sure it's fair to ask our panellists, unless somebody has an opinion. We're certainly willing to hear it.

I would like to ask a couple of quick questions, if I can, on behalf of the committee for further information. This started with a private member's bill on labelling of alcohol, and we said, no, we want a copy and some plan. This has been a two-year process, coming up with a comprehensive plan in what you've presented here today. I think we can be comforted in knowing we're seeing some progress. I have a couple of quick questions for the information of the committee. You had suggested to us that there's a national strategic project fund that is about to propose some recommendations as well as a national alcohol strategy development about to be released. Can you tell us the game plan? What are you expecting out of both of these? You make mention of them here—and some of the timelines as to when we can expect them.

Dr. Sylvie Stachenko: One is the national strategic projects fund.

The Chair: That's right.

Dr. Sylvie Stachenko: That one is ready to be released. I would say it will be within a matter of days.

The Chair: What do you expect out of it?

Dr. Sylvie Stachenko: We're then expecting to get the proposals on all this and to have some announcements, most likely around April or May.

The Chair: Around when?

Dr. Sylvie Stachenko: April or May of this year. Are you talking about the alcohol strategy?

The Chair: Yes, but just on this one, you're talking about a new solicitation for FASD. I have a difficult time understanding exactly what is going to be presented.

Dr. Sylvie Stachenko: There are two types of new solicitations. There is one that has already occurred. That one was a directed call, and it happened in December. My understanding is that we already have other proposals.

Let me have Kelly answer that one.

Ms. Kelly Stone: We had a directed proposal, such as the Canadian Centre on Substance Abuse, for part of the fund, just before Christmas. We're getting the proposals, but I couldn't say what they are at this point.

Any moment, any day, as soon as we can get it on our website, there'll be an open call for proposals related to the dissemination training tools, along with the diagnostic guidelines, in order to get some more movement on our diagnostic guidelines. We would expect it would be for funding that would commence this April.

The Chair: Is that under Public Health or is it under CIHR?

Dr. Sylvie Stachenko: It's Public Health.

The Chair: Okay. The second one is on the national alcohol strategy.

● (1630)

Dr. Sylvie Stachenko: I'll let Beth answer.

The Chair: I'd like the timeline on that as well.

Ms. Beth Pieterson: As I mentioned earlier, the alcohol strategy is being printed now. It should be released within the next couple of months.

We're making wide-ranging recommendations, as I said before, not only for the health portfolio but for other organizations of Canada. Once it's out, we're hoping that we will continue collaboration with all the other stakeholders involved to move forward on those recommendations. As I said, it should be released within two months.

The Chair: It will be within two months. How long has the study been going on?

Ms. Beth Pieterson: We started in December. We had our first meeting of an expert group in December of 2005. We met several times over a year. The report was then finalized, and it's being printed. It took about a year.

The Chair: It's actually completed and it only has to be printed.

Ms. Beth Pieterson: It's completed.

The Chair: Okay. Fine. It helps us with what we are to look forward to.

I know one of the things we had also asked was to have an annual review of progress on this subject, and we expect that will happen.

We appreciate that you came and presented.

I don't have any other people on the list for questions, but we would entertain them, if there was another one.

I see Mr. Szabo is there, but I'm sure he is very quiet on this subject and wouldn't have anything he would want to add.

Mr. Szabo, if you have a quick question, we'd allow it.

Mr. Paul Szabo (Mississauga South, Lib.): First of all, I want to thank the committee for allowing me to speak.

Secondly, I would thank Health Canada, the officials, and the minister for responding to your report.

I haven't had an opportunity to fully synthesize the response, but I think the question that Canadians will want answered is this. Have we moved away from describing our efforts historically towards establishing some kind of a benchmark and timeline to address FASD? That's the simple question.

If you look back at the subcommittee report of the health committee of the day in 1992, you will see a report called *Fetal Alcohol Syndrome: The Preventable Tragedy.* They describe all of the things we're saying today, every one of them, and every recommendation we're making today. It's from back in 1992, and it's a long time.

I think Canadians who are interested, the stakeholders right across the country, of which there are a very large number, would like to know there is some hope that we will take some concrete steps.

The Chair: Just on that, we'll ask for a response from the panel.

Mr. Paul Szabo: Okay. I thank you.

I think it's the question that maybe all stakeholders, including the members, would like to hear.

The Chair: We'll ask for a quick response, and then that will cut down and very much eliminate our time.

Go ahead.

Dr. Sylvie Stachenko: In terms of benchmarks against which we will be able to tell Canadians that we're advancing, I think, again, when we look at our framework for action and the various goals we have set for ourselves as a country, we are definitely moving and progressing in each one of these various themes. So in that context, it's been a long time in terms of the history—1992. I do recognize that.

But I would say that since we've had this framework, and the fact that this initiated a cross-sectoral response and a very strong federal family response, too, there has been acceleration of many activities, and synergies and efficiencies have been gained over time. I think that was a very important step in 2003, and I would say that there has been acceleration in the last few years.

The Chair: I want to thank you very much for coming in and giving us this report. We appreciate it very much. We'll be looking forward to progress in the future, particularly with these two initiatives that are about to be announced. Thank you very much.

With that, we'll take a very short break. We'll ask the committee members if they want to refresh their coffee as we change our witnesses and bring in the breast implant group.

● _____ (Pause) _____ ●

● (1635)

The Chair: Okay, we'll call our members back to the table and progress with the second half of our meeting today.

We have with us Neil Yeates, assistant deputy minister of the Health Products and Food Branch. We're pleased to have you here.

We obviously know and want to welcome again Ms. Sharma. Thank you for being here and giving us an update on breast implants.

We'll yield the floor to you and allow you to make a presentation, and then we'll open it up for questioning.

Neil, are you first?

Mr. Neil Yeates (Assistant Deputy Minister, Health Products and Food Branch, Department of Health): Yes, thank you very much, Chair.

We appreciate the opportunity to address the concerns that the Standing Committee on Health has raised in its third report on silicone gel-filled breast implants and to speak to the government response to the report, which was tabled on January 17 this year.

I intend to address these concerns by briefly discussing the actions taken by Health Canada, including the licensing decisions in the assessment of the six applications for silicone gel-filled breast implants and how these actions will fulfil the four recommendations made by the committee in your report.

It should first be noted that silicone gel-filled breast implants are some of the most intensely studied medical devices in modern medical history. The recent medical device licences issues to Inamed and Mentor in October 2006 for their implants were subjected to a high level of scrutiny by Health Canada due to the public input gathered, the expert advice sought by Health Canada, the volume of data submitted by the manufacturers, and the length of the review of this information to ensure that it met the safety and effectiveness requirements of the medical devices regulations. The process took four years.

This is but one of the actions that serve to directly address the recommendations put forth by the committee, which I will now address individually.

The first recommendation made by the committee is on a concern of possible health effects, such as hypersensitivity and autoimmune reactions. These have been addressed through requesting supplementary data on the science related to these concerns from the manufacturer, which was found to meet the safety and effectiveness requirements of the medical device regulations. However, we will continue to monitor these issues, and should new information become available, we will act accordingly.

The committee's second recommendation suggested changes to the special access program authorization form. These are currently being implemented by Health Canada. More space is being added on the form for information on risk and benefit, as well as a declaration stating that the physician has discussed the risks and benefits with the patient. Health Canada will implement this recommendation for all medical devices authorized under the special access program in about two weeks.

The third recommendation involved informed consent of patients receiving implants through the special access program. It should be noted that informed consent is a process that occurs between a patient and their physician and is considered to be the practice of medicine, which is regulated by provincial and territorial authorities through colleges of medicine.

While the issue of informed consent is not directly within our mandate, Health Canada has gone to great lengths to encourage it by ensuring that patients and physicians are provided with full, accessible information about the risks and benefits of silicone gel-filled breast implants through a decision-making aid that has been incorporated into the patient brochures issued by the companies.

The committee's fourth recommendation pertained to post-approval conditions that should be attached to these products in order to be authorized for sale in Canada. In licensing silicone gel-filled implants, Health Canada has included an extensive list of conditions upon the manufacturers. For example, as a condition of licensing, manufacturers are required to initiate large-scale studies to further investigate the potential for breast implants to be linked to any previously undetected adverse events.

Further to this, under the medical devices regulations, manufacturers are required to report problems with licensed products. Additionally, health professionals and patients can voluntarily report problems with medical devices to Health Canada.

Health Canada continues to review the published literature regarding the safety of breast implants, and as a continuing commitment to transparency has committed to update, on an annual basis, the publicly available summary basis of decision documents, including the problem reports for these devices.

In conclusion, I'd like to thank you for the report issued by the committee. We know the committee has put a lot of thought and effort into this issue. We hope that through our response to the report and by meeting with you today we have demonstrated not only that we accept and appreciate the spirit and intent of the committee's recommendations, but how we have acted upon each one of them within Health Canada's mandate, which affirms our ongoing commitment to protect the health and safety of Canadians.

Thank you, Chair.

● (1640)

The Chair: Thank you very much.

We'll open the questioning now.

Ms. Kadis.

Mrs. Susan Kadis (Thornhill, Lib.): Thank you, Mr. Chair.

Welcome.

I think you mentioned that there have been multiple ongoing studies, but I'm sure we'd all agree it's an area that warrants them for the potential ramifications.

You've referenced briefly something that's taken place in the interim since Health Canada stopped the sale of the breast implants. What has taken place significantly? Did studies show that they are safe? Were the studies done strictly by the manufacturers?

● (1645)

Mr. Neil Yeates: I'll ask Dr. Sharma to speak to the science, but I will say that our review of the literature and of the studies was very extensive, actually more extensive than we've ever done for any product. The investigation was very thorough.

But I'll ask Dr. Sharma to speak to some of the key science issues.

Dr. Supriya Sharma (Associate Director General, Therapeutic Products Directorate, Health Products and Food Branch, Department of Health): Just to clarify the question, are you asking what has happened in the science in the interim, from the time back in 1992?

Mrs. Susan Kadis: Yes. I understand that now they are allowed to be sold. They weren't during that interim, so something has to have taken place, presumably, to lead to this. I'm trying to understand what preceded the approval in October, recently, to sell them again.

Dr. Supriya Sharma: There are probably two large categories of things that have changed since 1992. One is the body of evidence we looked at and that was available to us to make the assessment about whether or not the products were suitable to be authorized for sale.

The other part of it is the manufacturing process. The way the silicone gel-filled breast implants are made has also changed.

On the information side, on the science side, just in this review when we did the literature studies, since 1950 there have been over 6,000 medical and scientific literature pieces of information that went into this review. When looking at the recent past, there are about 2,500 studies, and a lot of those involve thousands of individuals and have follow-up in the tens of years. So there has been a big body of information.

The things that have come up recently have been primarily around hypersensitivity to cancer involving breasts—whether or not there was an increased risk of cancer. There isn't. The other big category was around autoimmune diseases. That really was the big unknown, looking back to the 1980s and the 1990s. There were a lot of questions about whether or not it caused autoimmune disease. There have been large multiple studies looking at autoimmune diseases, and there hasn't really been a link.

In a nutshell, there has been a significant body of information we've had since that time that went into the review.

Mrs. Susan Kadis: I guess it begs the question of why there will be such an extensive requirement for post-approval. Obviously there are still outstanding concerns.

Dr. Supriya Sharma: There are usually follow-ups for medical devices once they're licensed. There were specific things we wanted the manufacturers to follow up on, post-market. The only way to specify that is to make it a condition of licensure. It's really our only regulatory tool to say, in a formal way, this is how we want the post-market surveillance information to come.

Mrs. Susan Kadis: Are you actually saying that when that approval went forward you were comfortable that most of the concerns had been addressed largely and enough, to the extent that it could go forward?

Dr. Supriya Sharma: By authorizing them for sale, what we're saying is that there are a series of safety, effectiveness, and quality specifications laid out in the medical device regulations, and when we license them we say that the products we have analyzed meet those requirements.

Mrs. Susan Kadis: Will doctors be required to give adverse information about problems with patients, or will it be optional?

Dr. Supriya Sharma: The actual problem reporting surrounding medical devices, as legislated, is for the manufacturers. That's what's mandatory. There is voluntary problem reporting, and it can be by practitioners, or by patients, or by members of the public. Anybody can actually voluntarily report a problem with a medical device.

Mrs. Susan Kadis: Thank you.

Mr. Chair, I would encourage that this information be provided and relayed, if we're to have a proper picture of any potential problems going forth.

Thank you.

The Chair: Thank you very much.

Madame Gagnon, the floor is yours.

[*Translation*]

Ms. Christiane Gagnon (Québec, BQ): Thank you.

I share the concerns of my Liberal colleague. We are quite worried regarding these new silicone gel-filled implants that have been put on the market by Mentor and that are being criticized as well by a certain community in the area of health in the United States, where these silicone gel implants have already been approved by the FDA.

It seems that the use of these new silicone gels has been approved not because there was a concern about the health of women, but rather for business reasons, following some pressures that have been exerted by the cosmetic surgery industry. How can you be certain that this product is safe? You said that there were many studies, that there was a follow up and that data were collected, but beforehand, the implants that were used on women also required follow-up studies in order to protect their health. Ten years from now, we may not be here to ask other questions to Health Canada about the impact that the use of these implants have on women.

So I believe that you do have an important role to play and a great responsibility. Health Canada authorizes the marketing of a product, and then declares that it is no longer their problem, that the patient and her physician will be able to deal with the whole issue of the control and safety of these breast implants. It seems to me that you have been rather irresponsible in allowing the sale of such implants, all the more so that they are being criticized elsewhere and that there could be a risk of puncture. As you said earlier, the use of these breast implants on women has some potential effects.

I would like to hear you on this issue, especially that you are talking about 2,500 different data. Could you explain what all these data are about?

● (1650)

[*English*]

Mr. Neil Yeates: Perhaps I can start, Member.

There are a couple of things. As you know, these products have been available in Europe for many years. It was Canada and the U.S. that had not licensed these products in the late 1990s and early 2000.

We conducted a very extensive review of these products, as did the U.S. FDA, and we were satisfied that they met the safety, effectiveness, and quality criteria that we meet. Now, those reviews, done by ourselves and the FDA, were done independently. We arrived at the same conclusion, a conclusion that Europe reached many years ago, I would just say.

So there are two things. One is that for all of the products that we deal with, right across the spectrum, for drugs and medical devices, there are risks of some kind, and we're always measuring the risks versus the benefits, what the appropriate use is. That's something we do every day. That's the nature of our work. So none of these products is risk-free. In the case of these devices, we have quite an extensive post-market follow-up strategy that's being undertaken, and as with any other medical device or drug, if there's new information that comes to light that requires a modification of the approval that's been given in terms of its use, or even if it's necessary, as occurs from time to time, that a product be withdrawn from the market, that's what we will do.

But the point we reached after extensive review was that it was appropriate to release these products to market, but the work will continue.

The Chair: Thank you very much.

Ms. Davidson, you have five minutes.

Mrs. Patricia Davidson: Thank you, Mr. Chairman.

Thanks very much for your presentation.

I certainly appreciate the fact that Health Canada has done extensive review on this, and that it's been a four-year process, which is probably unheard of with other devices. So I do feel that the science part of this has certainly been well explored, and I'm sure, from hearing what you have presented at other meetings, that the science is solid behind this recommendation.

However, we still see negative reports about things that are happening. I guess that's because, as you said, Mr. Yeates, none of these medical devices is risk-free. So regardless of whether or not there's good science behind it, there is still always a possible risk with any of these medical devices. You also went on to say that you were trying to address the safety and effectiveness requirements and, more particularly I think, the informed consent issue, although it wasn't under your mandate. So whose mandate is it under? Because that was something that we felt very strongly about: that the informed consent should be increased and be made clearer for the user.

You said you were going to continue to monitor the possible health effects, side effects, hypersensitivity and auto-immune reactions, and so on, and act accordingly on those issues. Could you just elaborate further on those points, please?

● (1655)

Mr. Neil Yeates: Certainly. I can start and then invite Dr. Sharma to comment further.

First of all, in terms of informed consent, that's the responsibility of physicians, through their relationship with patients. In terms of what we can do, there is a decision-making aid that is included in the patient brochures. We tried to follow the committee's recommendations for that and take that as far as we could. In terms of the special access program, as I think we'd said at an earlier appearance, it's really not being used anymore. However, we've still included a section on that form that requires a physician to certify that they have had a discussion with the patient on risks and benefits of the particular product. And we're doing that for all of the medical devices and applications, not just for breast implants. I think that's a very important system-wide improvement.

Sorry, what was the second part of your question?

Mrs. Patricia Davidson: You were saying that you were going to continue to monitor and act accordingly. What does that mean, actually?

Mr. Neil Yeates: For us, that really refers to our continuing efforts in what we call post-market surveillance. It really applies to all of the products we regulate. One of the previous members referred to problem reports, as they're called, for medical devices. The equivalent on the drug side is reports on adverse drug reactions. We collect those reports, not only Canadian reports but those from around the world. We look at the literature to see what kind of science is developing. We get updated reports from the manufacturers as well. We analyze all of that and determine whether there may be some kind of a signal that would indicate that we need to take regulatory action.

That's basically how we carry out our business. As I'm sure you see, every week we issue warnings, advisories of some kind. We update labels. That's what we do day in, day out in just managing this business. It's no different for these implants.

Mrs. Patricia Davidson: So how do the patient registration cards that Health Canada is requesting get sent to the manufacturer? How does that fit into this?

Mr. Neil Yeates: Well, it's another tool really in the arsenal. This is fairly common with medical devices. It basically allows for communication with the patient, should there be an issue develop with a particular product. Sometimes it can be a particular model or a lot number for which some issue arises. So it's another tool in the arsenal that can be quite useful. We tend to focus our communications to the public at large and to medical practitioners directly.

Mrs. Patricia Davidson: Thank you.

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

Mr. Steven Fletcher: I found it interesting that shortly after Canada made its decision on breast implants, the United States followed suit. I'd like to give you an opportunity to comment on the American decision and on how that decision was similar to Canada's.

Mr. Neil Yeates: I will start in a general way, Mr. Fletcher. As you probably know, the committee is well aware that these products were submitted to the FDA at a similar time as they were to us. The FDA conducted a very extensive review as well, very similar to what we did, and basically came up with the same kinds of conclusions that we did, again, quite independently. Also, one of the key conditions of licensing for the FDA is the post-approval study, the long-term study. So I think it is a very important common conclusion for the two agencies. The requirement for the manufacturer to maintain the patient registry is also common.

Basically, the two decisions were very, very similar.

Mr. Steven Fletcher: I would like to say, on behalf of the government and the minister and the committee, that most of us have been very impressed with your presentation and the professionalism that your team has brought forward, Mr. Yeates and Dr. Sharma. I think you deserve to be congratulated on a job well done.

● (1700)

Mr. Neil Yeates: Thank you.

The Chair: Thank you very much, Mr. Fletcher.

Ms. Kadis.

Mrs. Susan Kadis: Following along with what has been stated today, you don't feel the concerns raised by some physicians in the States, for example—I think they've been referenced as well—are really founded. There are doctors who are seriously questioning the recent approval. It seemed to happen, actually, around the same time as our approval. I'm not sure if there's anything to that, but they're also questioning that they're seeing adverse impacts in their patients.

Do you feel this is unfounded?

Mr. Neil Yeates: We know there are critics of these decisions, both in the U.S. and in Canada. As we said, there are risks with every product, and those do occur. So we are mindful and very obligated to continue to monitor those very carefully, and should a change be required in the kinds of approval conditions we've given, then we will certainly act.

So we review this continuously. There are always different points of view on many of these kinds of issues, and given this one, I think that's to be expected. We will continue to track it very carefully, as we know the FDA is as well. We're certainly in contact with them and with other regulators around the world. So we feel that internationally there's a lot of attention on these products, and we will have access to information from around the world as it becomes available.

Mrs. Susan Kadis: Are there additional surgeries required on a regular basis or generally within the first year after the initial surgery? Is that common or uncommon?

Mr. Neil Yeates: For these devices...?

Mrs. Susan Kadis: Yes, in a short period of time—

Mr. Neil Yeates: Dr. Sharma.

Dr. Supriya Sharma: It really depends on the patient. What we've done for these implants—there are six different implants—is we've published what we call a summary basis of decisions. So in that summary basis of decisions, it actually lists all the common adverse events that you see with the products, and it actually gives you, whether it's for a primary surgery or a subsequent surgery, what the percentage risk is for those occurrences. Again, depending on what the adverse event is, they will be different for different devices.

In general, beyond the fact that no medical device is 100% safe, these are not intended to be lifetime devices. We think the average lifetime of a silicone gel-filled implant is between seven and ten years. So they will require replacement, and that's a surgical process.

In terms of other adverse events, it really depends on what the adverse event is and what the reaction is in the person as to whether or not that would require additional surgery or some other form of medical treatment.

Mrs. Susan Kadis: So you're not aware of this happening on a regular basis. It is not on a common basis that patients would require additional surgery fairly soon following their initial surgery.

Dr. Supriya Sharma: When we're talking about immediate, the side effects that actually happen in the first six months to a year, most of them are actually self-limiting and don't require additional surgeries in terms of the numbers we're seeing.

Mrs. Susan Kadis: Okay. So I'm assuming that fundamentally it is erring on the side of caution.

Thank you, Mr. Chair.

The Chair: Thank you.

Ms. Davidson has another question, so go ahead.

Mrs. Patricia Davidson: Thanks very much, Mr. Chairman.

I have a couple of other quick questions. We've talked quite a bit about the tracking and the surveillance and so on. What happens if new information surfaces showing that there are new problems. What happens then? What is the process that's in place? And what happens if a manufacturer doesn't comply with the licensing?

Mr. Neil Yeates: I can start on that one, Member.

When new information becomes available, we assess its significance in terms of what action we might want to take. We have various levels of action. They stem from providing an information update on a product, perhaps a change in the label in terms of the use, to issuing an advisory of some kind—warnings or removal of the product. We have that entire continuum of actions available to us, depending on the nature of the information. In this case we have the large-scale follow-up study. That's going to be a very important source of information, one way or the other. That's basically how we would assess things from the information that comes to us.

Sorry, once again I forgot the second part of your question.

Mrs. Patricia Davidson: What happens if a manufacturer doesn't comply?

Mr. Neil Yeates: It would depend on how serious that is. We always retain the authority to remove a product licence. That would be the ultimate action we would take. There are many steps before that. At the end of the day, that option is available to us if we're not satisfied that we are getting the kind of compliance we feel is needed.

We should say that in the case of these applications we had very good cooperation from the companies involved.

● (1705)

Dr. Supriya Sharma: I have maybe one additional point.

This was a licence with conditions. Those conditions must be fulfilled within a year of licensure. If those conditions are not fulfilled, then the licence will be suspended for these products.

Mrs. Patricia Davidson: Are the conditions an ongoing thing, or do they meet them once? How does that work?

Dr. Supriya Sharma: The conditions placed on it are from a year perspective. But these conditions actually continue to provide information for a longer period of time, so they're basically renewed on a yearly basis.

Mrs. Patricia Davidson: Thank you.

The Chair: Do you have more questions? Madam Gagnon?

[*Translation*]

Ms. Christiane Gagnon: I am listening to answers given to questions, and it seems to me that you are dealing with this issue in a very reckless manner.

For example, when you talked about the risk, you said that it is a fact that there is always some risk involved in any surgery. It seems to me that you are playing down the risk in this issue of breast implants. Even if there is only one or two persons who die because of this, it still remains that two persons have died because of a punctured breast implant.

How many victims would you need for Health Canada to withdraw some implants from the market? One, two, three or one thousand? A physician said that out of 1,000 persons, 50% had either suffered a punctured implant after 10 years or that some harm had been caused to women. How far will it have to go before Health Canada show some courage and withdraw some licences from the market?

[*English*]

Mr. Neil Yeates: Member, I think that's actually unanswerable. I don't think there is a particular number. We would have to assess the information. We would have to assess the cause and effect. Often it's difficult to establish the cause and effect with adverse event reports. That's just the complexity, I think, of what we're dealing with.

Clearly if we felt there was a clear causal relationship and it was serious, then we would remove the product. That's what we do now.

The Chair: Okay.

Are you finished?

[*Translation*]

Ms. Christiane Gagnon: What I understood is that physicians in the different provinces will have the responsibility, together with their patients, to ascertain to what degree the patients have fully understood what they were getting into. In case of a punctured implant, who is responsible for compensating the patients? For example, if a patient is suing her physician, what is the responsibility of Health Canada who authorized the marketing of an implant that was questionable in terms of its safety for women?

[*English*]

Mr. Neil Yeates: That, I guess, would remain for the courts to determine. As you may know, Health Canada is from time to time involved in lawsuits in and around products, and we may be taken to court on our regulatory action. We're named as a party in various suits.

In the situation you described, it sounded to me like you may have an issue of malpractice by a physician, potentially. But of course these are always controversial.

And there could be issues in and around the role we've played as a regulator, and those cases do occur from time to time. But again, that's really the nature of the business we're in. There are thousands and thousands of products that we review and approve—some 50,000 medical devices or so, 20,000 pharmaceuticals, and 40,000 natural health products. We have a very broad scope of responsibility, and these risks are out there. But we take our role in taking responsibility for the review process extremely seriously. In this case, yes, we are satisfied that the conditions for quality, effectiveness, and safety have been met. That may change in the future if new information becomes available, as it might for any product that we oversee and regulate.

● (1710)

The Chair: Okay, thank you very much.

Just on that, for the information of the committee, when an individual or client decides to use the silicone gel-filled breast implant, does she have to actually sign off that she knows it's only adequate for seven to ten years and that the risks are there?

For every procedure we do, we know that there are some risks. I think we all understand that. My concern, particularly, is whether the patient understands the risk and is totally aware of it. How are we addressing that?

Mr. Neil Yeates: Well, our part of that has been to ensure that in the material that's provided with the product, there are decision aids and so on so that the patient and the physician have the material available that clearly outlines the risks and benefits. What the physician and the patient actually do is up to them. That's not something we regulate. That is the practice of medicine.

If somebody is having surgery, I think that basically, yes, they are required to sign a consent for surgery, but that is not something we oversee in Health Canada. That would be up to the hospital, the surgeon, and so on.

The Chair: But with the controversy around this one, and the potential for liability—I know we talked about it, and they're all hypothetical—you'd think it would be an easy thing to do as a government. We're there to regulate, to make sure that the individual, whoever is going to accept the risk—and that's what we're asking a person to do—is aware of the risk before having the procedure. It just seems to me that it would be a very easy thing to do. I just wondered why we wouldn't have put that in.

Mr. Neil Yeates: I think, very fundamentally, it's because we feel that this is not the role of the Government of Canada. That really is the practice of medicine, and that's up to the colleges of medicine and the physicians and so on.

As I say, we approve tens of thousands of products, and to me, it's a slippery slope in terms of seeking consent for that array of products. There are many products with risks attached to them, many pharmaceuticals, for example. So it's not something I think we could do for a single device, Chair.

The Chair: Yes, we're seeing the same problem with pharmaceuticals and so on. That's fine. It's not for us to debate it. I just asked the question as to why we wouldn't have considered it. I'm not sure I'm satisfied with the answer, but I have your answer.

Seeing no other questions, I want to thank you very much for coming in and presenting again to us. We appreciate the opportunity to have input on this issue. It's very important for many people in Canada, so thank you very much.

And thank you to the committee for their good questions.

With that, I will call the meeting adjourned.

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