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Chair

Ms. Bonnie Brown

Standing Committee on Health

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● (0910)

[*English*]

The Chair (Ms. Bonnie Brown (Oakville, Lib.)): Good morning, ladies and gentlemen.

It's my pleasure to welcome you to the 51st meeting of the Standing Committee on Health, pursuant to Standing Order 108(2), a study on silicone gel-filled breast implants.

We have before us today, at your request, witnesses from the Department of Health, which is conducting the study: Ms. Gorman, Ms. Gardner-Barclay, and Dr. Mithani.

Is that correct?

Dr. Siddika Mithani (Formerly Associate Director General, Therapeutic Products Directorate, Health Products and Food Branch and Director General Veterinary Drugs Directorate, Health Products and Food Branch), Department of Health): Yes.

The Chair: Thank you.

Ms. Gorman, would you like to begin?

Ms. Diane Gorman (Assistant Deputy Minister, Health Products and Food Branch, Department of Health): Thank you, Madam Chair and members of the committee.

I would like to introduce my colleagues, who the chair has just introduced.

Dr. Siddika Mithani until recently was the associate director general of the therapeutic products directorate, and Susan Gardner-Barclay is the director general of the office of consumer and public involvement.

[*Translation*]

I would like to thank the committee for having given us the opportunity today to explain how we ensure that decisions concerning the health and safety of Canadians are made in a transparent and unbiased fashion.

[*English*]

It is a process in which we at Health Canada, and more important, Canadians, have confidence. For example, almost 80% of Canadians consistently express confidence in Health Canada's ability to ensure the safety of the drug products they use.

One key area in which we are earning that confidence is through our efforts, led by a strong commitment from the Minister of Health, to open the regulatory process to external input from both experts and the public. The public input process that some of you witnessed first-hand at our recent forum on breast implants is groundbreaking internationally, and we are very proud of the significant advances we are making.

I would like to speak to you today in particular about how we use expert advice in our decision-making, how we select the experts from whom we seek that advice, and what we do to safeguard the integrity of the decision-making process.

[*Translation*]

In 2000, Health Canada adopted what is known as our decision-making framework. The principles which underpin this framework promote the importance of teamwork and of evaluating the best scientific advice available from a range of sources, as well as asserting the importance of openness and transparency in the decision-making process.

[*English*]

It is within this framework that we ask for external input in instances where the quality of our review requires additional expertise or experience. This expertise may include real-world knowledge of how a product is being used and its effect on patients, knowledge of new technologies that impact on the risks and benefits of the product, or perspectives on the acceptable level of risk from a consumer's or patient's perspective that could, as but one example, then be reflected in labelling information.

Panels are asked to respond to very specific questions posed to them by the branch. They review relevant information and deliberate on those questions. The result of a panel's deliberations takes the form of advice to the branch, which forms only one part of what Health Canada must consider when determining whether to license a product and what the conditions of that licence will be, if it is granted.

[*Translation*]

Panels are not tasked with deciding, or even making recommendations as to whether a product ought to be approved for market release in Canada. The ultimate decision is made by Health Canada alone after having weighed up all of the risks and benefits.

[*English*]

Selection of expert panel members is guided by three principles. Prospective members must have high-calibre expertise or experience related to the issue being discussed, have the demonstrated ability to participate in the discussion with an open mind and objectively review the information provided to the panel by Health Canada, and be free of any affiliation that would lead to the belief that they could not review the evidence before them objectively.

[*Translation*]

All of our panels are set up to provide a balanced approach and comprise people from varying backgrounds and of diverse opinions as, to our mind, diversity is essential in ensuring thorough debate, and, at the end of the day, stellar advice for the department.

● (0915)

[*English*]

The branch identifies experienced individuals by drawing on years of knowledge of the people in the field and through professional organizations and individuals who have knowledge of their communities. The branch recruits experts for individual panels and maintains a database, so the branch is always aware of experts in a broad range of fields and can access expertise in a timely fashion.

The department closely scrutinizes any affiliation prior to appointment to determine if they might lead to the candidate being in a real or perceived conflict of interest. Health Canada defines conflict of interest to mean a situation in which a person uses their position to further their private interests, whether financial or otherwise. Health Canada's conflict of interest policy and procedures seek to ensure that conflict of interest and bias are avoided and that there are mechanisms in place to deal with such situations should they arise.

All candidates for our expert panels are required to complete a security clearance and to declare any financial associations with the manufacturers of the products being discussed. They are also required to declare any public statements, including publications they have made. I'd like to provide a context that is important in this instance.

In order to have all the evidence to make good decisions, the branch often needs clinical or real-world experience. This type of knowledge is essential in bridging the gap between what we know from the information supplied to us in a product application and what we need to know about what happens when a product is used by real people—physicians, patients, and consumers in the real world.

[*Translation*]

This means that some candidates may have experience with a certain product and may, therefore, have formed an opinion on it. Candidates with extensive experience will certainly also have a certain affiliation with regulated industries, especially in a country such as Canada where their expertise may well be in demand.

[*English*]

Such affiliations do not necessarily constitute either a perceived or real conflict. Experts who are leaders in their fields, experienced clinicians, or who possess unique combinations of expertise and experience, are often exactly who we are looking for in order to obtain the best evidence. They are often asked to provide that expertise and experience to many organizations, including governments, not-for-government organizations, and manufacturers.

Internationally, all jurisdictions are dealing with this reality and recognize, as we do, that in many instances affiliations do not mean that person's judgment has been or will ever be compromised. Equally important, excluding all individuals with affiliations would likely result in a panel so removed from the issue that its usefulness to our decision-making would be limited at best, and at worst could result in risk to Canadians. Health Canada's selection process recognizes that fact.

[*Translation*]

Those candidates with a direct interest in the product in question, such as those who own shares in the company which produces the product, are excluded from the panel.

[*English*]

In all other types of affiliations, the expert with fewer or no associations with the company or product is preferred. However, where associations exist but the expertise that a candidate would bring is essential to the deliberations of the panel, Health Canada takes steps to minimize and manage the declared associations by, for example, declaring them publicly, as was done for the breast implant panel and the COX-2 expert advisory panel that we held last June.

All of the panel members for the breast implant forum were screened through the criteria I have outlined. Some have certainly provided manufacturers with their expert views on the science involved in the manufacturing and use of these medical devices. Many have diverse and informed opinions on their use, based on their experience and expertise in research, in women's health issues, or in working directly with patients and consumers.

[*Translation*]

Another important factor is that no member of the panel declared any affiliation which would result in him or her benefiting directly from any regulatory decision made. Their professional experience illustrated that they would all be able to approach questions put to them with an open mind. They are all recognized experts in their field.

[*English*]

Health Canada stands by this process and this panel. We are confident that collectively these individuals will provide us with informed advice that is grounded in evidence and diverse experience and that will support our decision-making.

The panel's report is expected in early November, and I can assure the committee that it will be made available to you and the public in both official languages.

Through motions, the committee has requested the production of papers and minutes of proceedings of the expert science panel, which met March 22 to 23, 2005. You were informed in a letter dated September 29, 2005, that the expert science panel had not produced minutes of its proceedings, nor had it filed a report or recommendations with Health Canada. This is true.

However, this past Tuesday, in preparing for my appearance before this committee, it came to my attention that a Health Canada official has possession of a copy of the chair's draft working notes pertaining to the March meeting. Health Canada provided secretariat assistance to the scientific advisory panel and in that capacity supported the chair in preparing his draft working notes. A copy of these working notes was retained by a Health Canada official. These working notes were eventually used by the chair to help brief the expert advisory panel, which met September 29 and 30 with regard to the work of the scientific advisory panel. To my knowledge, this is the only use to which these working notes were put.

As I indicated in my letter, the scientific advisory panel did not prepare a report of its deliberations. Rather, as I mentioned in November, Health Canada will receive a single, final report from the chair of the expert advisory panel. The report of the chair will reflect and will be based upon the results of the meeting in March, the September 29 public forum, and the September 30 deliberations of the panel.

I wanted to declare this awareness in a timely fashion, but I can assure you there was never any intention to mislead the committee with regard to the documents that had resulted from that discussion. I will follow up with a letter to the clerk of the committee to clarify my letter of September 29.

Canadian women deserve a complete analysis of all the evidence put before the expert advisory panel, and they will have that analysis when the final report is provided by the panel. Then Health Canada will complete its review. We will not make a decision to license unless we are satisfied with the evidence supporting the safety and efficacy of these products.

I'd like to conclude by addressing the process Health Canada used to ensure that members of the public could provide their views to the panel. The breast implants forum and the COX-2 forum before it represent the most extensive processes that Health Canada has ever undertaken to include such views in pre- and post-market reviews of health products.

● (0920)

[*Translation*]

All members of the public wishing to speak on the matter had the opportunity to do so. Thirty-two members of the public made oral presentations to the advisory panel on breast implants, and all were informed that they could submit additional written documentation, if they so desired.

[*English*]

Over and above the presenters, the branch also received approximately 60 online submissions from the public through a dedicated public website. These submissions were delivered to the panel for consideration in their entirety. They are also available to the public and to this committee through the Health Canada website.

This online option for public input is unique internationally among health product regulators. Recognizing the importance of an open process, Health Canada is the only regulator to provide an opportunity for members of the public, regardless of where they live, to submit their views to an expert panel.

[*Translation*]

The Minister of Health has requested your involvement on two important matters concerning openness and transparency.

[*English*]

In addition to the questions the minister has referred to this committee, you may also wish to consider including the issue of advisory panel selection and affiliation disclosure processes in the scope of your study. This has been a difficult issue for Health Canada. This could include, for example, adding a forum for independent, external review of potential panel members as a way of sustaining public confidence in the integrity of the regulatory process and decisions. We would welcome your advice on such issues.

Again, I thank the committee for the opportunity to address you today. My colleagues and I will be happy to answer any questions or respond to any comments you might have on this important issue.

The Chair: Thank you, Ms. Gorman.

We'll proceed now to questions and answers. I believe we'll begin with Mr. Merrifield.

Mr. Rob Merrifield (Yellowhead, CPC): I'll split my time with Mr. Lunney, so perhaps you can let me know when five minutes are up.

The Chair: Thank you. Yes.

Mr. Rob Merrifield: Actually, my position on this issue isn't so much on whether silicone breast implants should or shouldn't be used. I'm not a professional; I don't claim to be. I don't want to make that decision; I don't have the expertise to make that decision.

When the information came forward with regard to the panel and process...that I think does alarm all parliamentarians. That is our role, to make sure the process is as upfront as possible.

So, Ms. Gorman, your suggestion was that there was no perceived conflict of interest on the panel selection. This is an issue that we wrestled with, actually, on another piece of legislation—I believe it was reproductive technology. Do we set up a panel of experts, or do we set up a panel of wise individuals with the expert advise given to them? It was a decision of this committee that we would like to have wise individuals with expertise given to them, rather than have those experts manhandle a committee in that process.

Now, here's a perfect example of where you brought in experts and placed them on committees. Actually, I believe it puts them in a compromised position because they actually declared a conflict of interest in these issues when they sat on the committee.

This question isn't an attack on these individuals, but it is on the process. I'm wondering if you can explain to me, to this committee, why the minister, or you, or whichever department it was that appointed these people would decide to use this process in presenting their panel for this important decision.

● (0925)

Ms. Diane Gorman: Thank you for your question.

You mentioned “perceived conflict of interest” at the beginning of your question. Clearly, there is a perceived conflict of interest or we would not be having this discussion.

Mr. Rob Merrifield: That's right out of your criterion.

Ms. Diane Gorman: What we are looking for is a balance of individuals who can bring expertise to the issue and form independent and impartial advice to the department.

Secondly, we're looking for a mix of expertise among the panel members. So on that particular panel, as you know, you had people with different scientific professional credentials. You had people who had worked with consumers and patients. So it's the composite of all of this that we are looking for.

I think what is most important to remember, though, is this. Unlike the situation in the United States, where the panel members actually vote and give a recommendation to the USFDA as to whether or not the product should be marketed, that doesn't happen in Canada. The panel will provide advice to the department, and that's only one of the pieces of information the department will use in coming to its decision. The accountability is the Minister of Health's alone. It has been delegated to officials within the department, so we will make that decision.

If at any point we felt those individuals or any individual on the panel compromised the decision-making process, we would ensure that we were mitigating any risks that resulted from that. However, as I said, we have such confidence in the process and in the expertise in the discussions that were held that we believe, at the end of the day, we will have a far better report to the department than we would have had we not had that level of expertise and that healthy level of debate.

Mr. Rob Merrifield: But that level of expertise can be given to that committee. It doesn't have to sit on the committee to be valid and to be recognized. In fact, it taints it when it's on the committee, making the actual vote on the recommendation.

I agree with you 100% that this is a decision that is left in the minister's hands. That's why my recommendation to this committee was to have the minister here, because he's ultimately responsible for this decision. It's the advice coming from this panel that is perceived to be tainted at this present time, and it's because of the selection of these individuals with the perceived conflict of interest.

I'll say it again. I don't attack these individuals. In fact, I think they were in a compromised position when they were placed on this panel. It becomes a situation where the public, whom we're here to represent, felt like they had an inferior opportunity to be able to impact the decision-making in this process of being listened to by a panel. Obviously, when it gets behind closed doors, these experts have a more significant amount of impact on the decision-making than the public would in the process.

I think there's something here that we can learn. I'll leave it to my colleague for further questions.

The Chair: Thank you, Mr. Merrifield.

Mr. Lunney.

Mr. James Lunney (Nanaimo—Alberni, CPC): I appreciate you being here for this important discussion.

I'll express, first of all, that when officials are appearing here they often have a prepared text that we can review while you're making your presentation. Some of the remarks you've made I would have liked to have been able to refer to directly. We'll have to wait for Hansard in order to be able to do that.

I was quite surprised, when you listed the criteria for selecting your panel, that you wanted people with clinical or real-world experience. You said, I think it was the third point...let me see, how did that go...?

Ms. Diane Gorman: Would you like me to read it to you?

Mr. James Lunney: Would you read the criteria again?

● (0930)

Ms. Diane Gorman: All three of them?

Mr. James Lunney: Only the last one.

Ms. Diane Gorman: Be free of any affiliation that would lead to the belief that they could not review the evidence before them objectively.

Mr. James Lunney: Exactly—be free of any affiliation.

Now, we know that some of the panel members declared a conflict of interest and said they had received money, although there was a spot on the form for them to declare how much money they had received and that was not filled in. You know, the whole purpose of conflict of interest guidelines is to prevent this kind of thing from coming up when decisions that are going to affect the lives of people are at stake. It really alarms me that Health Canada fails to understand this very basic thing on conflict of interest.

When money is involved, a whole range of expertise is available. People who have a direct interest in the product and have actually been paid to do research on it, or to speak on behalf of the manufacturer in lawsuits, or to defend the product, and who have their professional reputations and careers tied up in promoting a particular product have a conflict of interest. It's apparent to anybody.

It says here even an appearance of a conflict. I am surprised that Health Canada wouldn't have more interest in trying to protect the process. That is what we're concerned about here, the process. This is a process, by the way, that is not new to this conflict. Back when this issue was big, in 1994 and 1995, there were important studies that came out on breast implants, and some very, very serious conflicts of interest, which actually weren't disclosed, came out under questioning on this very issue. Principals in major studies had millions of dollars donated to the university they just happened to be affiliated with, where they had already represented they had clear conflicts of interest on this very issue, and it was part of what made this such an inflammatory issue in the first place.

It puzzles me, Madam Gorman, that Health Canada would disregard the concerns that were already a flagrant problem in previous discussions on this issue. Yet here we are again.

Ms. Diane Gorman: May I say, Mr. Lunney, that we share exactly the same concern. It would not be in Health Canada's interest, given that we make the decision and have the accountability, not only for the decision but the health and safety of Canadians...that we would obviously share exactly the same concern and we would want to ensure the integrity of the process.

That having been said, this is a very difficult issue. The term "conflict of interest" I think implies to people that someone truly would have benefited by participating in a process. We assured ourselves that this was not happening. I think in a country the size of Canada—the discussion is not limited to Canada, it's an international discussion—it would be highly unlikely that you would find somebody with that kind of expertise who did not have some affiliation. That does not mean that they were paid by the industry or that they promoted...and some of those statements, to the best of our knowledge, are not founded.

Mr. James Lunney: This is the problem. You're making an assumption here that only the people who have done the primary research are capable of evaluating. I would take exception to that. We have many very well qualified scientists who work in the field who are not comprised and do not have a direct interest or have not received money for working on a particular file.

I think the whole purpose of this is that you can bring the experts representing a company or a product before a panel to do their best to present their product and make their case, but when they're actually sitting in the enclosed group that's going to make that decision, you have compromised the information coming to the minister. Canadians' confidence in the process is therefore undermined.

Ms. Diane Gorman: If we felt at any point that the—

Mr. James Lunney: "If we felt"—that's all subjective, Ms. Gorman. So now it comes down to the idea that we have to be subjective about this. What are conflict of interest guidelines for if it all becomes subjective?

Ms. Diane Gorman: Let me correct myself. If we had evidence that at any point the advice that was being given to us was compromised, then we would make decisions around the quality of that information.

You're speaking of conflict of interest as well in monetary terms. Our definition also talks about conflict of interest in other terms. Somebody who enters into the discussion with a bias and does not have an open mind—that equally is a conflict of interest.

The Chair: Thank you, Mr. Lunney.

We'll go on now to Madam....

There's a point of order over here from Ms. Dhalla.

Ms. Ruby Dhalla (Brampton—Springdale, Lib.): If it's at all possible—unfortunately, it won't work for Mr. Lunney at this time—can we get a copy of your text? I believe it's not translated, but if we could have the clerk photocopy it and give it out to us for the remainder of our questions, it would be helpful.

● (0935)

The Chair: Is it just in English, Ms. Gorman? Is that why we don't have it?

Ms. Diane Gorman: It is. That's right.

The Chair: Can I have the unanimous consent of the committee to have it photocopied and distributed so that people who wish to refer back to it in their questioning could do so? Is there any objection?

Ms. Nicole Demers (Laval, BQ): Are we talking about the text on the conflict of interest process for Health Canada?

Ms. Ruby Dhalla: We're talking about Ms. Gorman's text.

The Chair: No, we're talking about Ms. Gorman's remarks.

I have another thing to add to this. I've got a sheet of statistics here, provided by Madam Demers, but once again only in English. I'm wondering if I have your permission to have this photocopied so that you can look at it as well.

Is that agreeable to you, Mr. Thibault?

Hon. Robert Thibault (West Nova, Lib.): I will not give unanimous consent on production of documents that are not bilingual.

[*Translation*]

We have an Official Languages Act in Canada.

Ms. Nicole Demers: Bravo! Robert.

Hon. Robert Thibault: The House of Commons has to respect the Official Languages Act. I am of the opinion that both English and French-speakers are entitled to receive the documentation at the same time.

[*English*]

The Chair: I should reassure you, Mr. Thibault, that this is a chart with numbers on it.

Hon. Robert Thibault: We were talking about the—

The Chair: From Health Canada. It's a Health Canada chart.

Hon. Robert Thibault: But the first time you asked for unanimous consent it was on the speaking notes.

The Chair: The speaking notes was first and I got unanimous consent.

Hon. Robert Thibault: No, I don't give unanimous consent. You don't have unanimous consent.

Ms. Ruby Dhalla: Could we put it to a vote then, please?

Hon. Robert Thibault: Unanimous consent is unanimous.

The Chair: We need unanimous consent.

A very interesting development.

Thank you very much.

Madam Demers is the next questioner. Go ahead, Madam Demers.

[*Translation*]

Ms. Nicole Demers: Thank you, Madam Chairperson.

I do not doubt that you are acting in good faith, Ms. Gorman. As a woman, I would imagine that women's health issues are near and dear to your heart. However, I would like you to explain to me how it came about that the expert panel was appointed before the beginning of March, given that the first meeting took place on the 22nd and 23rd of March, yet the affidavits stating conflicts of interest were not signed and posted on the Health Canada website until September. The exact dates were the 20th of September for Dr. Brown, the 21st of September for Dr. Brandon, 23 September for Dr. Wells and 26 September for Dr. Brook.

How can you explain such a situation?

[*English*]

Mrs. Susan Gardner-Barclay (Director General, Office of Consumer and Public Involvement, Health Products and Food Branch, Department of Health): If I understand your question completely, you're stating that the conflict of interest declarations appeared over a period of time?

[*Translation*]

Ms. Nicole Demers: No, my point is that the declarations completed by the doctors whom we suspect of having a conflict of interest were not signed and posted on the Health Canada webpage until the end of September, a mere week before the public forum was held.

[*English*]

Mrs. Susan Gardner-Barclay: Yes, each of the panel members is asked to complete a declaration form in advance of their appointment, but there is a process by which those forms are scrutinized. In many cases the department in fact goes back to those members to ask for additional information.

I would not be able to speak directly to those three cases, but it's a frequent practice that we do go back and ask for clarification. The information on the conflict of interest declarations is in fact in some cases private information, so we are then obliged to return the forms to the panel members to gain their consent for posting the information.

Without speaking to my staff, I would suspect that this is why the information appeared at somewhat variable times, because there is a somewhat unpredictable process by which that information is collected and then posted.

[*Translation*]

Ms. Nicole Demers: On the matter of the selection process used to appoint experts to a panel, the Health Canada webpage states the following:

> External members of Health Canada are required to comply with conflict of interest requirements, recognizing that confirmation of a situation of conflict of interest can result in limiting the members' role in a particular discussion [...]

If indeed a member of the panel's role is to be limited, how can it be explained that Dr. Wells, who has a glaring conflict of interest, is chairing the expert panel?

● (0940)

[*English*]

Mrs. Susan Gardner-Barclay: The situation you referred to, Madam Demers, is the fact that Dr. Wells provided an affidavit to the Department of Justice Canada and that he is being asked to contribute to some litigation that involves another manufacturer and another type of breast implant. It was our judgment that this did not constitute a conflict of interest, since the manufacturers are different, the medical device is in fact different, so he was included in that panel.

[*Translation*]

Ms. Nicole Demers: Following the selection process, during the term of their mandate, what is your policy as to what activities these experts can undertake, given that they are already in a situation of conflict of interest? For example, are they allowed to do as Dr. Brown, who has a conflict of interest, did, and, during their mandate, sign a journal article encouraging people to use silicone gel breast implants as they are of far superior quality? You state that panel members should in no way benefit from any decision that is made. But, Dr. Brown is a plastic surgeon who uses silicone gel breast implants in his work. I imagine that were Health Canada to decide to reintroduce silicone gel implants, Dr. Brown would benefit.

Would you not agree that your earlier statement is antithetical to what we have just seen?

[*English*]

Mrs. Susan Gardner-Barclay: With regard to Dr. Brown and others on the panel...as a panel member he brought expertise that was particularly helpful to the questions that were before the panel in that he is a very experienced, highly qualified plastic surgeon, who brings the clinical experience that we're in fact looking for in being able to understand and bridge the gap between what we know is in the manufacturer's application with regard to research and the information that we need to have on how the product is actually used in the real world, by real physicians, with real patients, and what the effects of that would be.

Dr. Brown was able to bring that expertise to us. In our view, that expertise was quite essential and outweighed the risks that would be inherent in his actual affiliation with regard to using the implant.

[*Translation*]

Ms. Nicole Demers: While Dr. Brown is working as an objective consultant for Health Canada, he is allowed to continue singing the praises of silicone gel breast implants and offering them to his patients. Is that what you are telling me?

[*English*]

Mrs. Susan Gardner-Barclay: We reviewed the advertisements in journal articles that you're referring to, Madam Demers. There was consensus in the department that those articles in the journals represented his description of his own clinical experience with breast implants, rather than promotion of them.

Diane, is there something you'd add?

Ms. Diane Gorman: Could I add one comment? This goes back to the remarks I made earlier.

On the very difficult choices we have to make—the need to have somebody who has had clinical experience with these kinds of products—one of the things that I observed during the questioning of the panel during the public portion of the forum was really around what kind of information should you have had, do you need to have, should be required, in order for you to make decisions about such products? Certainly a clinician who has dealt with that kind of situation brings an expertise that we would not be able to obtain in any other instance.

That having been said, we, as Ms. Gardner-Barclay has said, did review that article and did not see that he was either promoting the product or endorsing the product.

The Chair: That's it, Madame Demers.

There was an ad by that same individual saying something like, “When these new silicone gel breast implants are approved, you can come to me to have your work done”. It was some phrasing like that. So before the decision was made, one of the panel members was putting in an advertisement in a public source—I can't remember if it was a newspaper or a magazine—that when those new silicone gel breast implants were approved, you could go to him and he would help you out.

● (0945)

Hon. Robert Thibault: I have a point of order, Madame Chair.

That was raised by the chair, or, specifically, by the chair at another meeting. I have a copy of the ad here. There's no such thing in it. There's no wording that, when it is approved.... The chair might like to see this.

The Chair: Maybe it was in an article, because it seems to me that I read those words.

Ms. Nicole Demers: Mr. Thibault, is it translated in French?

Sorry, I have a point of order.

Hon. Robert Thibault: No.

Ms. Nicole Demers: What's good for the goose is good for the gander!

[*Translation*]

Hon. Robert Thibault: You are absolutely right.

[*English*]

The Chair: In any case, it's now Mr. Thibault's time. He may go ahead with the questioning.

[*Translation*]

Hon. Robert Thibault: Thank you.

Firstly, I would like to return to the matter of official languages. It is unfortunate, and indeed deplorable, that a federal government department saw fit to table a unilingual presentation this morning.

Last night, I spent three hours with Canada's official languages communities; they sang the praises of Health Canada for the work that it had done with the communities. It beggars belief that the department was unable to provide its brief in both official languages for a standing committee of the House of Commons. I hope that this will not happen again.

[*English*]

I want to make a few comments and then ask the panel of experts to discuss these, in whatever time we have remaining.

First is the question by Mr. Merrifield, which I think is pertinent but might have been partly answered. Should individuals with the expertise be feeding the decision-making or should they be the filter of the decision-making? Should they be witnesses or should they be panellists?

In this case it is a little bit different because they are not the decision-makers; they are a panel of experts, I understand, with the capacity to ask and understand these questions and filter the information, but not make the recommendation or the decision.

In the document that was circulated this morning in both official languages, in the English version on page 21, specific questions are asked. When I look at these questions they're sort of leading. There's sort of the assumption when I read them, that this will eventually make its way to the market, and what are the conditions? But I understand that doesn't mean the decision has been made or it will go; it's more of a should. I think it's important for everybody to review these decisions. They are very much based on safety and science, and not on personal opinion.

The other point I want to make is on the question that's raised too loosely here about conflict of interest. I've had the responsibility of administering conflict of interest guidelines in law as a municipal official, and conflict only appears when the interest cannot be managed in an unbiased way. If a person has an interest, has had prior affiliations, or has potential future benefits from an outcome or a decision, and no separation can be made between those interests and the unbiased decision-making process, then it is in conflict. But we haven't demonstrated this conflict. We always say these individuals are in conflict—the members say that—but I put no opinion on it. I'm not defending individuals and I'm not attacking them, but I think it's important that we know that distinction.

One of the individuals in particular was talking about somebody who had at one point appeared as an expert for one of the companies in another process. I watched the O.J. Simpson trial, as I'm sure a lot of us did. I became a lawyer watching that. I have no formal training, but now I'm an expert. I saw one scientific individual of great renown appear and give expert opinion on DNA. What's important to know is that he did not make a comment as to the guilt or innocence of the accused. He was presenting expert opinion in the area of his expertise.

Of course, the company would not bring an individual forward if they thought the evidence was different from what they would like to put forward. But if the individual is a person of integrity, then his testimony will be limited to his area of expertise. That does not constitute a conflict. It could constitute a conflict if that person could not sit on the panel and render unbiased work. An individual could join the panel with a personal opinion that these devices should not be licensed, but that would not mean they couldn't sit on the panel. All that is required is that they be unbiased in their approach in answering these questions.

Finally, it is important to note that this is not a decision-making process. Perhaps our officials could explain to us how a decision like this on whether to reintroduce it or not would have been taken five years ago and how this introduction of the panel changes or modifies that process.

● (0950)

Ms. Diane Gorman: Health Canada has a long history of using external advice. Panels have been constituted for specific issues, and they have brought in expertise. We have also had standing types of committees to deal with cardiac issues, for example. So we have a long history of that.

We use expert panels because we cannot retain in-house experts in all areas, especially when technology and science are advancing so quickly. In addition to that, we want to benefit from the experience of practitioners—people who have actually worked with the products and patients, as opposed to referring solely to any literature or regulatory information we might have. So we have a long history of using panels.

To go back to Mr. Merrifield's point, we certainly have the option of asking somebody to be an adviser, as opposed to a member on a panel. However, your point is absolutely correct. Given that these individuals were not voting and there was a wide array of views—including some very conflicting opinions—that would have been brought to that debate, we did not see any advantage in having people as advisers as opposed to members of a panel.

So yes, we have a long history of these processes and managing these processes. As I said earlier, it is only one piece of the information we are using.

On the very technical questions that were put to the panel, you can see that a number of them go to levels of information, such as whether the issue was well-studied, and what kind of labelling information would be needed if these products were to be marketed, and so on.

If I could just go back to one point of clarification on Dr. Brown's article, I think the committee should be well aware of the actual documents that are being referred to from some of these individuals. We can provide them if the committee doesn't have them. Dr. Brown's article talks about North America, and you should know that the product has already been given a conditional licence in the United States. I'm not going to speak for him, clearly, but he was talking about the North American market.

Hon. Robert Thibault: Thank you.

The Chair: Does he practise in the United States? Of what relevance is that information if he doesn't practise in the United States and the product isn't approved in Canada where he practises?

Ms. Diane Gorman: I'd have to check where the article was published. Again, he was being sought for his professional experience and views on the risks and benefits of the products.

The Chair: Thank you.

Mrs. Crowder.

Ms. Jean Crowder (Nanaimo—Cowichan, NDP): I can say exactly where the article was published. It was in *Plastic and Reconstructive Surgery*, volume 116(3), on September 1, 2005, and he does absolutely say “the North American market”; however, he practices in Canada. Any Canadian reading this would be led to believe they were going to be reintroduced in Canada.

Mr. Merrifield is absolutely correct; we are here about process. Your comments around Canadians needing to have confidence in the process and around—I went to the Health Canada website, and it says “real or perceived conflict of interest”.... One of the reasons, I would suggest, Canadians probably don't have confidence in the process goes back to an article that is in the National Research Center for Women and Families. It was written by Zuckerman and Lieberman in March 2005. They're talking about studies that were done. I'm quoting from the article:

> Almost all of these studies were funded by implant manufacturers at a time when they were preparing their defense against escalating legal challenges from women reporting serious health problems.

When the industry is directly involved in supplying expert witnesses, or people are being paid by industry, the confidence of Canadian women is undermined—and of men, because it's not just women who receive these implants. The issue we're talking about here is whether or not the process was such that Canadian women will have faith that the recommendations that are made are such that we can trust them.

This is in an article from *The Hamilton Spectator*, September 26, 2005. A McGill University professor—Abby Lippman, from the McGill Faculty of Medicine—summarizes quite nicely why there are some concerns around this. She says:

> What is the point of collecting information about conflict of interest and then doing absolutely nothing about it? If a judge declares a conflict of interest, the judge doesn't just sign a paper and everyone says OK, that's fine. The judge recuses herself or himself from the case. Why do we have such different standards for something like this?

That is a very good question.

Mr. Thibault talked about future benefit. If somebody could guarantee me that none of these panel members would ever receive any money from any manufacturer again, I might have some degree of comfort, but one of the tests is future benefit. I'm not impugning any of these people's integrity or their credibility; this is about process. If you stand to gain financially at some future point from a decision that could be made—and Dr. Brown is a plastic surgeon who does reconstructive surgery. Why should we have any faith that he will not receive future benefit?

My final point is about the affidavit. The case that's currently before us is one of regulatory negligence, the claim that Health Canada was negligent in upholding a regulatory duty to protect the public in allowing these products on the market. Four panel members were requested to sign affidavits in the government's defence. For Wells and Brown, who are on the panel, I have the copies of their affidavits here. Why should we trust that they're going to be able to make recommendations?

I wonder if you could answer those questions.

● (0955)

Dr. Siddika Mithani: It is important to remember that some of the questions that were posed to the panel were very scientific, and the scientific questions really required the expertise that was there. The panel is not tasked to answer the question as to whether there is a recommendation of approval of these products or not. It's important to remember that there's a lot more work that needs to be done after we receive the advice from these panel members.

The panel members have been charged with specific questions on which they will provide advice. There is a lot more work. What will be required after the report is received by Health Canada is further safety information that will be requested from the company, because we are aware that there's an ongoing study in the U.S.—a clinical trial registry type of study—that may generate data. There may be, based on the report we receive from the expert advisory panel, a need to go back to the manufacturers to ask for additional studies, additional clarifications. A decision has not been made, and if there is any concern that there may be safety concerns about these products—

Ms. Jean Crowder: Excuse me. We've been trying to get a study from 1996. Mr. Thibault assures us that something's being done. There is inconsistent information in the scientific community about whether these implants....

We've been asking for the cohort study. Produce that and let us take a look at that, at least.

Ms. Diane Gorman: Could I just give an answer on the cohort study? That is actually a document that is—

The Chair: Excuse me, but before we go on to that, Mrs. Crowder was asking about conflict of interest and process. Dr. Mithani answered about science, and that distracted us and took us back to the science and the cohort study. I want you to go back to Mrs. Crowder's question about future benefits. Was that evaluated at the time of the appointments, under conflict of interest? This is not for Dr. Mithani, who is a scientist, I believe. This is not her area. I believe it would be one of the other two ladies who had something to do with putting this process together, because this is a discussion about process.

● (1000)

Ms. Diane Gorman: We would certainly have considered future potential benefit or perception of benefit. We will talk about the process. I will not talk about individuals and individual situations. But, yes, we would have considered that. I think when we use the words “conflict of interest”, we obviously have a different definition of conflict of interest. So that, in combination with the fact that there were other members on the panel who held very strong views about these products as well, would have resulted in a balanced panel.

The Chair: Why do you think we have a different definition of conflict of interest? It's usually pretty simple. It has to do with pecuniary advantage. It has to do with money—past, present, and future.

Mr. James Lunney: And reputation.

The Chair: Well, there are other things as well, but the ones the taxpayers are most interested in have to do with pecuniary interest. That's the big one. So how would you differ? It's about money to be made. That's what it's all about.

Mrs. Susan Gardner-Barclay: Perhaps I can add at least some information to the debate on this. There is a widely accepted notion among all international regulators that the private, public, and academic domains are integrated, given the nature of the work and the need for funding for science. So those who work in academic areas may well have affiliations with manufacturers in order to receive the funding they need, for example, to conduct studies, because there is no source of funding for that kind of research anywhere else.

That principle that these domains are, by virtue of their nature, interrelated to some extent is recognized in conflict of interest policies around the world. We ourselves have recognized that reality in the policies we have developed.

If we were in fact to exclude expert scientists from our panels completely, we would be in a situation where our panel members would be, in many respects, not terribly helpful to us, because we would not have access to the kind of expertise that comes from working in that scientific environment, which brings with it certain connections with academic institutions and manufacturers.

It's conceivable that some of our committee members have provided advice to non-government organizations, but that doesn't appear on their conflict sheets, because they would not have been remunerated for that. It doesn't mean they don't have an affiliation with those organizations.

I would also—

The Chair: We are concerned about future benefits. I want to go back to the very good thought put forward by Mrs. Crowder: future benefits.

Mrs. Susan Gardner-Barclay: We do, as a rule, as Madam Gorman noted in her remarks, exclude any panel member who has any financial interest in a manufacturer whose product is being reviewed. If they own any stocks, for example, or have ever worked as an employee of that manufacturer, they are excluded from the panel.

I will point out that this is different from the FDA process, where there are in fact bands of vested interest permitted among their panel members. So we do in fact have a far more rigorous system than the FDA for excluding the kind of interest that would result in future benefit.

The future benefit—

The Chair: That's enough. Thank you.

I beg the forgiveness of my colleagues because I intervened in the middle of Mrs. Crowder's time, and I'd like to give her another couple of minutes, if I may.

Ms. Jean Crowder: Actually, I'm fine, Madam Chair. You very nicely brought the point back that I was trying to make around future benefits.

But I do just want to ask for some clarification on the issue around affidavits. You have panel members who are testifying on Health Canada's behalf in a negligence case. There's clearly another tie, not only to the manufacturer but to the government in this case. Although I would argue that they didn't particularly have a huge benefit on this particular one, they do have a direct tie and some interest in having Health Canada appear in a favourable light in a negligence case. I wonder if you can comment on how that was considered in this process around conflict.

● (1005)

Ms. Diane Gorman: Ms. Gardner-Barclay mentioned in her response to another question that those cases deal with different products, different manufacturers, and the—

Ms. Jean Crowder: Sorry, I know the products are different. This is Dow Corning we're talking about. So I'm well aware that the products are different. However, they are still testifying on a similar product, even though the manufacturer is different. So it's all in the realm of doing something on behalf of Health Canada with breast implants.

Ms. Diane Gorman: But I think it comes to exactly the same issue. There is very little expertise in some of these areas in Canada; therefore—

Ms. Jean Crowder: But does it have to be Canadian? Surely there are scientists somewhere in North America who have this expertise, who could provide that kind of an overview, that kind of rigour that we would expect from the scientific community. I don't know, but surely not every scientist who has this kind of background has been in the employ of INAMED at some point.

Ms. Diane Gorman: The assumption is being made that we will not be able to make a good decision because of this panel.

The Vice-Chair (Mr. Rob Merrifield): Your time is over.

Ms. Dhalla.

Ms. Ruby Dhalla: Thank you very much.

Ms. Gorman, to start, just for my knowledge and that of other committee members, how many times have you appeared before the health committee in the past?

Ms. Diane Gorman: I would have to estimate about ten times, but don't quote me.

Ms. Ruby Dhalla: Numerous times, and I think from my knowledge, and if I recollect correctly, the majority of times you've appeared you've always provided us with your notes, translated. I think that should have been done this time as well, because I, like Mr. Lunney, would agree that many of the items you stated in your opening remarks would have been beneficial for us. So I'm going to go from hearsay slightly, based on what you have said.

In terms of the individuals concerned, I think it has been stated previously as well that none of us want to impugn reputations. They have a tremendous wealth of knowledge in their particular area of expertise, but we are concerned about women in this country who utilize these services and about ensuring they have confidence in the process that has been put in place. Could you explain to me how the process was looked at to get to these individuals?

Ms. Diane Gorman: Are you asking how the panel was selected?

Dr. Siddika Mithani: I can go through that with you.

Generally, when panels are selected they are based on the identification of issues. For any product where issues have been identified, where questions have been posed, and where there is a need for an expert advisory panel, you first identify the issues and the questions. Based on those questions, you then determine the type of expertise you require.

Ms. Ruby Dhalla: How was this panel identified, though? How was this particular panel put into place?

Dr. Siddika Mithani: I will go through the process.

The panel was put into place based on the database of experts we had, how much they published, whether they were renowned scientists in that field—recognizing the fact that the questions being posed to the expert advisory panel are very specific in terms of the expertise that's required. So that was the process by which the panel members were selected, or the areas where the expertise was required were selected.

We then had an internal working group, which consisted of scientists; policy-makers; the office of consumer and public involvement, which had the expertise in openness and transparency issues; legal services; and the women's health bureau, which helped us in the nomination and selection of these particular individuals. So it was an all-encompassing, comprehensive internal working group that looked at these particular individuals who were chosen.

Ms. Ruby Dhalla: Based on the database Health Canada has, how many plastic surgeons would you happen to have in that database?

Dr. Siddika Mithani: I can't tell you right now, but I can get you the information. I don't have it offhand.

Ms. Ruby Dhalla: I would think that in a population of 30 million plus in Canada, we would have thousands and thousands of plastic surgeons. Would you know perhaps why certain individuals are picked, certain plastic surgeons like Mr. Brown, whose talent and expertise you deemed outweighed every other plastic surgeon in this country who practises in this field?

● (1010)

Dr. Siddika Mithani: It is not only about expertise, it's also about availability, timing, the fact that an expert advisory panel had to be struck. Normally when we look at expert advisers, it's not based on only one person. Three or four people are identified and then, based on their availability, expertise, and the questions we need to pose to that expert advisory panel...those are some of the criteria that decide on how these members are picked.

Ms. Diane Gorman: If I follow the line of reasoning in the discussion we have had in this committee this morning, no plastic surgeon could have been asked to sit on that panel, and that would have been a detriment to our advice. These are people who do plastic surgery, whether it's with breast implants or other types of products, and they know the level of information their patients need. They know how they need to advise women in order to help them make these decisions, in this particular instance. So if you follow the reasoning to its limit, there would have been no plastic surgeon on that panel.

Ms. Ruby Dhalla: Ms. Gorman, I'm going to have to beg to differ. I think the advice of a plastic surgeon is beneficial, because they obviously know all the intricacies and the dynamics involved, but having an individual who is not being paid, has not been paid, or will not be paid by a manufacturer is the question.

There are a number of individuals with many, many years of expertise who are retired. I personally know of individuals we can add to your database as necessary, who are retired, who perhaps 20 or 30 years ago were involved with a particular manufacturer, but at the moment, and in the future, they will not practise and will not be taking any money from manufacturers because they are no longer practising.

Ms. Diane Gorman: Therefore, their expertise may not be current.

Ms. Ruby Dhalla: There are many, many plastic surgeons out there whose expertise is perhaps current, and if the search base had been broader in nature, we wouldn't be discussing this.

If I have the time, may I squeeze one question in?

The Vice-Chair (Mr. Rob Merrifield): Your questions are gone. Actually, you're quite a bit over, so we'll leave it for Mr. Fletcher and maybe we can get back to you.

Mr. Steven Fletcher (Charleswood—St. James—Assiniboia, CPC): My concern in hearing this debate leads me to a larger issue about how Health Canada conducts these reviews. Totally unrelated to you, there's a review going on about online pharmacies this week, and I've heard very similar concerns about that process, about various interest groups, with vested interests, maybe taking the process, but also about people not being heard in the way that I think the Canadian public expects it will be heard.

As with this discussion, I find it interesting that, as Ms. Dhalla has pointed out, in other presentations the materials have been in a bilingual format, and for whatever reason, they're not today. If one were cynical, and we have a problem with the process, I think that only adds to the committee's concerns.

Add to that the fact that we asked to have these materials distributed. Everyone at the committee, including three of the four Liberal members and the Bloc, to their credit, had no problem with that material being distributed, but the parliamentary secretary seemed to have a problem. He's there to protect the minister and he's there, rightly or wrongly, to stick up for...is perceived as trying to protect the process that he was involved in setting up, directly or indirectly.

The whole perception of this meeting is not good, nor is the reality. If the minister is going to be given a lot of power in making the decision, but the panel seems to be tainted...how is the minister going to make good decisions if the panel is tainted and the process is flawed?

I think we have a lot of valid concerns here, and I wonder what the remedy is as well. I wonder if you can comment.

● (1015)

Ms. Diane Gorman: Thank you for your question. I'll answer the several pieces of it.

First of all, I do apologize again and again that the committee did not have the documents in both languages. I was making revisions to them late last night and wasn't able to have some of the revisions translated. I will commit to getting it to the clerk of the committee in both official languages before the end of today—and I do apologize again.

With regard to your point about Canadians being heard, that is always a challenge in a democracy. We do feel very strongly that this process was as open a process as it could have been. There was a website; there were over 60 submissions made to that website. People were not limited by their ability to be in Ottawa on September 29. Everybody who said they would be there and wanted to be present was given that opportunity. There were some people who did not show, but everybody who asked was given an opportunity. As well, in addition to the time they were given, the panel had many questions of the public to help the panel clarify some of the points that had been made. I would argue that there was ample opportunity for Canadians to be heard on this.

At the end of the day, what we make our decision on—which was the second part of your question—as delegated by the minister, is the evidence that exists on the safety of these products and the benefits of these products—or any product; this is not limited to the example that's before us. Part of that safety and benefit examination also goes to whether there has been sufficient study, whether there is sufficient clinical data, and if there might be any risk, how we mitigate that risk. I don't know what this panel is going to recommend, but they may well recommend some things that don't currently exist in Canada, like a breast implant registry.

Mr. Steven Fletcher: But how can we have confidence in the panel when there seem to be no minutes of previous meetings that have taken place?

Ms. Diane Gorman: I mentioned during my remarks that I became aware on Tuesday morning, in preparation for this committee, that the chair had prepared some draft working notes he used in order to capture the discussions that had been held in March, and he shared those draft working notes with members of the new panel that was convened on September 29 and 30. I have not—

Mr. Steven Fletcher: Perhaps he censored, consciously or unconsciously, what actually transpired.

Ms. Diane Gorman: I'm not going to impugn the reputation of a very fine expert. I'm not sure why it would be in his interest to do that.

In any event, that information will be used by the panel in drafting their final report to Health Canada, which, as I said, we will receive in November.

To continue to answer your question about how the minster then makes decisions, I can say that is one piece of the information we have and will use in coming to a final decision, and our decision is not limited to whether the product will be licensed or not. It also goes to what kind of information Canadians need. If the products are marketed, what kinds of labels do they need? What kind of education might users of those products need to have?

I think we learned a great deal from the COX-2 hearing. There were some recommendations that would be extremely helpful to the safety of Canadians, and I would expect the same from these recommendations.

The Chair: Thank you, Mr. Fletcher.

Madame Demers.

[*Translation*]

Ms. Nicole Demers: Thank you, Madam Chair.

You mentioned in your statement, Ms. Gorman, that Health Canada wanted to ensure that these breast implants were safe for women before putting them back on the market. You therefore told us that you would make sure that you checked the studies, and not just the comments of the expert panel.

However, over the last 10 years, under the SAP, the Special Access Program to medical devices for serious or dangerous illnesses, Health Canada distributed silicone gel-filled breast implants. There have been 19,801 requests for these, usually for two breast implants. Of this total, some requests were not assessed and had no long-term study done, and these were implants whose safety you cannot guarantee, and which, in most cases, were not necessary: 12,639 of these requests were for breast augmentation, 7,619 for breast replacement and only 3,935 for reconstructive surgery.

Given that Health Canada did not have all the information about the safety of these devices, how can you explain that Health Canada nevertheless allowed plastic surgeons access to them?

You spoke about the conditions imposed by the FDA, Ms. Gorman. The fact is that some of these conditions are frightening. One of them is that women must sign a document waiving the liability of surgeons and the companies which produce the breast implants. If there is no problem with these implants, why is it that women are required to sign these waivers?

Ms. Gorman, I must tell you that as a woman, as a Quebecker and as a Canadian, I am very angry that Health Canada has distributed so many of these implants. However, in 1997-98, when the class actions started to produce some answers, Health Canada distributed no silicone gel-filled breast implants. You are not crazy! I am very angry, Ms. Gorman.

I would like some answers, please.

● (1020)

Ms. Diane Gorman: Thank you for your question. I agree that this is a very important matter.

[*English*]

Parliament, through the Food and Drugs Act and the food and drugs regulations, and in this instance the medical devices regulations, has determined how products can be available in the marketplace.

The medical devices special access program provides professionals with an opportunity to provide to their patients the products that are not otherwise available in the market. Under the medical devices regulations—we can provide the committee with a copy of those regulations, if that is helpful—the professional provides information to the department that this product should be accessed by their patient. Under the medical devices regulations, the wording is that the minister “shall” provide the product, so there is not a question of discretion on the part of the minister. If the professional has made that recommendation to the department, the department shall provide.

I think what is really important about your question—and this is why I am looking forward to our final advice and conclusion with regard to these products—is that those products are provided without perhaps all of the information available to both the professional and the woman, information that we may have the benefit of having as a result of the advice of this panel.

So I think the advice of this panel is important and is timely, given, as you said, that a number of professionals are seeking those products for their patients. We will have an additional level of information that we do not now have.

[*Translation*]

Ms. Nicole Demers: Do I still have some time, Madam Chair?

[*English*]

The Chair: One short question, with a short answer.

[*Translation*]

Ms. Nicole Demers: I have all the information here about the Special Access Program, Ms. Gorman. In order to apply, the woman's condition must require surgery of this type. I don't think there is a single condition in the world that requires breast augmentation, Ms. Gorman. If we are talking about breast reconstruction or replacement, that is different, but I do not think there is any condition whatsoever that requires breast augmentation. We are talking about elective surgery. I do not think we are talking about a serious, fatal or dangerous illness here, Ms. Gorman.

● (1025)

[*English*]

Ms. Diane Gorman: Again, as I said, that is a judgment to be made between the patient and their practitioner, and the recommendation would come to us. We ensure that the medical device regulations are respected. That's our responsibility, and I can assure you that we do that. We're not in a position to make a judgment or to replace the physician's judgment. That is a recommendation he makes, and the regulations read that the minister “shall” provide.

The Chair: Thank you, Madame Demers.

Mrs. Chamberlain.

Hon. Brenda Chamberlain (Guelph, Lib.): Madam Gorman, I have a really simple question. In your opinion, can the chair of that committee make money from this product? Will he?

Dr. Siddika Mithani: We would have to check that out, but I would suspect not, because he's an epidemiologist and not a plastic surgeon. That would be my guess, that he wouldn't be able to make money off these products.

But I'd really like to go back and talk a little bit about the fact that these guys are answering questions specifically on science in the Canadian context, how the particular product would be used in Canada and what kinds of risk management strategies are absolutely essential for these types of products. I think we need to focus a little bit on the science and what's required of this expert advisory panel.

Hon. Brenda Chamberlain: I appreciate the science you're speaking of very much, but the problem here.... You don't have an answer to it, and I want an answer to that question because I think it's a key question. There isn't that pecuniary interest anywhere in public life; that is the basis for conflict of interest. There are other pillars, but that is the basis. If we can't answer that and if Health Canada can't answer it, then that's quite serious. You're telling me you don't know the answer to that.

Mrs. Susan Gardner-Barclay: With Dr. Wells in particular, as you know, there was public information posted with regard to his affiliations prior to the panel meeting. His responses to all of those questions were quite unequivocal: he does not have any financial or other affiliations with the products in question.

Hon. Brenda Chamberlain: So he cannot make money from this product?

Mrs. Susan Gardner-Barclay: I'm repeating the answers he gave, and they were very clearly structured for us to be able to determine whether there was any kind of financial interest in the future or presently. He answered no to all of those questions.

Hon. Brenda Chamberlain: Can anybody else on the panel make money from this product?

Mrs. Susan Gardner-Barclay: That's a simple question about a difficult area in some respects. Some of the members were plastic surgeons, and they will continue to use those devices in their practice if they are approved, and if not, perhaps through the SAP program. I don't know what the outcome of that process will be, given that we have to make a regulatory decision. There were many on the panel who did not have any financial interest in those products either directly or indirectly.

I would go back to the points we made earlier around the balance we were seeking on the panel. There are certainly individuals on the panel who have used those products and have views about them based on their experience. There are also members of the panel who have dealt with patients who have used those products or received those products. What we intended was to have that kind of diversity of experience, so that when the panel deliberated, both of those kinds of experience could come together and we would have a vigorous debate about all of the issues the committee has raised today.

Hon. Brenda Chamberlain: I'm going to interpret what you've said to me: that would be a pretty clear yes, that some people do benefit financially from this product. Do I hear you right on that? That's what I thought you said to me.

Mrs. Susan Gardner-Barclay: Some of the members on the panel use the product in their practice.

Hon. Brenda Chamberlain: So they benefit financially.

● (1030)

Mrs. Susan Gardner-Barclay: I'm not aware of the connection between using one and—

Hon. Brenda Chamberlain: You see, here's something that really hit me when Madam Gorman was speaking a few minutes ago. The case was made that the reason we have these people is that a lot of people weren't available. “Availability” and “timing” were the words you used. These people happened to be available and the timing was correct for them. It bothers me no end that if somebody had a financial interest in something, they could perhaps make themselves available within the timing. That's tremendously troubling to me.

Ms. Diane Gorman: Actually, it wasn't me who said that; I think it was Dr. Mithani. But in any event—

Hon. Brenda Chamberlain: You did say that just a few minutes ago.

Ms. Diane Gorman: I'm finding it a bit difficult to talk about the process without talking about an individual, so let me try to talk about the process, okay?

The fact that somebody might have a practice that could include breast implants does not necessarily mean their livelihood depends on breast implants. They may have a much broader practice, first of all. And even if an element of that practice were breast implants, that would not mean that the individual would be so unethical as to give us biased advice so that they could use that product in their practice.

Think as well of the consequences for that individual were something to go wrong with that product: they are liable. So in some ways they have a very direct interest in giving us good advice so that they mitigate the risk from products that would be available in the marketplace.

Hon. Brenda Chamberlain: I see you're taking this very personally. However, the problem is you have a panel that is to do rules on this, and if they are making a financial gain or if they have a direct interest in this product being okayed, approved...plus what you said about the fact that there just wasn't anybody else, that the availability and timing suited these people, that just puts up a huge red flag for me.

How come there isn't anybody else out there who can help us, but these people who are directly involved in this all of a sudden have the time and the availability? I'm not suggesting other than...it just seems passing strange to me that we would not want to have an unbiased group of people who would have an interest in this to make these recommendations.

I just put that on the table. It doesn't add up.

Ms. Diane Gorman: I agree with everything you've said, and we believe we accomplished that.

Hon. Brenda Chamberlain: And you what? Pardon me?

Ms. Diane Gorman: We believe we have accomplished that. I agree with everything you said.

Hon. Brenda Chamberlain: Even though these people have a financial interest in it and have declared a conflict of interest? That's a question. You believe you accomplished it, even though those are the two things that actually are a conflict of interest?

The Chair: Ms. Crowder.

Ms. Jean Crowder: Thank you, Madam Chair.

I know you've already addressed the issue around not having the briefing notes, so I may be misquoting you here. My understanding is that you said the women's health bureau was involved in helping to choose the panel. Is Madeline Boscoe with the women's health bureau?

Ms. Diane Gorman: The women's health bureau is an organization within Health Canada that ensures we're looking at women's issues, and it also provides funding, as I understand it, to organizations outside of Health Canada.

Ms. Jean Crowder: Okay, so it's not an external body; it's a government organization.

Again I may be misquoting you, but I wrote this down. You said Canadian women deserve a complete analysis, and I think we certainly would agree with that. So in that context, we talked about answering questions on the science, and as you know, there's a great deal of conflict with the science out there. The Institute of Medicine—and I'm coming back to the report I mentioned earlier—completed a report in 1999 on the safety of silicone breast implants. The report did not involve any new research but was a review of the literature that existed at the time.

The IOM report concluded that breast implants frequently result in local complications, some of them serious or debilitating. Little attention is focused on these findings.

Then they talked about the actual research, and they found a couple of key areas. They said the shortcomings included that the studies had too few women with breast implants; the women in the studies did not have implants long enough to develop most of the diseases—they did not include any women who had breast implants for more than 2.5 years; the control group or comparison sample was inappropriate; the studies did not include medical exams—and this was a particular cohort study.

But I think my point is that we're talking about Canadian women deserving a complete analysis. We're talking about some conflicting scientific information, and then we're talking about a scientific panel that met in March that isn't producing any report. So it feels a little uncomfortable about there being the kind of transparency that we would expect.

Were any of you at that scientific panel in March?

● (1035)

Dr. Siddika Mithani: No.

Ms. Jean Crowder: Not one of the three of you were at that scientific panel on March 22 to 23?

Dr. Siddika Mithani: No.

Ms. Jean Crowder: So none of you can comment on what happened at that panel?

Dr. Siddika Mithani: I can certainly make a few comments regarding that. The comment I have is that following the March meeting—the March special advisory panel—it was decided that we really needed to broaden the scope of information. That's why the second panel would include other members. For example, in the first panel we did not have a surgical oncologist. We would include that. We did not have patient consumer groups represented. They would be included.

Therefore, a decision was made that the report that will be submitted to Health Canada in early November, which Diane talked about, will include some of the recommendations from the March as well as the September meetings.

Ms. Jean Crowder: My question, though, is this. Is it common practice to hold two days' worth of scientific panel hearings and not have a written report?

Dr. Siddika Mithani: Again, we need to understand the fact that it was the same issue. We were really looking at broadening the scope of information.

Ms. Jean Crowder: That's not my question. Is it common practice to hold two days of hearings or two days of scientific consideration and not have a report?

Ms. Diane Gorman: Let me answer. This was unusual in the sense that those two days were not the conclusion of the panel's discussion. So in effect, the panel suspended its activity until September 29 and 30, and there will be a full report coming out based on the four days.

Ms. Jean Crowder: Again, is it common practice to hold those kinds of meetings with no minutes?

Ms. Diane Gorman: Yes, that is common practice, so there is not attribution—

Ms. Jean Crowder: It does leave some questions about transparency. How do we get access to that kind of information?

Ms. Diane Gorman: I mentioned to you in my remarks, which you should have had in writing, that I became aware on Tuesday that—

Ms. Jean Crowder: About the chair's written notes.

Ms. Diane Gorman: —the chair did have written notes.

Ms. Jean Crowder: So can we get copies of those notes?

Ms. Diane Gorman: Because that just came to my attention on Tuesday, and because I have not personally seen them, I have asked the Department of Justice to look at whether or not they could be provided. They undoubtedly contain proprietary information, which would need to be severed. In any event, the information that was gained as a result of those two days would have been incorporated into the discussions on the 29th and 30th and will form part of the final report.

Ms. Jean Crowder: Thank you.

The Chair: Thank you. Your time is up.

Our next speaker is Mr. Maloney. Welcome, Mr. Maloney.

Mr. John Maloney (Welland, Lib.): Thank you, Madam Chair.

How many people serve on this panel we're discussing this morning?

Dr. Siddika Mithani: For the September panel there were 12 plus the chair—13.

Mr. John Maloney: Four of whom have declared conflicts of interest, subsequently.

Ms. Diane Gorman: Four of whom completed a conflict of interest form.

Mr. John Maloney: Why didn't the others?

Dr. Siddika Mithani: They all completed them. Four of them declared affiliations.

Mr. John Maloney: So it was roughly a third. Does someone review the nature of these conflicts of interest, review whether the individuals should be excused?

Dr. Siddika Mithani: One of the functions of the internal working group I mentioned earlier was to really look at that and come to some decisions as to whether these panel members would still effectively be able to function in that particular group—recognizing that a lot of the questions were very technical—with the types of expertise, like materials science, like fatigue study, that was required in order to answer some of those scientific questions.

● (1040)

Mr. John Maloney: Who makes up the internal working group?

Dr. Siddika Mithani: As I mentioned, there were some science people from the department. So there was the medical devices bureau, there was legal services, there was the office of public involvement and consultations, and the bureau of women's health and gender analysis. So there were a fair number of people that deliberated on the nominations.

Mr. John Maloney: How many is a fair number—ballpark?

Dr. Siddika Mithani: I would say about 12.

Mr. John Maloney: So 12 individuals reviewed the declared conflicts of interest and found that, in their opinion, they could still continue on this panel.

That panel is not the only source of information upon which the decision is made. What are the other sources of information?

Dr. Siddika Mithani: That's a really good question. I'm glad you bring it up, because it's very important for people to understand.

The scientific questions and the answers to those will help us in formulating some of the risk management strategies. There are a couple of options based on the advice we obtain from the expert advisory panel. There may be an opportunity, based on that advice, to go back to the companies for additional safety data, for additional clarification, or for additional studies.

When we look at all that up-to-date information on safety and identify safety concerns as a result, clearly a decision can be made to refuse the applications. That will then have an implication on the special access program, because if you have safety concerns with a particular medical device, you are not able to authorize this type of device through the special access program.

If, for example, there is reason to believe additional studies are required and the best way to manage some of those risks would be to look at a breast implant registry, we need to ask that other fundamental question of whether these registries are implementable. What would it require? Is this something that can be done within the context of where we're working, and if that's possible, what kind of data do we want to collect? What kind of active surveillance do we want in order to ensure we are protecting Canadians when they're using these products?

A third question to ask is what kind of additional information consumers require, and what kind of additional information health professionals require, to make informed decisions about these implants.

Ms. Diane Gorman: In addition to having the panel, we would also have reviewed the submissions from the industry and all the data provided, the scientific literature that exists internationally. We'd talk to other regulators internationally and we would ensure we had information that is state of the art at this point in time in the world.

Mrs. Susan Gardner-Barclay: I will add two points to that. With regard to the breast implant applications, public submissions will also be part of what Health Canada reviews. We know from our experience in COX-2 that public input into regulatory decision-making can make a difference in the ultimate recommendations from a panel and in the decision Health Canada makes, so there's that aspect.

I would also point out that all the evidence the panel provides to us, as well as evidence coming from outside the panel process, is reviewed inside the department by a very experienced team of experts who belong to Health Canada and who bring to that process all kinds of background in toxicology and epidemiology, so there is independent filtering of all of that information done within the department as well.

Mr. John Maloney: You had 32 members of the public who made oral presentations and you had 60 who had online submissions. Are these screened for conflicts of interest as well?

Ms. Diane Gorman: Yes. There is a voluntary—

Mr. John Maloney: For bias?

Ms. Diane Gorman: There is a voluntary declaration.

Mr. John Maloney: Ultimately, who makes the decision?

Ms. Diane Gorman: The authority rests with the minister through the act; the minister has delegated that authority to the department, but ultimately the accountability is the minister's.

Mr. John Maloney: Okay. I appreciate the ultimate accountability, but within the department, who makes that decision?

Ms. Diane Gorman: It's the director general of the therapeutic products directorate.

Mr. John Maloney: Is there a panel of Health Canada that hears all these—

Ms. Diane Gorman: Based on the reviewer...the staff of Health Canada, people we call reviewers.... Based on a report, recommendations come from the reviewers, who are the team of people Susan began describing.

Mr. John Maloney: Okay.

Thank you, Madam Chair.

The Chair: Mr. Merrifield is next.

Mr. Rob Merrifield: It's an interesting morning as we unfold what is actually going on.

I'm really interested in the information. It was the line of questioning to the last two individuals the committee had, which was about what you base your decision on. I had asked, through this committee, for the cohort study. That was three years ago. We still haven't seen it.

That's taxpayers' money. The people who pay for the study should have the ability to see the study. It was supposed to be released in 2000, and we still don't have it.

So you don't have that information?

● (1045)

Ms. Diane Gorman: Can I just clarify on that point? I'm sorry. Either Ms. Crowder or Madame Demers asked a similar question, and I didn't have an opportunity to respond to it.

The Public Health Agency of Canada is the owner of that study. It's not Health Canada, and therefore they would need to answer the question on the status and when they might release it. Just to correct, we—

Mr. Rob Merrifield: We've asked for that information, and supposedly it's public information.

Ms. Diane Gorman: There is somebody here from the Public Health Agency who could answer that question.

I want to clarify the second point, which is yes, we do have the study at the health products and food branch. As I said, it's important in our review of all the literature that we know what was studied and what the—

Mr. Rob Merrifield: So you have the study, but you haven't given it to the committee.

Ms. Diane Gorman: We do not own the study. It's the property of the Public Health Agency. There is somebody here to answer that question, if you would like.

Mr. Rob Merrifield: It's disturbing on its own that you actually have the study. We have asked for the study, which was paid for by public funds.

Ms. Diane Gorman: We have it for the purpose of ensuring in our review that we have the most current and fulsome scientific information.

Mr. Rob Merrifield: You're saying the health committee has asked for that study, you have it in your hands, and you cannot or will not give it to us.

Ms. Diane Gorman: I cannot give it to you. The question will have to be asked to the Public Health Agency.

Mr. Rob Merrifield: So who makes the authority? Who makes the decision on...?

The Chair: How can the Public Health Agency own it when legally there is no such entity? The bill has not passed.

How can they possibly own a document? You owned it. You say you've handed it to them, but legally they don't exist until the bill passes. So essentially, the ownership must still rest with Health Canada.

Ms. Diane Gorman: We received the study when we became aware of it in order that we could benefit from whatever is contained in—

Mr. Rob Merrifield: When you became aware of it? We asked for this three years ago. This study is—

Ms. Diane Gorman: I'm sorry. The Public Health Agency needs to answer that question. I'm sorry, I cannot.

Hon. Robert Thibault: Madam Chair, a point of order. The representatives of the Public Health Agency are here. I would agree that we not take from Mr. Merrifield's time and that we get an answer to that question, because I think it's of interest to all the committee. Then we could return to Mr. Merrifield for the rest of his time.

The Chair: Do you want to call them to the table?

Hon. Robert Thibault: Yes.

The Chair: Is there someone here from the Public Health Agency who could approach the table and answer this question?

Madam, could you introduce yourself, please?

Mrs. Vivian Ellis (Senior Policy Advisor and Acting Manager, Integrated Chronic Disease Policy, Centre for Chronic Disease Prevention and Control, Public Health Agency of Canada): Hello. My name is Vivian Ellis. I'm with the Public Health Agency of Canada and the Centre for Chronic Disease Prevention and Control.

To answer the chair's question, the agency does exist by order in council. The study in question was begun by the Laboratory Centre for Disease Control, which formerly existed in Health Canada. The study is now with the centre that I'm with, the Public Health Agency.

The study was not complete in terms of the data set until June 2003. The epidemiological analysis was done between 2003 and late 2004.

The study's initial article was in peer review within the health portfolio. It has been submitted to a journal. I am happy to be able to report that yesterday morning the Public Health Agency of Canada received notice from the *International Journal of Cancer* that this article has been accepted for publication.

The Public Health Agency is doing its best to get consent, both from the journal and from the contractors in the provinces of Ontario and Quebec, who provided the data for the study and who are its co-authors, such that the key results can be shared with the committee. At this time, we do not have these consents in place. The Public Health Agency has been working assiduously to get consents such that we could share the key findings with the committee. But at this time, legal counsel advises that we are not yet in a position to do so.

I am able to undertake that when we do have those consents in place, senior officials and physicians from the Public Health Agency of Canada will be able to come to the committee and speak to the results.

The Chair: Thank you.

Mr. Steven Fletcher: That's just not acceptable. May I speak, since we're not eating into Mr. Merrifield's time?

● (1050)

The Chair: Go ahead, Mr. Fletcher.

Mr. Steven Fletcher: This committee made a request for a report. Drafts have obviously been undertaken. If there's an issue about confidentiality, we can certainly have an in camera session.

I have to say what I just heard seems not to be in the interest of Canadians and may show a severe disrespect to the committee.

The Chair: Mr. Thibault.

I believe I owe you another minute, two minutes.

Hon. Robert Thibault: Madam Chair, I don't have expertise in the legal matters pertaining to this. What I would recommend, in regard to the suggestion being made by Mr. Fletcher, is that perhaps we organize an in camera discussion of this document or this study. Perhaps we could ask our clerk to ask the legal counsel from the committee to be in discussions with the Public Health Agency and see if there is a possibility of organizing something of that nature.

The Chair: The clerk will do that.

We'll go back to Mr. Merrifield and his questions.

Mr. Rob Merrifield: I only have a couple of minutes.

I really think that what has been displayed to us is the discomfort and actual open admission of a perceived conflict of interest on this panel that taints the outcome of the panel.

Ms. Gorman, when you say it's not the primary interest of the individual who's on the panel, I find that a hollow excuse for conflict of interest. That's not ever been the case of any conflict of interest situation I've witnessed or seen on any board that I've ever sat on. It's always that if you have a pecuniary interest, it is something you must declare, and you must remove yourself from making a decision that puts you in a compromised position.

Nonetheless, the minister has to be in charge of making this decision. He can't just pass it off to the department. He can't pass it off on you. He can't pass it off to a review team. It really falls in the lap of the minister.

I think what the minister is going to make his decision based upon. It's a study that is not public, a core study, supposedly. It's a panel and it's the industry, and it may be some international experience. That's what you came forward saying. The panel is tainted. The corporations have a vested interest, and the international information is not necessarily in the national interest, so I don't believe the minister is going to be making this decision based on his expertise as a lawyer with tainted information that perhaps is coming from a panel that has obviously had a perceived conflict of interest. We have a serious situation. It is a situation where the process has been tainted to the point that the decision-making, no matter what it is, is going to be questioned. That's what this session this morning was all about.

I'm disappointed, because I thought you would give us a lot more comfort in that process. I know you have tried to defend it, but in doing so you have been very clear at reaffirming our suspicions that this panel and the process it is going through to make the decision the minister has to make is flawed.

I don't know if there's a question there, but it is certainly something that we'd better take very seriously as a committee, Madam Chair.

The Chair: We are in the unfortunate circumstance of having another committee coming in here at 11, and I have five names and five minutes.

Mr. Thibault, you have one minute.

Hon. Robert Thibault: Madam Chair, one minute is quite tight.

To sum up, what's important to remember is that we are bandying about the term "conflict of interest" a little bit loosely. If there is conflict of interest by the guidelines, they are not on the committee. They declare if they have an interest or affiliation and then the decision is made as to whether conflict exists, and that's not irregular.

If you have a physician, he has an interest in having as many tools as possible to work with in his practice, and he can be part of the decision-making process. If he's trying to get one particular implement, or tool, or medication approved, and he has a financial interest in that particular one, there is a conflict. If that person is unbiased and cannot sit on that committee or panel, I think—you have to let me finish.

● (1055)

The Chair: I'm sorry, I said one minute. I have five people who are very anxious to speak.

I'll go to Mr. Lunney now, please, for one minute, sir.

Mr. James Lunney: Thank you, Madam Chair.

I wonder if panel members.... Mr. Thibault would be interested in this as well.

The Chair: We have five minutes left and five speakers.

Hon. Robert Thibault: After the time of the committee runs out we leave. In the meantime, the rules allow me to have my five minutes.

The Chair: We don't always stick that closely to the rules, in the sense that everybody wants to participate and I do my best to make sure everybody can, but now we're wasting time talking about process. I said at 10:55 that we had five speakers and they could have one minute each, and now you're using up more of other people's time.

Mr. Lunney, go ahead.

Mr. James Lunney: Thank you.

Colleagues, one week ago today, the *Globe and Mail* carried an article that's pertinent to our discussions today on conflicts of interest—and I see Madame Gorman nodding, so perhaps she's aware of it. *Nature* magazine had reported on conflicts of interest in practice guidelines that our doctors follow.

Also, the *Vancouver Sun* carried the article and quoted the editor of the *Canadian Medical Association Journal* in talking about conflicts of interest in practice guidelines that doctors tend to follow—very serious conflicts.

There are Canadians and there are men and women of integrity in the medical system who are very, very concerned about conflicts of interest when people writing the practice guidelines are receiving funds or stock in the companies whose products they're recommending.

The Chair: Sorry.

Ms. Dhalla.

Ms. Ruby Dhalla: I think integrity and ethics are so paramount. We see it on a daily basis in politics. I think from you coming here today we've just seen perhaps your definition and the department's definition of conflict of interest and ours, which seem to be at opposite ends of the border.

Could you just provide us with one piece of information, please? You had spoken about the special access program. There have apparently been about 19,000 requests from physicians. Please let this committee know if the individuals, the plastic surgeons who are sitting on this panel, have made requests to this program. That will perhaps give us more insight into whether or not there were conflict of interest guidelines broken.

The Chair: Thank you.

Madame Demers, you have one minute.

[*Translation*]

Ms. Nicole Demers: Thank you, Madam Chair.

You said that the minister has to approve the special access requests. On the Health Canada site, there is a question about whether a special access request can be turned down. And the answer is yes. It states on the site that a request can be turned down if it is decided that the potential risk involved in using the device exceeds any possible benefits. There is another Health Canada site which states that most women with breast implants will experience complications.

So I am wondering how you can determine that the risk is acceptable and therefore offer breast implants to all these women without having any long-term studies?

[*English*]

The Chair: Thank you.

We're now at one minute, and Mr. Thibault is very anxious to get back in. He can have a minute right now.

Hon. Robert Thibault: I have one quick question.

You mentioned the fact that some of these physicians or people on the panel had been treating patients who had received these implants. Were these people who had positive responses to the implants or people who had negative reactions, or both?

Mrs. Susan Gardner-Barclay: I would assume that his knowledge of that would have been brought to the deliberations in the second day of the panel meeting, and I wouldn't be able to speak to that.

The Chair: On behalf of the committee, I want to thank the panel very much.

Ms. Gorman, we are aware that this whole open consultation situation is fairly new, and we understand that you are feeling your way. I think you have two or three under your belt now: COX-2, silicone gel, and so on. We can't help but have opinions about that process, and I think perhaps our deliberations will assist you to enrich and strengthen that public consultation process.

Certainly we are laudatory of the minister's initiative in this regard. However, those of us who attended that particular consultation were more than a little dismayed, as you probably read from our body language while we were there.

We hope to be helpful to you. We would request that the questions that have been asked of you today be answered in writing and translated as quickly as possible, because we'd like to put this issue to bed in order to communicate our opinions to the minister.

So I have a suggestion for the committee. At next Tuesday's meeting, I think there are about three items. One is the terms of reference for the drug study. A second one, as you'll recall, is Mr. Ménard's floating motion about asking for reports on what's happened about cigarette smuggling. He'll need a few minutes. But I'm thinking we might save half an hour of that meeting for a discussion about what you wish to do next, having had this meeting on this topic.

● (1100)

Mr. Rob Merrifield: I understood that we were going to have an update on the avian flu.

The Chair: That's on Thursday, so on Tuesday maybe we can clean up two or three different topics, including our plans for the study we hope to begin very soon.

Mr. Steven Fletcher: Shouldn't that include online pharmacies?

The Chair: That will be discussed on Tuesday as part of the terms of reference.

Is everyone in agreement with that plan for Tuesday?

Some hon. members: Agreed.

The Chair: Thank you.

Madam Gorman, if we could get that information for Tuesday's meeting we would be really grateful, because it would guide some of our discussions around this topic. I hope that doesn't put too much pressure on. But I think you have a question from Ms. Dhalla and a question from Madam Demers. I don't remember any others. Maybe you took notes and you have a couple of others.

Ms. Diane Gorman: I will try to get my remarks in both languages to you by the end of the day.

The Chair: Good. In actual fact, if you could send us a package in preparation for our Tuesday meeting, that would be good.

Thank you very much.

This meeting is adjourned.

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