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Tuesday, June 13, 2006

—
Chair

Mr. Rob Merrifield

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•(1235)

[English]

The Clerk of the Committee: Because of recent changes in the membership of the committee and pursuant to Standing Order 106 (2), we will now proceed with the election of the first vice-chair.

[Translation]

I am now ready to receive nominations for the position of first vice-chair. The nominee must be a member of the official opposition.

[English]

Do I have a mover of a nomination?

Ms. Tina Keeper (Churchill, Lib.): I nominate Ruby Dhalla.

Mr. Steven Fletcher (Charleswood—St. James—Assiniboia, CPC): I'll second that.

The Clerk: It has been moved by Tina Keeper that Ruby Dhalla be elected first vice-chair of the committee.

Are there other nominations?

Is it the pleasure of the committee to adopt the motion?

(Motion agreed to)

The Clerk: I declare Ms. Dhalla first vice-chair of the committee.

Some hon. members: Hear, hear!

The Chair (Mr. Rob Merrifield (Yellowhead, CPC): Congratulations, Ruby.

Ms. Ruby Dhalla (Brampton—Springdale, Lib.): I wish my election were that easy.

The Chair: Ms. Demers has put notices of motion before the committee.

Ms. Demers, we need to know whether you want to move those today or whether you want to wait for the report.

Ms. Nicole Demers (Laval, BQ): I'd like to move them today.

The Chair: Okay, fair enough. Then the floor is yours.

[Translation]

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

I would now like to read excerpts from motion #1B, which among other things, notes the following:

There have been no objective, long-term studies on silicone gel breast implants and their effect on women's health.

Further on, there is a lengthy reference to testimony given by witnesses who last week provided the committee with information on silicone gel breast implants. The following is further noted:

The team of Doctor Robert Guidoin, a specialist in biomaterials at the Université Laval, demonstrated that the silicone gel prostheses implanted in 12,000 Canadian women can deteriorate, mix with tissue and release a potentially carcinogenic product into the human body.

Therefore, I am asking the minister to postpone her decision on silicone gel implants until we have definitive proof that these implants do not pose a health risk for women. The situation is becoming ridiculous.

[English]

The Chair: That's the first motion?

[Translation]

Ms. Nicole Demers: That's correct.

[English]

The Chair: You have the motion before you. We will open the floor to debate on the motion, if you want.

Mr. Fletcher.

Mr. Steven Fletcher: I'll speak to the first motion.

There have been numerous long-term, evidenced-based, scientific studies on the safety and effectiveness of silicone gel breast implants. These have been considered, along with conclusions arrived at in the study of Drs. Guidon and Tweed and the opinions contained in the document *Decisions in the Dark*, by Health Canada during the review process. In addition, Health Canada is aware of the unsubstantiated claims of fraud made in the media by the former Mentor employee. This employee has subsequently pleaded guilty to charges of theft from the company. None of the information presented is new to Health Canada. All these studies have been reviewed during extensive evidence-based pre-market evaluation of safety and effectiveness evidence available for these medical devices.

When Health Canada has received an application for licence of a medical device, the department is required by law to review and make determinations with respect to the application. Given the extensive data and evidence gathered by Health Canada in the context of licensing applications for silicone gel-filled breast implants, there is no need to postpone the decision-making process. Therefore, I suggest to the committee that we vote no.

•(1240)

The Chair: Is there any other discussion?

Ms. Demers.

[*Translation*]

Ms. Nicole Demers: If no one else wishes to speak...

[*English*]

The Chair: Ms. Dhalla.

Ms. Ruby Dhalla: I think as a woman, and having spoken to and having been in contact with a number of women across the country who have been impacted, I think we as a committee should be voting yes on this motion. When you take a look at some of the statistics, especially in light of the fact that over 70% of implants have been removed after 11 years because they were perforated, those are very alarming statistics. What we do in this committee with respect to this issue has a tremendous impact on many women in this country.

I think it's important that we show some leadership. I think it's important that we also ensure that next time around, if there is a next time when Health Canada puts together an expert advisory panel or a scientific advisory panel, it is unbiased and objective.

In light of some of the incidents that have occurred in the past, in addition also to the statistics we have, I think we should be supporting this motion.

The Chair: Ms. Priddy.

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

The other thing that would concern me is that when these first came out and when they had their second generation, people said there had been enough research to prove they were safe. Clearly, there had not been enough research to prove they were safe. Until there really is something substantive, I could not support—I mean, I do support Madame Demers' motion and think it would almost be irresponsible on my part not to.

The Chair: Is there any further discussion?

Mr. Batters.

Mr. Dave Batters (Palliser, CPC): Could I move an amendment, Mr. Chair? Just looking at this and some of the preamble, I would strike the preamble, because I don't think we can agree on that around this table. I'll read the amendment as I would propose it. It would just start with the final statement:

In light of all the information collected and heard to date, we are asking the Department to postpone its decision on silicone gel breast implants...

The statement would then continue by saying,

...until it has received enough scientific information to make an informed decision on the safety of silicone gel breast implants.

The Chair: Does the mover see that as a friendly amendment?

[*Translation*]

Ms. Nicole Demers: No, Mr. Chairman.

[*English*]

The Chair: The clerk is clarifying—I'll ask her to just clarify.

The Clerk: In the original version you were sent, the English said “the Department of Health”, while the French said “Minister of Health”, so I've changed it now in the English also, so where Mr. Batters said “Department of Health” it's “Minister of Health” instead.

The Chair: We'll let Ms. Demers close the debate because she sees that as an unfriendly amendment.

Mr. Fletcher.

Mr. Steven Fletcher: Ms. Demers, I ask if you could reconsider it, because I think the wording of my colleague is something we could support; then we get the whole committee onside. Wouldn't that be better, and meet your goal?

• (1245)

[*Translation*]

Ms. Nicole Demers: Mr. Chairman, I believe Dave was asking that the preamble be deleted.

An hon. member: That's right.

Ms. Nicole Demers: I want the preamble to remain. It's important to the decision-making process. It outlines our reasons for moving this motion. If we delete the preamble...It's extremely important that it be a matter of public record, just like the decision. If something happens later, then we'll know that we, the members of the Standing Committee on Health, assumed our responsibilities and made an enlightened decision by choosing to support this amendment.

[*English*]

Mr. Steven Fletcher: You could read it into the public record, and we'd just vote on the motion.

The Chair: Mr. Fletcher, just hang on. We're not going to allow the debate between the two of you.

You're seeing it as an unfriendly amendment. The amendment, just to clarify it, was to strike the preamble—that's what I heard—and to add the little clause at the end, right?

Hon. Brenda Chamberlain (Guelph, Lib.): Would he agree to leave the preamble and just do the little bit on the end?

The Chair: That's up to the mover.

Mr. Batters, are you prepared to leave the preamble, add your amendment, and see that as a friendly amendment?

Hon. Brenda Chamberlain: Add the bit on the end and you could leave the preamble.

Mr. Dave Batters: Absolutely, Mr. Chair.

The Chair: Does the mover see that as a friendly amendment?

Ms. Nicole Demers: Can you repeat it?

The Chair: Okay.

We're not going to wait forever here.

Mr. Dykstra.

Mr. Rick Dykstra (St. Catharines, CPC): I think one of the concerns we have is that the motion actually makes conjectures that may be based on interpretation, but it's very difficult when we've got statements like the one that says the company was hiding data on ruptures. It potentially puts this committee in what I think could be a very awkward position with respect to actually making a declaration on what may or may not have happened. I'm not a medical expert. I'm not prepared to make those kinds of statements.

I support the amendment, but I can't support the—

The Chair: It actually doesn't matter now, because the mover has said that he's not prepared to allow the preamble in.

Mr. Dave Batters: On second thought, Mr. Chair, I'm not able to do that.

The Chair: Let's carry on. We have a motion before us.

Madame Demers, do you want to close debate?

[Translation]

Ms. Nicole Demers: Mr. Chairman, the motion is drafted this way because we want our reasons for asking the minister to postpone her decision to be clearly stated. We're talking about real documented cases, not about mere rumours or allegations. That's important to bear in mind.

I'm not a doctor or an expert, but it's important to remember that Health Canada receives \$41 million per year to approve licensing requests. It's not normal for the department to act as both judge and defendant. Therefore, we must insist that the minister assume her responsibilities, postpone her decision and wait until we have definitive proof that these breast implants are not a health hazard.

[English]

The Chair: Thank you, Madame Demers.

We're going to ask for a vote on the amendment at this time. The amendment is to eliminate the preamble and to add, after the word "implants", "until it has received enough scientific information to make an informed decision on the safety of silicone gel breast implants."

Ms. Ruby Dhalla: They didn't accept the amendment—

The Chair: That doesn't matter—therefore, she doesn't see it as a friendly amendment—but it is an amendment, and it was tabled.

We're voting on Mr. Batters' amendment. I'm going to read it one more time.

The amendment was to eliminate the preamble and, after the word "implants" at the end, to add the words "until it has received enough scientific information to make an informed decision on the safety of silicone gel breast implants."

That's the amendment.

(Amendment negated)

● (1250)

The Chair: We'll go to the main motion.

(Motion agreed to)

The Chair: Let's go on to the second motion.

Madame Demers.

[Translation]

Ms. Nicole Demers: Mr. Chairman, this motion aims to tighten conditions for the Special Access Program for Medical Devices. We've noted that Health Canada and program administrators have eased up on restrictions since the program's inception in 1993. While only 17 requests for silicone gel implants were approved in 1993 and 1994, a total of 8,53 requests were approved in 2005-2006. A program developed to help special cases is now becoming a program

accessed for breast augmentations in 80 per cent of the cases, not breast reconstructions, as originally intended.

Mr. Chairman, we are asking the Minister of Health to tighten eligibility conditions for the Special Access Program for Medical Devices by allowing surgeons to obtain silicone gel implants only for post-cancer breast reconstructions. I would also be willing to allow surgeons to use these implants for reconstructive surgery related to specific deformities.

[English]

The Chair: Are you making an amendment to your motion?

[Translation]

Ms. Nicole Demers: Before we debate the motion, I'm prepared to add that stipulation. Some women have certain deformities. In such instances, the use of silicone gel breast implants could be acceptable.

[English]

The Chair: We need the exact wording of the motion. Could it be "other disfiguring conditions"?

[Translation]

Ms. Nicole Demers: Yes.

[English]

The Chair: Or "disfiguring conditions"?

[Translation]

Ms. Nicole Demers: Mr. Chairman, I don't know what the correct term would be, but I wanted to make this point before we started debating the motion, because some found this upsetting.

[English]

The Chair: We'll have to express it before we move it; that's the dilemma I'm in.

[Translation]

Ms. Nicole Demers: Mr. Chairman, I will table my motion as is. Perhaps someone will want to move an amendment. The last paragraph reads as follows:

We are asking the Minister of Health to tighten the conditions for the Special Access Program by allowing surgeons to obtain silicone gel implants only for post-cancer breast reconstructions.

[English]

The Chair: Okay. The motion is as it is. We'll open the floor to debate; we may get an amendment to it.

Ms. Dhalla.

Ms. Ruby Dhalla: While I support what Madame Demers is trying to accomplish here, I just have a little bit of trouble with the last paragraph in her motion, which states that we're asking the Minister of Health to tighten the conditions of the special access program by allowing surgeons to obtain silicone gel implants only for post-cancer breast reconstructions.

I wouldn't feel comfortable overriding the diagnosis that a surgeon would put forward. I think we need to make an amendment in regard to that, to broaden it a little bit, and not be seen as overriding the judgment of a surgeon who specializes in that area. Perhaps we could say, "to obtain silicone gel implants for other than breast augmentations".

The Chair: Is this your amendment? What is the amendment?

Ms. Ruby Dhalla: I think we want to get the wording. We want something to say it's for other than breast augmentation.

The Chair: Do you have the wording?

Ms. Sonya Norris (Committee Researcher): The regulations currently state that their application has to indicate a diagnosis, a treatment, or a prevention. They don't actually ask for that in the application form currently; they ask for the medical condition.

Ms. Ruby Dhalla: The wording is "medical condition", right?

Ms. Sonya Norris: And it should be "diagnosis, treatment, or prevention".

The Chair: I'm just looking for wording. I'm getting my technical hat on.

John.

Mr. John Maloney (Welland, Lib.): Would the word "therapeutic" fit?

The Chair: Ms. Dhalla, this is your amendment. Can you come up with a definite amendment? Then we will debate that amendment.

Mr. Steven Fletcher: Ms. Dhalla, why don't we say...that only while consulting with a physician can they have these gel implants?

Ms. Ruby Dhalla: But to go to a surgeon, they would have been referred by a physician in the first place. You can't just go directly to any surgeon.

•(1255)

The Chair: Okay, while you guys wrestle with that, I'll have Ms. Priddy take the floor.

Ms. Penny Priddy: I want to go back to the wording you just used, Sonya. Where did that come from—"diagnosis, treatment, and prevention"? Some people do this for prevention, for familial breast cancer.

Ms. Sonya Norris: It came from the medical devices regulations, part 2, special access.

Ms. Penny Priddy: Did you say that's been taken out?

Ms. Sonya Norris: I don't know why there's a change with what the application asks for; the application asks for a medical condition that they are treating.

Ms. Penny Priddy: Is that where we get into the idea that small breast size is the medical condition being treated?

Ms. Sonya Norris: Yes.

The Chair: Do we have an amendment, Ms. Priddy?

Ms. Penny Priddy: The one I had suggested was "clearly medically necessary".

The Chair: Is that your amendment?

Ms. Penny Priddy: Yes.

The Chair: Okay. We have an amendment on the floor. Does the mover see that as a friendly amendment to start with?

Madame Demers, do you see Ms. Priddy's amendment as a friendly amendment?

An hon. member: What did she say?

Ms. Penny Priddy: I said, "clearly medically necessary". It could probably still use a little bit of work, but it's closer.

Hon. Brenda Chamberlain: It's closer. The only thing about that is...what about psychological? What about that?

The Chair: Just a second. I need an answer as to whether the mover sees that as a friendly amendment or not.

[Translation]

Ms. Nicole Demers: With these two amendments, namely the one from Ms. Dhalla and the one from Ms. Priddy, it would probably be preferable, because saline implants are available on the market for persons with psychological problems.

We want the use of silicone gel implants restricted, because there is no clear proof that they do not cause health problems.

[English]

The Chair: Let's have this for a recommendation, because we're getting bogged down here. Nancy and Sonya have come up with a recommendation. Go ahead.

This may work.

Mrs. Nancy Miller Chenier (Committee Researcher): Thank you.

It actually means stopping the motion at the end of the first sentence. You have a preamble that has already laid out many of the conditions you want the Minister of Health to consider, and it gets the committee away from specifying access conditions that they may not have heard enough about, so if you say you're asking them to tighten the conditions, it would still relate back to the earlier data.

The Chair: You're saying to use just the first lines, with a period after "program": "We are asking the Minister of Health to tighten the conditions of the special access program."

Are you good with that as an amendment?

Mr. Steven Fletcher: You have to take out the fourth "whereas" to go with it. You would have to take out the fourth "whereas".

Ms. Nicole Demers: No, that's what it was intended for. That's what it was intended for, Steven; it's clearly written in Health Canada's program.

The Chair: Excuse me; the clerk is suggesting that we would have to add "medically necessary", rather than "breast reconstruction".

Let's leave the preamble. Madame Demers, as the mover of the question, are you okay with that as an amendment?

[Translation]

Ms. Nicole Demers: Mr. Chairman, I don't know if that goes far enough. If we merely ask that conditions be tightened, without being specific, then it's unclear as to how this will done. I want to prevent situations where restrictions are relaxed and implants are approved for breast augmentations. That's the only thing I'm trying to prevent.

[English]

The Chair: Are you saying no, you don't see it as a friendly amendment?

[Translation]

Ms. Nicole Demers: No.

[English]

The Chair: All right.

Ms. Dhalla.

Ms. Ruby Dhalla: Perhaps Madame Demers can accept what I had originally stated in regard to a friendly amendment. It would just basically read as follows:

We are asking the Minister of Health to tighten the conditions for the special access program by allowing surgeons to obtain silicone gel implants for purposes other than breast augmentation.

• (1300)

[Translation]

Ms. Nicole Demers: That would be acceptable.

[English]

The Chair: We have a motion, a friendly one. We've got a motion that's acceptable as amended.

Hon. Brenda Chamberlain: What is it, pray tell?

Yes, I like it.

The Chair: All right, we understand what we're doing. Let us have debate on that motion.

Mr. Fletcher.

Mr. Steven Fletcher: Mr. Chair, I think it's really important that this committee focus on the science. They're either safe or they're not. If they're safe, this committee shouldn't be making moral judgments on what is appropriate or inappropriate.

I would like to say some things for the record. Silicone-gel-filled breast implants were voluntarily withdrawn from the Canadian market in January 1992 to allow Health Canada time to review new evidence of the safety and effectiveness of these implants.

The moratorium was lifted in January 1993, when manufacturers were informed that they would need to reapply for market authorizations and provide additional clinical evidence of the safety and effectiveness.

Health Canada is nearing the end of an extensive, thorough, and lengthy review of several licence applications for silicone gel breast implants. The results of this review will have an impact on the need for special access authorizations of these medical devices.

The requirements of the medical devices special access program are clearly stated in part 2 of the medical device regulations. During the review of special access authorization requests, Health Canada reviews the risks and benefits as determined by health care professionals for individual patients.

Health Canada cannot legally refuse a licence or special access authorization to a medical device that meets the regulatory requirements set out for its sale and importation in the Food and Drugs Act and in the medical device regulations. If a silicone-gel-filled breast implant is safe and effective for use in a cancer survivor, it is equally safe and effective for the same indicators in a person seeking augmentation or replacement of an existing device.

In summary, it is not Health Canada's role to determine the appropriateness of specific treatment for specific patients; these

decisions are made by the treating physicians in consultation with their patients.

If we can make an amendment that would agree with that principle—that it's a relationship between the patient and the physician—I think we could support it, but it's not the role of this committee to go beyond that.

The Chair: Okay.

Is there any other discussion on the motion?

Mr. Batters.

Mr. Dave Batters: Well, Mr. Chair, I agree with everything that Mr. Fletcher has just said, which really runs contrary to the entire spirit of this motion. I don't know if this is amendable so I could support it. I'm not going to support the motion, but I want to explain to Ms. Demers and this committee why not.

Just very simply, I agree with the parliamentary secretary. It needs to be determined whether or not these implants are safe or unsafe, rather than getting into the validity of who should qualify and for what reasons, whether they be for reconstructive surgery or for augmentation.

Madam Demers, I see from your body language that you don't agree with me—but I think their safety is the key, and that needs to be determined. Perhaps you agree with this point, that we need a decision from the department, yes or no. Granted, you're saying that in the meantime, before that decision is made, and along the lines of Ms. Dhalla's comments, that it be approvable other than for augmentation.

I guess what I'm pushing for here is: let's have a decision, and get away from this special access program altogether. Let's have a decision: they're safe or they're not safe. That's why I'm not going to support it, but I wanted you to know why.

• (1305)

The Chair: Okay, fair enough.

We will let you complete the debate.

[Translation]

Ms. Nicole Demers: Yes, Mr. Chairman. I don't know where the parliamentary secretary comes up with his figures get his ideas. I have a document that I received from Health Canada advising me that the sale of silicone gel breast implants is currently outlawed in Canada and that there is no experimental testing under way in Canada involving this type of breast implants.

It's incorrect to state that the moratorium was lifted in 1993. In 1996 and 1997, silicone gel breast implants were no longer available through the Special Access Program for Medical Devices because the United States had deemed them to be too great a health risk and had banned their use, even for breast reconstructions. Despite this ban, a total of 24,000 requests were approved and requests from women continue to be approved, although they are not given any information and made aware of the risks. They are only informed after the fact, once they are ill and experiencing problems. A program initially developed to help people maintain their health should not normally be used for this purpose. This has to stop.

[English]

The Chair: Okay.

So we have the amended motion; it is a friendly amendment.

Do we have the exact wording, Ms. Dhalla?

Ms. Ruby Dhalla: Yes, I just gave it to you. Do you want me to just read it out?

The Chair: Yes, read that out, so everybody knows what we're voting on. We've seen it as a friendly amendment.

Ms. Ruby Dhalla: The friendly amendment would read as follows:

We are asking the Minister of Health to tighten the conditions for the special access program by allowing surgeons to obtain silicone gel implants only for the purposes other than breast augmentations that are medically necessary.

(Motion agreed to)

The Chair: The meeting is adjourned.

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