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# Standing Committee on Health

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## Thursday, December 7, 2006

## Chair

**Mr. Rob Merrifield**

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● (1535)

[*English*]

**The Chair (Mr. Rob Merrifield (Yellowhead, CPC)):** I call the meeting to order. This is our first meeting on the reproductive technology regulations. It's on section 8, which is consent.

We have a panel of witnesses before us today from the Department of Health. I'll let them introduce themselves and explain what their role is exactly. Representatives from the Canadian Institutes of Health Research are here as well.

We will start with the Department of Health. We look forward to your presentation.

Quite a few, actually. She's like an old welcome face.

**Ms. Francine Manseau (Senior Strategic Policy Advisor, Assisted Human Reproduction Implementation Office, Department of Health):** *Merci*. It feels like home almost.

**Ms. Hélène Quesnel (Director General, Policy Development Directorate, Department of Health):** A second home.

Over the summer, we at Health Canada developed a plan that will allow the agency to begin its licensing and enforcement activities as soon as possible. I'll address this strategy in a few minutes, but first I'd like to make a few other comments.

This standing committee has played a significant role in shaping the legislation we now have in place. Over the next few years, as we work toward the full implementation of the act, this role will continue, especially with regard to regulations under the act.

As you know, the act received royal assent in March 2004. Since then, the department continues to work toward the full implementation of the act, which essentially consists of developing a regulatory system and establishing the agency, Assisted Human Reproduction Canada.

I would now like to present a brief overview of the activities of the implementation office to support this implementation.

We have drafted proposed regulations to address section 8 of the act related to the issue of informed consent. The draft regulations were pre-published in the *Canada Gazette* in September 2005 for comments by stakeholders. The act requires that the minister table the regulations in Parliament with this committee, as well as with the Senate committee. We have now tabled these regulations and we're looking forward to the review.

[*Translation*]

We also organized workshops and are currently carrying out consultations with interested parties to examine certain issues, such as consent, counselling, health reporting information, and clinical and laboratory practices.

We are focussing our consultations to seek policy advice on various clinical activities and laboratory activities carried out in clinics, as these are complex issues requiring a detailed and in-depth knowledge of procedures before regulations can be developed. We must also include the opinions of those affected by these activities, especially parents and the children of these technologies, along with donors.

We are also looking at other ways of obtaining additional information and expert opinions, including on-line consultations, so as to speed up the regulation development process.

● (1540)

[*English*]

We have now secured temporary office space for Assisted Human Reproduction Canada in Vancouver, B.C., and have done extensive work to develop the necessary governance and accountability structures, business plans, processes, and management tools. We are continuing to work toward the setup of the information systems for the agency, including the personal health information registry.

Another important step we have taken has been the development of a memorandum of understanding with Health Canada's inspectorate. This MOU has been concluded on behalf of the agency to provide compliance and enforcement support through in-house inspection staff. Twenty-three inspectors have been designated, and eleven are currently concluding outreach activities to encourage compliance by improving awareness of the act, providing information regarding the provisions of the act, and educating the stakeholders about their responsibilities under the act. We began these outreach activities in the fall of this year.

As you heard from the Minister of Health when he appeared before the committee in late November, the government anticipates it will soon be making an announcement on the president and other members of the agency's board of directors.

I would now like to go back to the regulatory development and share with you Health Canada's approach.

In the AHR field, very little currently exists as far as established Canadian guidelines or standards. Following a rigorous planning exercise earlier this year, a new approach to the development of regulations was devised. A refocused set of priorities was identified that will deliver on key regulations within a shorter timeframe. We will concentrate on a core set of regulations covering the licensing of in vitro fertilization activities with people using their own gametes. This will enable the agency to begin its licensing activities sooner.

[*Translation*]

In vitro fertilization is the main authorized activity of the clinics. We have reached the last stage of a consultation in three cities that began in Montreal on November 24, continued last week in Toronto and will wind up in Vancouver tomorrow and Saturday of this week, during which we discuss documentation on the 10 activities governed by the IVF legislation.

We are also taking this opportunity to discuss the licensing framework and health reporting information with the sector we will be regulating. These discussions will help us better understand the problems, issues and concerns with respect to the development of regulations. Barring any unexpected circumstances, the regulations should be put in place in the next 18 to 24 months.

[*English*]

I do, however, want to reassure this committee that while our goal is to get the regulations in place that will allow the agency to begin its licensing activities sooner, by focusing on IVF regulation, work is continuing on other regulations necessary to fully implement the act. It is my sincere belief that this new approach will produce the expected results.

In a moment, I will turn to Kata, who can elaborate further on the proposed consent regulations under section 8.

As you know, the proposed section 8 regulations deal with consent issues as they relate to the use of human reproductive material and in vitro embryos.

It should be noted that the act addresses consent in a number of provisions and in different contexts. For example, section 14 requires that licensees make counselling services available to any person donating human reproductive material or an in vitro embryo, or anyone providing health reporting information. Licensees must also ensure that these counselling services are received.

Section 14 of the act also requires that donors of human reproductive material and in vitro embryos, and persons providing health reporting information, provide written consent indicating they were informed of the requirements of the act respecting the retention, use, provision to other persons, and destruction of the human reproductive material or in vitro embryos, as well as the retention, use, disclosure, and destruction of health reporting information.

However, this section—section 14—and the accompanying regulations are dependent on the licensing framework being in place. Regulations respecting licensing are the ones we are currently developing.

I will now turn it over to Kata, who can elaborate further on the proposed consent regulations.

● (1545)

**Ms. Kata Kitaljevich (Acting Director, Assisted Human Reproduction Implementation Office, Department of Health):** My understanding is that committee members have already received the deck on section 8, so I won't presume to go over it. We can respond to questions following this.

I want to give a few highlights of the deck. Section 8 regulations were developed first, because section 8 is the only prohibition not yet in force. You'll probably be hearing that story over and over again this afternoon. While section 8 is not the only section in the AHR Act that addresses the issue of consent, it provides the essential minimal requirements for consent to protect users of AHR services.

As Hélène said, section 14, once in force, will require, among other things, that licensees inform a person in writing of the requirements of the act respecting the retention, use, provision to other persons, and destruction of the human reproductive material or in vitro embryos. Licensees will also be required to obtain written consent to the application of these requirements, and they must ensure that counselling services are received.

[*Translation*]

Additional regulations will be developed to deal with issues related to the conservation, transportation and destruction of human reproductive material and in vitro embryos.

Section 8 deals with the issue of written consent for the use of human reproductive material and in vitro embryos and the posthumous removal of human reproductive material.

[*English*]

The proposed regulations require that donors be informed of the allowable uses for their human reproductive material and in vitro embryos and of the conditions for withdrawal of consent. They also require that donors provide a written consent that is attested to by a witness.

The section 8 regulations conform to the provisions of the 2002 CIHR "Human Pluripotent Stem Cell Research Guidelines", as required by section 3 of the AHR Act, notably with respect to the following issues: the reiteration of consent, the withdrawal of consent, and obtaining the consent of the original gamete provider if they are not the same as the in vitro embryo donor. The regulations include transitional provisions for human reproductive material and in vitro embryos that were obtained prior to the regulations coming into force. They can still be used as long as written consent was obtained.

That concludes my remarks.

**The Chair:** Thank you very much.

That's all, Francine?

**Ms. Francine Manseau:** Yes.

**The Chair:** Okay.

We have CIHR. We'll entertain your remarks at this time.

**Dr. Burleigh Trevor-Deutsch (Director, Ethics Office, Canadian Institutes of Health Research):** Thank you, Mr. Merrifield.

My name is Burleigh Trevor-Deutsch. I am the director of the Ethics Office at CIHR. With me here is Dr. Pierre Chartrand, who is the vice-president of research.

First of all, let me thank you for inviting us here today.

[*Translation*]

Canadian Institutes of Health Research (CIHR) is the major federal agency responsible for funding health research in Canada. It aims to excel in the creation of new health knowledge, and to translate that knowledge from the research setting into real world applications. The results are improved health for Canadians, more effective health services and products, and a strengthened Canadian health care system.

[*English*]

CIHR carries out its mission in collaboration with a wide cross-section of partners, including our colleagues in the health portfolio, and these, of course, include Health Canada and the Public Health Agency of Canada, other federal departments, such as Industry Canada, CIDA, and Environment Canada, and we also collaborate with provincial health research agencies, charities, and other non-profit organizations, as well as industry.

Today, with an annual budget of $737 million, CIHR is supporting over 10,000 health researchers in universities, research institutes, and teaching hospitals across the country.

CIHR takes a problem-based and multidisciplinary research approach to health challenges facing Canadians. We bring together all the disciplines of health research under one umbrella, and these include biomedical, clinical, health systems and services, and population and public health. These are the so-called four pillars of CIHR.

Stem cell research is one of the areas funded. Stem cell research can potentially lead to effective therapies in the treatment of a number of health care conditions and diseases, including Alzheimer's, Parkinson's, diabetes, kidney failure, heart disease, spinal cord injury, and most recently—you may have read in the *Globe and Mail*—cancer.

CIHR is committed to funding health research that meets the highest standards of science, excellence, and ethical conduct. A number of systems have been put into place to uphold these standards for the research that CIHR funds.

In the area of stem cell research, a number of oversight mechanisms are in place. Of course, CIHR complies with the Assisted Human Reproduction Act, which, as you know very well, provides a legislative framework within which all public and private human embryo research can be undertaken. Complementing this legislative framework, CIHR's stem cell guidelines set out conditions under which CIHR will and will not fund human pluripotent stem cell research.

The guidelines operate within the legal framework created by the act, and it's also worth mentioning that the consent provisions of our stem cell guidelines are incorporated by reference into the act itself.

● (1550)

[*Translation*]

CIHR is currently working closely with Health Canada to ensure that guidelines on stem cells are completely harmonized with the implementing regulations of the Assisted Human Reproduction Act now under preparation.

As the federal agency responding for funding health research in Canada, CIHR will continue to support, in cooperation with all its partners, the Canadian research community. This is a community based on excellence, once that respects ethical standards and that definitely will help to improve the health of Canadians.

[*English*]

These are my introductory comments.

My colleague, Dr. Chartrand, and I will of course be pleased to answer your questions.

**The Chair:** Thank you very much for your presentation and for being here. I'm sure we'll have lots of questions in regard to this.

We'll start with Ms. Bennett. You have ten minutes.

**Hon. Carolyn Bennett (St. Paul's, Lib.):** Thanks very much.

The whole issue of consent is one where all of us feel we ought to be able to do better. What people think they consented to sometimes isn't what is really on offer, and people aren't necessarily told in detail about the real risk-benefit ratio or some of the stories.

With the opportunity to set up a new agency, do you think we should go further in this particularly difficult area, where patients can be particularly vulnerable and particularly prone to charlatans and other things that have a very tiny risk of success, and take this opportunity to do a better job?

I think some of you have heard me say at committee before that I think the Toronto Medical-Legal Society looked at some American models, where people had to look at a CD of people who had the procedure and everything went well, and people had to look at a CD of people who had the procedure and things went terribly wrong. Until you actually understand both sides, you can't really give informed consent. Do you think this could or should be an opportunity for us to go further on this?

If you wouldn't mind, I would like you to describe what happened in the public consultation on this. In examining this, do you feel that the kinds of infertile couples who we didn't hear from enough at this committee were part of the consultation? Could you also describe the process for public consultation that brought you to this and whether or not you think it is sufficient?

I really believe public consultation isn't supposed to be only occupational therapy. They said we're supposed to have public consultations. Can we show the people who bothered to participate in this that changes were made to what you had on offer before the public consultation? How did it change after you'd listened to people? Are you comfortable that you listened to enough people and to people who are the most vulnerable in this file?

● (1555)

**Ms. Hélène Quesnel:** I will start by commenting that I of course totally agree. Informed consent associated with counseling will be key to how we proceed. I would only like to confirm that section 8 consent is very specific to a certain type of consent under the act, and of course section 14 of the act provides fuller coverage.

In regard to what we heard during consultations, I think I would like to ask Francine to comment more specifically on that.

**Hon. Carolyn Bennett:** In that answer, could you let me know what you think counselling is? Is it a nurse handing over a clipboard and asking a person to sign something?

**Ms. Francine Manseau:** As Hélène was saying, if you look at section 14 of the legislation, it provides a broader framework for consent. It basically says that before you can accept gametes from a patient or before you even do a procedure, you have to make sure counseling is provided as per the regulations. You have to provide the patient with information that the agency will be collecting and making available about outcomes. You also have to provide information on what the regulation says about what's going to happen to the gametes and the information it will need to provide.

As Hélène said, section 8 is certainly very narrow in terms of the consent and the information required. It's really to use your gametes to create an embryo, and it's with respect to reproductive autonomy. It's a small part of the broader consent and information that's going to be provided.

**Hon. Carolyn Bennett:** Yes, go ahead, Rob.

**The Chair:** I have a clarification.

This is specific consent for the gametes, and that's fair enough. I think Ms. Bennett was referring to consent for the procedure, which you refer to as being under section 14.

**Ms. Francine Manseau:** Yes.

**The Chair:** I would question whether we should be putting some reference to section 14 in here, because we don't have 14 yet. I suppose the discomfort that we don't have 14 is being reflected in the question, so we have a difficult time judging this without 14, especially when there's no reference to 14.

**Hon. Carolyn Bennett:** Unfortunately, in our country, a lot of this is still carried out in private clinics that have a monetary advantage from people going forward with the procedure.

Are you going to put in place within the agency a 1-800 number for neutral advice, such that people can hear all sides of it, not from somebody who gets paid the more people who show up and have it done?

**Ms. Francine Manseau:** Yes. The agency has a mandate to provide educational material and information to patients.

**Hon. Carolyn Bennett:** But one on one, human interaction, with a knowledgeable person on the other end of a 1-800 line? If I'm trying to decide whether to have the procedure, can I call somebody who is completely neutral and disinterested on whether I go forward or not?

● (1600)

**Ms. Francine Manseau:** I cannot talk for the agency, but certainly they have a responsibility within the mandate to provide educational material and information to patients. As I said, they will also be publishing outcome information that's going to be made available to the patient, that's going to be unbiased and verifiable information.

**Hon. Carolyn Bennett:** My problem is, in adult education, we know that handing people pamphlets and pieces of paper doesn't work. Adults only learn in an interactive way by being able to ask questions. So I'm worried that unless we define what educational material, unless people in their own language can be asking the questions—

**The Chair:** Go ahead.

**Ms. Hélène Quesnel:** When regulations are developed under section 14, what constitutes informed consent, what constitutes counselling, will be the subject of the types of issues you raise today. They're valid questions, of course. We will have the opportunity of talking to parents, to children from these procedures, as well as to clinicians and practitioners to find out the current practices, as you referred to some of them, and what will constitute adequate education.

In terms of what the obligations will be on the clinics, we're not there yet. This particular section of the regulations is very specific to section 8. Section 14 will deal much more with the types of issues you raise today.

**The Chair:** When we last looked at the piece of legislation as a committee, one thing we insisted upon was a third party, unbiased consult. That's pretty specific, and I think this is what the discomfort is with regard to this area of the section. If it's all in 14 and we're dealing with consent in 8, and 8 is here, perhaps some reference to section 14 should be put in this area of the regs. That would help me feel better about it. I don't know how the rest feel, but thank you very much.

Madame Gagnon.

[*Translation*]

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

This Act is very important for the Bloc Québecois. Some twenty sections are being challenged by Quebec, including section 8.

In the event the regulations are adopted and the Act is thus implemented, would it be applicable in Quebec, since this province is challenging it?

**Ms. Francine Manseau:** I can’t speak to the legal consequences. All I can say is that Parliament approved the Bill and, consequently, we are obliged to develop the regulations and set up the agency.

**Ms. Christiane Gagnon:** The Act is still not implemented because the regulations haven’t been established. It is the regulations that are being challenged, including the one relating to section 8 on the application of consent. I thought you could clarify the legal ramifications. If the regulations were implemented, would Quebec be obliged to opt out?

**Ms. Francine Manseau:** Unfortunately, I do not believe we are qualified to answer that question.

**Ms. Christiane Gagnon:** You say that section 8 is very complex and that other provisions of the Assisted Human Reproduction Act with respect to consent bring up practical problems, but you cannot give us all the whys and wherefores of these problems.

Regarding what issues with respect to consent are you unable to provide more information?

**Ms. Francine Manseau:** Section 8 contains one of the last prohibitions not yet implemented. It is precisely for this reason that much importance has been given to the development of the regulations; we want to allow the implementation of section 8.

The purpose of section 8 is to recognize the importance of a person's choice whether to reproduce or not. It states that an embryo cannot be created without the written consent of the person who provided the gametes. Furthermore, the use of an embryo requires the consent of the people who provided the gametes necessary for its creation.

Section 14 states that the person who accepts the donation of gametes is required to make sure that the donor has been consulted and received information on the requirements of the Act with regard to the use that will be made of his gametes, etc. All this requires the creation of an agency, since it will be doing the licensing. It is also partly why we are still developing this structure, because it is necessary for the application of this section. However, section 8 can be implemented immediately. We want to make sure that people can really consent to reproduction.

● (1605)

**Ms. Christiane Gagnon:** There are references to compulsory counselling so as to enable people to make a more enlightened choice. Where can people get this counselling? Who will provide it? Will it be left to the discretion of those who make the request, or will it be a more structured counselling given by specialists in the field?

**Ms. Francine Manseau:** We've consulted people who currently give counselling, and we've met with patients to find out what type of information they need. We then developed a consultation document that presents various options. It will be available in the weeks to come.

The counselling will in fact be more structured.

**Ms. Christiane Gagnon:** Thank you.

[*English*]

**The Chair:** Thank you.

Ms. Davidson, you have five minutes.

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

And thank you to the presenters.

I have a few questions on the public consultation process. I think there were regulations gazetted in September of 2005, and then following the public consultation process. Is that correct, that those were gazetted after the public consultation process?

**Ms. Francine Manseau:** They were gazetted, and that triggered a consultation process. But there was consultation prior to that also.

**Mrs. Patricia Davidson:** Okay.

What major changes were made then, after the public consultation? What came up during those consultation processes?

**Ms. Francine Manseau:** Most of the comments we heard through those processes were requesting.... It's not that the people were not in accord, I guess, with what was proposed, but that they sometimes required more clarification. That's what we did, I guess, with some of the modifications we made after the proposal was put in the *Canada Gazette*, part I.

There was clarification as to the time of withdrawal of a consent. There was clarification also to ensure that the original gamete provider is donating for third parties. That person would also have to provide consent for research, because that person will be told that those in vitro embryos are created for third-party reproductive use. If they have surplus to the reproductive need of the couple for whom the embryo would be created, that couple could decide to give them to research. The original gamete provider will have to have given consent for research also. These are the types of clarification.

We also had a transitional period that was taken into consideration, knowing that there are already gametes that have been donated and are there waiting, I guess, to be used. We want to ensure that with the coming into force of the regulations, we would not allow the use of those unless there was a written consent, which would have been dated.

Also, there was a clarification, I would say, to the definition of an in vitro embryo donor, making it clear that it is the individual or the couple from whom the in vitro embryo was created.

**Mrs. Patricia Davidson:** Just further to that, "consent" has been defined in section 3 of the act.

**Ms. Francine Manseau:** Yes.

● (1610)

**Mrs. Patricia Davidson:** The guidelines have been updated twice since then, though. They were updated in June 2005 and then again in June 2006. So what are the implications of the updated guidelines on the definition of "consent"? Do you have to change the definition? How does that affect that?

**Ms. Francine Manseau:** The relevant provisions of the CIHR guidelines that are pertinent to the consent, because this is where they overlap, have not changed.

So there has not been an impact on the proposal that you have in front of you. We also have been in consultation with CIHR when they were thinking of making modifications. Where we do overlap with the CIHR guidelines, those relevant sections have not changed. In that sense, there is not at this point any problems.

**Mrs. Patricia Davidson:** In 2002 the guidelines only refer to frozen embryos, and then subsequently they refer to fresh or frozen. So how does that change or affect the informed consent?

**Ms. Francine Manseau:** The legislation doesn't make a distinction between frozen or fresh embryos. It just talks about the use of an in vitro embryo for research.

**Mrs. Patricia Davidson:** Okay, thank you.

**The Chair:** I need a clarification for the committee on that. All embryos are created for the purpose of reproduction. That's the sole intent.

**Ms. Francine Manseau:** There are three purposes for which an embryo can be created.

**The Chair:** Isn't research one of them?

**Ms. Francine Manseau:** No. It is to improve knowledge on AHR. It's dictated in the legislation. It's to improve or provide instruction in AHR and also to create a human being.

**The Chair:** Right, so for reproduction or scientific...very narrow.

**Ms. Francine Manseau:** Very narrow, yes.

**The Chair:** Okay. When it gets to the fresh ones, that becomes something that I see has been a change here. When a young lady wants to become pregnant and has embryos produced, the only way they would be fresh and used for anything other than those two purposes would be if there is solely consent given to use them for the scientific research and not the reproductive research. Am I right? If they are for reproduction, they would be frozen. They wouldn't know whether the reproduction process was successful or not for some time after.

That has become a little difficult on the consent side of this, as to how you would have a fresh embryo, with consent, for scientific research.

**Ms. Francine Manseau:** Basically, as I said, the legislation doesn't make a difference. The legislation is very clear that you need to get consent from the individual from whom the embryo was created.

Also, the legislation requires that even before you can do research, the agency will have to be satisfied before issuing a licence to someone to use an vitro embryo for research. As you know, the agency has to be satisfied that the use of the in vitro embryo is required for the purpose of the research, and in the case of stem cell research, as stipulated in subsection 43(1), they would also have to have the signed consent of the gamete or embryo donors before they can make a decision about issuing a licence.

**The Chair:** Okay. So let me put this in a different question. If someone were to come in, give you written consent for scientific research on the embryos and create those embryos solely for that purpose and not use them for reproduction, would that be against this law?

**Ms. Francine Manseau:** The purposes for which you can create an embryo are very clear, and you are allowed a consent form. It's only for the purposes that are written in the legislation. You can only create an embryo either to create a human being or to improve or provide instruction. When individuals are going to consent under section 8, they will have to tick for which purposes in vitro embryos can be created, and it is only for those purposes.

**The Chair:** Okay, so you're saying no.

**Ms. Francine Manseau:** Once they are created, the option is there for the individual to decide what they want to do after they have used them for their reproductive—

**Mr. Steven Fletcher (Charleswood—St. James—Assiniboia, CPC):** Mr. Chair, should we just not go around and ask the questions?

**The Chair:** We will do that. I just wanted clarification from the researchers on the past question.

Ms. Priddy, you have five minutes.

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

I have several questions. Some of them are really easy, so I just need quick answers.

First, is there any restriction on who can be a witness to the consent?

Second, the education material that is to be created by the agency or is the responsibility of the agency, given that they have a fairly large budget and not an active board, but lots of money that we seem to have approved last week or the week before...I'm wondering if some of that work has been done currently and whether there's anything we could actually look at.

Third, I want to follow up Dr. Bennett's comment. It's one thing to have education and awareness material “available”. I don't know how I know it's available. If I've gone to a private clinic, are they going to say to me, here's the 1-800 number you call and there will be a trained, experienced person on the other end of that? And how many languages will this line be available in, because that's a major concern across this country these days?

I've come into this a bit late, and this may be a foolish question, but when somebody signs an organ transplant card, is there any way that sperm is included under organ transplant? I'm just curious. I'm wondering if under those circumstances, if the donor is dying and we talk about a donor who has died or is dying...I'm not sure how one actually goes about getting consent for how sperm can be used.

My last question, and I think the chairperson was getting at this point, is if you're going to run a stem line or create a stem line using the in vitro, does it say somewhere in the consent how far you can and cannot go with that stem line and with those stem cells in terms of research that will produce—and maybe it's covered off by the word “reproduce”—a human being? So is there something that says the research can only go this far if you're running a stem line and collecting stem cells?

Thank you, and maybe they weren't so easy.

● (1615)

**Ms. Francine Manseau:** If I remember all your questions, in terms of the first one on the restriction of the witnesses, no, there have not been restrictions, but there has to be a witness. The signature needs to be witnessed, but there are no restrictions.

I don't know if you want to answer the question about the agency or in terms of the education material or the.... Your question was about whether we had started to do some work since you voted the budget for the agency.

Hélène, do you want to respond?

**Ms. Hélène Quesnel:** I can basically say that while the agency was established in January, it cannot begin its operations until a board of directors has been appointed. So it will not begin its operations until the board of directors is named.

**Ms. Penny Priddy:** For another time, okay.

**Ms. Hélène Quesnel:** Kata, do you want to answer the other questions.

**Ms. Kata Kitaljevich:** No. I was just going to talk about the board.

You were talking about the funding of the board, and therefore because it's not operational it cannot access the funds that have been set aside for that board, and until—

**Ms. Penny Priddy:** Another time. Okay, go to the other answers.

**Ms. Francine Manseau:** For the organ transplants, and you're talking about sperm, basically it's very clear in the legislation. I don't think it's part of the organ transplant. I think it's seen as separate, because of the potential it has, basically. And you have to sign a consent even if you die and somebody wants to take your sperm afterwards for the purpose of creating an embryo.

If it's for other purposes, the legislation doesn't cover it, but for the purpose of creating an embryo, you would have had to sign a consent prior to, to get your material withdrawn from you, and a consent to be able to use it to create an embryo for your spouse or your common law partner.

**Ms. Penny Priddy:** So you wouldn't then get a consent from somebody who was dying?

**Ms. Francine Manseau:** You would have to have gotten it before —

**Ms. Penny Priddy:** Why? Because organ transplants are often gotten at the very end of life, I must admit.

**Ms. Francine Manseau:** Yes, but if the purpose is to create an in vitro embryo for reproduction, you would have to have thought about it beforehand and signed a consent with a witness.

**Ms. Hélène Quesnel:** Your question about dying is a very important one, and I appreciate you raising it. One assumes that the person is conscious. So, obviously, if a person is dying—

**Ms. Penny Priddy:** No, I understand.

**Ms. Hélène Quesnel:** If a person is dying and wishes to... provided they follow the procedure, then—

**Ms. Penny Priddy:** And is it raised at the same time organ transplant is? People will talk about organ transplant at the end of life if someone is conscious. Would sperm donation come up at the same time?

**Ms. Francine Manseau:** It could. I cannot answer that. It could be coming up at the same time.

**Ms. Penny Priddy:** Okay. What about stem lines?

**Ms. Francine Manseau:** On your last question about stem lines, what I can say is that the regulations you have in front of you don't go into the details of the information that would be.... Regulations are going to be developed under section 10, the controlled activities, which deals with research and the information that should be provided for the different kinds of research that would be allowable. It will be raised in that set of regulations; it will be covered there.

● (1620)

**Ms. Penny Priddy:** The one we missed was the availability of education and awareness material.

**Ms. Francine Manseau:** Yes, in different languages—

**Ms. Penny Priddy:** I mean material in different languages, from a real person, all of that, as opposed to being in the form of "Guess what? You can get material if you want it."

**Ms. Francine Manseau:** That's a responsibility we leave to the agency. It's difficult for us to speak on behalf of the agency. I think their mandate is, similarly, to make information available, and also to try to provide information about prevention, I guess. But I cannot speak for them. I'm sure they should be making it.

**Ms. Penny Priddy:** Okay. Thank you.

It has raised a number of questions about consent, though, Mr. Chair, the answers to which won't be available in this section.

**The Chair:** Yes. We have spent three years. Don't worry. There are going to be more questions.

Mr. Batters.

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

I can see why you would have taken three years on this topic. This is really quite a fascinating and very difficult subject.

May I say, Ms. Priddy, I thought your questions were superb.

I have a very short question. It's a short question, but it's a very complicated question for the witnesses. First of all, thank you very much to all of you for being here today.

In Health Canada's presentation, there's a statement that says:

> Violation of section 8 carries with it the consequence of criminal penalties, therefore:
>
> the scope of the regulations must be clearly defined and focus only on the essential elements; and,
>
> the regulations must be very clear to prevent inadvertent contravention of the law.

In my five minutes, I'd like each of you to talk to me and educate me about what types of contraventions we're talking about here. If you can, list as many under the sun as possible. What are the penalties? We're talking criminal penalties. What penalties are being contemplated? Where are we in that process? Is the justice department involved in this process? Are the penalties already defined? That's what I'd like you to talk about in the five minutes, please. Thank you.

**Ms. Francine Manseau:** The penalties are already defined in the legislation in section 60. It says if you're in contravention of any of the sections 5 to 9, which are the prohibitions, which is what we're talking about here, a person:

> (a) is liable, on conviction on indictment, to a fine not exceeding $500,000 or to imprisonment for a term not exceeding ten years, or to both; or
>
> (b) is liable, on summary conviction, to a fine not exceeding $250,000 or to imprisonment for a term not exceeding four years, or to both.

These are the penalties to which we could be subject.

**Mr. Dave Batters:** There are no mandatory minimum penalties?

**Ms. Francine Manseau:** No, that's what the text says.

**Mr. Dave Batters:** What type of violation are we talking about? I just want you to talk to me about the scope and educate me as to the scope of what violations we're talking about here—as many as you can name within the five minutes, seriously.

**Ms. Francine Manseau:** Section 8 details the information somebody needs to provide to a person before the person can give consent. If you miss something there, if you don't have one of the components, you could be in contravention of section 8.

You also need to make sure that the person will consent and that the consent shows for exactly what purpose. He's going to say he wants to have his gametes used to create an embryo, either for his own reproductive use, for a third party, or to improve...and each one of them will have to be noted, if you want. So all of those requirements and all the information would need to be there—maybe that's the part that's going to be part of it also. So if you miss something, you are in contravention, basically.

**Mr. Dave Batters:** Who is in contravention? Who do you see as the potential criminals here? You talk about criminal penalties. Who would be in contravention?

**Ms. Kata Kitaljevich:** Can I just explain? In this context, it would be the licensees, the licence holders. You're also drawing a very straight line between a contravention and criminal action.

The enforcement power is going to be entrusted with the agency, and what the agency will probably do.... We've contracted with the Health Canada inspectorate, and, as Hélène said, we have 23 inspections officers who go out and visit clinics and other sites and talk to the clinics. Right now they're doing outreach, information exchange, and things like that.

Once the regulations are in place, they'll be going out and doing inspections, and if they see a contravention of the regulations—

● (1625)

**Mr. Dave Batters:** Then it will be referred to the RCMP.

**Ms. Kata Kitaljevich:** They will be talking to the clinic. Basically, they'll be pointing out what the contraventions are, seeking compliance. It will be quite interesting to see whether they would go to the RCMP unless it were a very serious infraction. The objective is to seek compliance in the best way possible for the clients and the clinics.

**Mr. Dave Batters:** This is my last question, Mr. Chair.

What we need, though, in all our laws is consistency and uniformity in how those laws are applied. How are we going to see that in this case?

**Ms. Hélène Quesnel:** With regard to consent, section 8, what I wanted to add to that is that it will be the clinics, of course, but it will also be other individuals who currently, under provincial law, can practise in this field. We know GPs are practitioners. We know that some of the gynecologists and obstetricians are as well, so consent section 8 applies to them as well.

**Ms. Francine Manseau:** If I may add, the regulation is very clear that the person who is liable is basically the person who is making use of, say, the gametes, and that person will have to ensure that the other person who signed a consent was informed of everything he needs to be informed of. Basically it's very clear.

I think uniformity is a very good point. That's the purpose of those regulations, to ensure more uniformity across the country.

**Mr. Dave Batters:** This is my key point, though. At what point do you say, there, there, a slap on the wrist, you have to do things differently, this is terrible? And at what point are you talking about a potential $500,000 fine and imprisonment? That's something that's really important, to work out exactly how that's going to work.

**Ms. Francine Manseau:** Once the regulations are in force, everybody will have to abide by them.

**The Chair:** Thank you very much.

Ms. Fry.

**Hon. Hedy Fry (Vancouver Centre, Lib.):** Thank you very much.

I just have two questions. One is that we've never talked about fresh and frozen, but now we're talking about it. I wonder if you could clarify that for me.

Secondly, do you know when the board will be completed and decided on? Why is it taking so long? What is the criteria for someone to sit on a board that has so many complex issues facing it, ethically and scientifically? Will there be criteria, or are we going to have just anybody on this board?

**Ms. Francine Manseau:** Maybe I'll answer the first question and I'll leave the others to Hélène.

With regard to fresh and frozen, yes, that subject was raised a bit earlier. What we've said is that the legislation doesn't make a distinction between the two. Basically, if you want to use an in vitro embryo for research, there will be a condition you'll have to meet to get a licence. We don't make a distinction between the two. In any case, before issuing a licence, there's an obligation for the agency to be satisfied that there is a need to use an in vitro embryo for the purpose of the research, and if it's for stem cell research, there's also an obligation for the agency to have the consent forms of the donors of the in vitro embryo in front of them to make that decision.

This would apply to frozen or fresh embryos.

**Ms. Hélène Quesnel:** Regarding the second question, with regard to the agency, thank you for raising that question.

The selection process, in our view, has been an open and transparent one. Certainly it's a GIC appointment process, so it was widely publicized. In our view—

**Hon. Hedy Fry:** That doesn't make it open and transparent.

**Ms. Hélène Quesnel:** —it resulted in a good representation from all the areas.

**Hon. Hedy Fry:** Are there criteria other than regional ones?

**Ms. Hélène Quesnel:** The criteria stipulated in the act are that the representation on the board would be a cross-representation of the community involved in AHR and Canadians.

● (1630)

**Hon. Hedy Fry:** That's pretty vague, isn't it?

**Ms. Hélène Quesnel:** Well, clearly that's the challenge in naming this committee.

In terms of the process itself, it essentially was one of recruitment. The government advertised in the GIC publicized process. We did this process in 2005. With the prorogation of Parliament, there was a delay. We again did a wider, if you will, selection or search process this last summer, and all the candidates who had applied last year were considered in the current process. We anticipate that an announcement will be made as soon as the government is ready to do so.

**Hon. Hedy Fry:** I would hope that the people on this board will have knowledge of the issues scientifically, will have strong ethical backgrounds in terms of understanding medical ethics under the law, and that in fact there will be some consumers, some people, who will benefit from the use of reproductive technologies.

I would certainly hope that we won't have people who haven't a clue and will therefore use vague reasons and moral and other reasons for denying what is, in effect, a huge problem for many people in this country who are seeking reproductive help when they're not allowed to have children. I am hoping we will have a board and that those of us who see the board will feel comfortable that it's going to do the things it is set out to do. If that isn't so, as a physician I will be very upset and concerned.

**Ms. Hélène Quesnel:** Thank you.

**The Chair:** Thank you.

We'll go to Mr. Fletcher for five minutes.

**Mr. Steven Fletcher:** Thank you, Mr. Chair.

Thank you very much for coming, everyone.

You have put in a lot of effort, and certainly, since the regulations became public, I have received a lot of positive feedback about the work you've done.

I wonder if you can confirm for the committee that for the consultations that were undertaken, due diligence was done and legal advice was provided and everything is within the intent and expectations that were outlined when the bill was passed.

**Ms. Francine Manseau:** Basically, in terms of consultation, as I said, certainly there was a consultation period after they were tabled in the *Canada Gazette*, part I. But also, prior to that, we had a consultation document that was distributed to more than 500 people. It's even available on the Health Canada website, so whoever wanted to could have access to it. We sought input from that process and we sought input afterwards with the *Canada Gazette*, part I.

In terms of legal advice, we were working with legal advisers as we did that. As you know, before they could even go into the *Canada Gazette*, part I, they needed to be approved—scrutinized, if you will—to ensure that they would be within the mandate that was provided in the act.

**Mr. Steven Fletcher:** Some of this consultation happened under the previous government, and some of it has happened under this government. It's above any kind of repute, and everyone is satisfied.

**Ms. Francine Manseau:** Consultations started in November 2004. And in September 2005, they were again published. So it's been ongoing, I would say.

**Mr. Steven Fletcher:** Okay. It is important that these regulations pass the committee.

**Ms. Francine Manseau:** Yes, to bring the last prohibition.... That will ensure the uniformity that you raised and make sure everything is very clear and that there is what is required to respect the reproductive autonomy of every individual.

**Mr. Steven Fletcher:** I have to say that what you have done is very impressive. Again, I've heard a lot of positive feedback. I gather that your professional advice to the committee is that these are good regulations and that the committee should support them.

**Ms. Francine Manseau:** I would agree, yes.

**Mr. Steven Fletcher:** It is unanimous among the group.

Thanks. I look forward to implementing the regulations, because, as you say, it's important.

I would like to say, on a personal note, that stem cell research provides people with hope, and it's really important. I hope future governments, regardless of their political stripe, support the research that is done in this field to help improve the lives of countless people.

Thank you.

**The Chair:** Thank you.

We won't get into where those stem cells come from. That's the difficult part of this piece of regulation.

Madame Demers, you have five minutes.

[*Translation*]

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

Thank you for being here. I just learned something. I'm not very familiar with this field. The factors that concern me most are ethical ones.

I'd like to address my questions to Mr. Trevor-Deutsch.

Have you attended all the public consultations? If so, what were the primary concerns of the witnesses or groups consulted? Do you believe that Health Canada responded adequately to these concerns and that the necessary changes were made?

● (1635)

**Dr. Burleigh Trevor-Deutsch:** CIHR is a funding agency, it does not develop regulations. Therefore, we did not play a role in the consultation process.

Unfortunately, it is impossible for me to answer your question.

**Ms. Nicole Demers:** However, you did consult the documents on stem cell use and on section 8. Do these documents address certain concerns we, as citizens, should have regarding the use of stem cells?

**Dr. Burleigh Trevor-Deutsch:** Our concern is making sure that research is done ethically. We don't touch legislative issues because they are not part of our mandate. I would not be comfortable giving an opinion, as it would be my own and not that of the interested parties.

I'm sorry, but I can't answer your question.

**Ms. Nicole Demers:** Witnesses can say anything they want to, and I believe them, but I find it unfortunate that none of them can give us an outsider's objective opinion on the document. I am in favour of research and stem cells and I know how important this is, but I would have liked for someone to be able to tell us if the documents address people's concerns.

[*English*]

**The Chair:** Some witnesses will be coming forward on that at our next meeting. But your point is well taken.

[*Translation*]

**Ms. Nicole Demers:** Thank you.

[*English*]

**The Chair:** Ms. Dhalla.

**Ms. Ruby Dhalla (Brampton—Springdale, Lib.):** Thank you very much for coming before the committee today. I just want to follow up on a few questions my colleague Madame Fry asked. I believe you responded to them, but I would like some more detail.

Even though it is a GIC appointment, have names been brought forward? If so, how many names do you have under consideration right now?

**Ms. Hélène Quesnel:** Obviously people applied, and all candidates were considered. Their CVs were scrutinized and the selected criteria were applied. I'm sorry, I don't recall the number of individuals who sent in their CVs over the last year and a half or so, but there were 100, if not more. All of those individuals were considered. As I mentioned, the act stipulates a cross-representation of the community as well as the expertise, so they were all considered in that regard.

**Ms. Ruby Dhalla:** Has the board been finalized but just not announced yet?

**Ms. Hélène Quesnel:** I'm not in a position to answer that question. It's a decision that will be taken by the government. The decision will be announced when the government is ready to announce it.

**Ms. Ruby Dhalla:** Is Preston Manning one of the names under consideration to head up the board?

**Ms. Hélène Quesnel:** I'm definitely not in a position to respond to that question.

**Ms. Ruby Dhalla:** Thank you. It never hurts to ask.

**The Chair:** Mr. Batters.

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

A question just occurred to me. We're dealing with a very controversial subject, a very difficult subject, perhaps. I think about couples I know where one person has been tragically lost in an accident and the remaining spouse wishes with all—in this case—her heart that they had been able to have a baby. It was just a terrible tragedy that prevented it.

As I sit in this committee today, I've learned an awful lot about this subject, but Canadians coast to coast to coast probably don't know the regulations, the rules regarding consent, and section 8, in this very important and controversial subject—technical subject, I guess.

My question is, has there been any discussion about how we're going to educate the Canadian public regarding this? Perhaps there could be pamphlets made by Health Canada for general practitioners to have in their offices concerning questions regarding assisted human reproduction. This is something that obviously would be very difficult for someone to contemplate and plan for, but I can tell you that when it happens—God forbid that it happens and there's a tragic loss—I know people personally who wish they might have had an avenue to have a baby.

I wonder if you can answer that question about education on the subject for Canadians. Thanks.

● (1640)

**Ms. Kata Kitaljevich:** It's actually a really pertinent question, but as stated previously, one of the important roles of the agency is to provide education and outreach, and it would be probably one of the roles; this would be one of the things the agency would seriously be considering.

**Ms. Francine Manseau:** The agency is not yet established and functional, but if you look at other countries that went through a similar process and have an agency, such as the HFEA.... If people go to their website they will start to learn that there's an agency responsible for those issues. I could see something similar in Canada, where you'd have information for patients. You click on it, and there's all sorts of information provided about what you can do and so on. So there's a way of doing it.

**Mr. Dave Batters:** I appreciate that, Ms. Manseau, but what about materials? Is it contemplated that you'll perhaps design materials for physicians' offices, for general practitioners' offices? For me, that makes the best sense—to educate Canadians.

**Ms. Francine Manseau:** It's another avenue that will be looked at and could possibly be done: pamphlets that could be dropped in different places where those individuals might be seeking the information.

**Mr. Dave Batters:** Yes, or saying if they have questions, to ask their doctor for information, and that information can be made available regarding rules of consent.

**Ms. Hélène Quesnel:** This is what's been happening in other countries, where this area has been—

**Ms. Francine Manseau:** Where there are examples you can look at.

**Ms. Hélène Quesnel:** Yes, examples.

The other point, just to respond to one of your issues, is that one of the big roles the agency will have is outreach, education, engagement. We've seen in other areas of real public concern, when agencies like this have gone out and engaged individuals, that awareness rises immediately with that type of activity.

We hope the agency will be doing that, along with the members of the board. That would be one of their key roles—along, of course, with enforcement. Outreach, engagement, awareness will be key roles for the agency to take up. Like the members of this committee, we look forward to having an agency.

**Mr. Dave Batters:** Thank you very much.

Thank you, Mr. Chair.

**The Chair:** Ms. Keeper.

**Ms. Tina Keeper (Churchill, Lib.):** I would like to thank the panellists for their presentation today, because I have very limited knowledge about this area as well.

My question is about the Canadian Institutes of Health Research, the guidelines that were developed for embryonic research, and what kind of impact the regulations will have on those guidelines.

**Dr. Burleigh Trevor-Deutsch:** The CIHR guidelines predate the statute and predate, obviously, the regulations. CIHR takes very seriously its role and obligation to be subject to the law, and at present the guidelines are in compliance with the law. This is the advice we've had from Justice Canada.

This is the way things stand now. If the statute or the regulations change in a way that is inconsistent with the guidelines, of course, the guidelines will change. It's not the tail wagging the dog; the statute speaks.

● (1645)

**Ms. Tina Keeper:** Thank you.

**The Chair:** CIHR is doing embryonic stem cell research now, I understand. Is that true?

**Dr. Pierre Chartrand:** Yes.

**The Chair:** Since we're talking about consent, what consent practice are you using on those embryos?

**Dr. Burleigh Trevor-Deutsch:** CIHR established a research ethics board, an REB, the Stem Cell Oversight Committee, to ensure the research the agency funds complies with the guidelines. Within the guidelines are a number of criteria for consent. The Stem Cell Oversight Committee makes sure that consent forms and the whole protocol conform with these ethics guidelines.

**The Chair:** Are they just frozen embryos, or are you using fresh embryos in the research?

**Dr. Burleigh Trevor-Deutsch:** The Stem Cell Oversight Committee has considered protocols involving frozen and non-frozen.

**The Chair:** The embryos you're using now, do you know whether they were from frozen or from consent and fresh embryos?

**Dr. Burleigh Trevor-Deutsch:** There are a few things here. CIHR, the Stem Cell Oversight Committee, has considered protocols —

**The Chair:** I'm not interested in protocols; I'm just wondering if you're using one or the other.

**Dr. Burleigh Trevor-Deutsch:** Yes.

CIHR is not doing the research. The research is being done out there by researchers. Not only that, but the Stem Cell Oversight Committee—

**The Chair:** Yes, but do you know? You've set up the protocols. You don't know?

**Dr. Burleigh Trevor-Deutsch:** I'm sorry. Could I ask you to reframe the question?

**The Chair:** Okay.

Are you currently funding research using fresh embryos?

**Dr. Burleigh Trevor-Deutsch:** The answer is no.

**The Chair:** They're all frozen embryos.

**Dr. Burleigh Trevor-Deutsch:** Correct.

**The Chair:** That's all I wanted.

Yes, Mr. Thibault.

**Hon. Robert Thibault (West Nova, Lib.):** To clarify that same question, I understood the CIHR protocol was that surplus embryos could be used, but embryos could not be created for research. If a researcher applies and is using surplus embryos, whether or not they are frozen wouldn't be in the qualification criteria for that research funding. The question was that the embryos could not be created for the purpose of that research.

**Dr. Burleigh Trevor-Deutsch:** That's correct.

**The Chair:** Describe to me, for clarification for the committee, how you would have an embryo that is not frozen, that is created and used for the purpose of stem cell research. How could that take place?

**Dr. Burleigh Trevor-Deutsch:** That's a good—

**The Chair:** How could it not be frozen? When an embryo is created, it's for the purpose of reproduction. When it's placed into a womb, we don't know whether it's going to work or not until the next cycle. The leftover ones have to be stored until we know.

**Mr. Steven Fletcher:** How does this relate to the section?

**Dr. Burleigh Trevor-Deutsch:** Imagine a situation in which a woman or a couple were to say they were prepared to go through one cycle, but no more. Under those circumstances, all the embryos except the ones transferred into the woman would be surplus. That is an example.

I should also tell you the stem cell guidelines require all this to be explained in great detail, including the consequences of not freezing one's embryos.

**The Chair:** Yes. I was just wondering how it would take place, and you described it. That's fine.

Are there any other questions from the committee? I don't have any others here.

I want to thank you very much for coming in and giving us an overview of the piece of regulations, section 8. It was very interesting. Thank you very much for your presentation and for the questions. Next time we'll have some third-party, shall we say, individuals coming in to address some of the problems of Madame Demers. Thank you very much for your attention.

For the committee's information, we were to look at the steering committee's report. I'm wondering if we should leave that to the next meeting, since three of the steering committee are not here. I'm the only one here, and there's some controversy. Why don't we leave that until next meeting? Is that fair?

**Some hon. members:** Agreed.

**The Chair:** The meeting is adjourned.

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