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Chair

Mr. Rob Merrifield

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● (1545)

[*English*]

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

I want to thank the witnesses for coming and testifying before the committee. This is actually a reacquaintance of some old, familiar faces, and I understand you're probably getting together at the back of the room talking about this issue. We spent three years on it. It seems like four lifetimes, three years.

I certainly appreciate you coming back as we deliberate about the section 8 regulations we have before the committee right now. We do have some questions on that, and I'm sure you have some input that would help the committee as we take a look at these.

We have with us, from the University of Alberta, Timothy Caulfield; from Dalhousie University, Françoise Baylis; from the Society of Obstetricians and Gynecologists of Canada, Dr. André Lalonde; and from the Canadian Fertility and Andrology Society, William Buckett. It's good to have you here. Thank you for coming.

We'll start with Mr. Caulfield. The floor is yours.

Mr. Timothy Caulfield (Professor, Health Law Institute, University of Alberta): Thank you very much for this invitation to come and speak today. This is a topic I have great interest in and have had the opportunity to examine for some time. Also, it's nice to see that we're to the regulation stage.

My comments are brief. In general, I support the regulations and applaud the emphasis on autonomy and the goal of ensuring that patients' interests are protected. This is something that's noted throughout much of the Health Canada documentation and the other documentation that has supported this legislation and the regulations.

My comments are rather narrow, focusing on part 3, which is the research section, and explore the implications of limiting the right to withdraw. More broadly, this analysis is meant to serve as sort of an example to inform the question of whether the rationales for the regulations are sufficient and clear enough to justify varying from well-established consent norms.

The requirement to obtain informed consent in both the clinical and research setting, as everyone here knows, has existed for virtually decades, and it flows, in part, from a post-World War II emphasis on autonomy and human rights. I think this tremendously strong consent norm is informed by research ethics policies here in Canada and internationally, provincial legislation, and the common law, including negligence and fiduciary law.

The regulations really, in many ways, add little of substance to the standard of disclosure. We're not here to talk about in section 8 regulations, really, the standard of disclosure, but they do, however, help to create, at least in some areas, a clear national standard that must be met by all. They also provide the agency with the ability to monitor consent practices, which I view as a good thing, and they create a degree of certainty about consent responsibilities and rights of the various potential donors and third parties.

To be fair, not all agree with how those rights have been assigned, but nevertheless the fact that they are creating certainty is valuable.

One can question whether the creation of this unique consent regime is justified in this context, and some commentators have questioned this. In other words, are there unique risks and social issues that require the creation of this framework? Is the possibility of a lack of conformity to existing norms especially high in this context, particularly when you compare it to other areas of clinical research practice? As noted on page 4 of the government's background material, there's really little empirical evidence to support the contention that existing norms would not be complied with.

Having said that, on a practical level and subject to the comments I'm about to make, I don't think this unique framework and the policy issues around the creation of a unique framework are major policy concerns. For the most part, the consent regulations should help to enhance a culture of consent, which can only be viewed as a good thing. Moreover, the social controversies that have surrounded this entire area, and the tremendous importance of maintaining public trust in this area, would seem to support some form of adoption of these regulations. This has again been noted by several commentators.

The long-term legitimacy of the regulations would benefit from some more explicit clarity as to why a unique regulatory regime is required in this area, and I think that's doable. The rationales for the approach should be clearly articulated and reconciled with existing consent and research ethics norms. I'd like to give one example of what I mean by that, and it's in the area of the right to withdraw.

One of the most fundamental consent and research ethics principles is that patients and research participants retain the right to withdraw their consent at any time. The right to withdraw is rarely qualified in guidelines and extends to identifiable health information and linkable tissue removed from the body. We see this again articulated in numerous research ethics guidelines by the Supreme Court of Canada, etc.

Consent to research is not a binding contract. Research participants retain the right to change their minds without repercussion, regardless of what they agreed to at the start of the research project. It stands as a basic tenet of research ethics. It has been articulated in numerous documents, such as the Declaration of Helsinki. The proposed regulations before us significantly limit the right to withdraw to when a researcher acknowledges in writing that the embryo has been designated for research.

From the perspective of the researcher and for the purposes of administrative efficiency, it makes sense to limit withdrawal. It would be tremendously disruptive to have consent withdrawn from research after it has commenced. But as a general rule, the goals of research and administrative efficiency do not supercede individual rights. In fact, it's rare to find that happening anywhere in research ethics policy. That point has been enshrined in national and international policy statements throughout the world. I can give you various examples, but article 5 of the Declaration of Helsinki is one that's often cited to support that contention. In analogous situations, such as in biobanking projects where people donate genetic material, most guidelines explicitly support an ongoing right to withdraw at any time. A good example of that is the big U.K. biobank project.

If emerging stem cell policies are to deviate from this well-established tradition—and to be fair, almost all guidelines around the world deviate—particularly in regulations supported by legislation, then the special circumstances warranting such deviation must be shown to exist. In the context of stem cell research, there are reasons why this right might be viewed as particularly important. The research remains controversial, and I think it's going to forever remain somewhat controversial. It involves highly contested and strongly held moral positions, and in such an environment, ensuring donor wishes are respected seems especially important.

In addition, consent will be obtained in a clinical setting where donors are involved in sensitive medical procedures. With the passage of time and distance from the clinical encounter, donors' opinions may change. We've seen this, and some research supports that this may happen. In addition, one of the most important points is that stem cell lines are capable of revealing health information about donors. The stem cell line created from an embryo can be viewed as an extension of the donor's health record—DNA from the gamete donors or the embryo donors—something that patients clearly retain the right to control traditionally.

● (1550)

I encourage the standing committee to explore the justifications for the position on the right to withdraw and use this as a springboard to perhaps explore some of the other presumptions underlying the regulations. This exploration should start with the presumption that research participants retain the right to withdraw, and any variation from this norm should be as minimal as possible. I would be happy in the question period to explore some of the options I've been thinking about.

There are many other issues you could use. You could do a similar analysis severing the rights of individuals who donate to third parties. If you were a gamete donor and you donated an embryo to a third party, you would no longer have any interest in controlling that embryo and its disposition. That embryo might in fact create linkable cell lines that had the donor's DNA.

The issue of using a blanket consent in this context could also be seen as somewhat controversial as well as the requirement for written withdrawal. I think there are sound justifications that could support all those positions, but they need to be more clearly articulated.

In closing, I would like to set out where I receive my funding. I think it's important for the standing committee to know that I do research in this area. My research is supported by the Stem Cell Network, the Alberta Heritage Foundation for Medical Research, the CIHR, and several other NCEs, such as AFMNet and AllerGen. I also receive funding from Genome Canada.

I would like to thank you for this opportunity, and I look forward to your questions.

The Chair: Thank you. I think you've stimulated a number of them. We'll get to them as soon as we're through the testimony.

Françoise Baylis, the floor is yours.

[*Translation*]

Dr. Françoise Baylis (Professor, Department of Bioethics, Novel Tech Ethics, Dalhousie University): I'd like to thank you for having invited me. It is a great pleasure to be here with you today. I hope to have the opportunity to come back when you will study other parts of this legislation.

I will make my presentation in English. However, I drafted a text that is available in French and in English. Moreover, I am ready to answer your questions in either French or English.

● (1555)

[*English*]

I do have a text that's available to you. I will not be following it tightly. There's much more there than I could possibly read in the time that's available to me. I want to highlight a couple of the points, but I thought it might be helpful for you at a later stage to go back to see that.

In the context of the issue of consent, I would like to suggest that there are a number of pivotal questions one needs to attend to, and from my perspective they are questions about who should consent on the basis of what information, when should this consent be requested and by whom, and what should be the limit on the right to withdraw. I'm going to speak very briefly to each of those, and as I said, we'd be happy to answer questions later.

With respect to who should consent, I'd like to say that it's very clear, both in the legislation and the regulations, that attention has been paid to the importance of ensuring that both the donors of the human reproductive material, the gamete providers, are consenting, as are the embryo donors. They may or may not be the same persons as when donor gametes are used, and I think the regulations pay good attention to that, something that ought not to be changed. Some people might argue that this consent process is complex by virtue of the many people who might have to be involved, but I think it's the right thing to do.

Having said that, I do think that for me, as somebody who is reading both the bill and the regulations, I would say that I found it surprising not to have a clear definition of the donor of human reproductive material and the donor of human embryos in section 1 on “Interpretation”. Now, to be fair, the definition of a donor of human reproductive material can be found in the bill, and possibly from a legal point of view you don't repeat that, but the bill does explicitly say that it is the regulations that will define who the donors of embryos are. The regulations do in fact do that, but they do that in section 10, rather than in section 1, which is the set of definitions that are set out at the beginning.

The reason I think this is important is that one of the terms that is defined is the term “third party”, and “third party” refers to the embryo donor. We don't know who the embryo donor is until section 10, much later in the regulations. So it's a small point, but I think there would be value in being clear about those terms in the definitions section, and then throughout, never to use the term “donor” alone, but rather to be clear about which donor we are speaking about at which time.

My second point is, I think in the regulations, at least for someone like me who's been following this relatively closely, it's quite clear who the donors can be when we're speaking of the embryo donor: they're the persons for whom an embryo has specifically been created. I do think, however, that there are two possible scenarios where there might be a misunderstanding in terms of its actual application in the real world, and I wonder whether there's room for some precision here.

As I said, it's clear the donors are the persons for whom the embryos have been created. However, I think it's conceivable that one could imagine a clinician-scientist who is using human reproductive material to create embryos in accordance with the legislation for one of the legitimate purposes, who, after having used that material perhaps for educational purposes, now actually has an embryo and is thinking that they could become an embryo donor rather than having to discard this material. As I said, I think the regulations are clear on this from a strict point of view. I think there needs to be a fair bit of education to understand that.

The other point where I think this comes into play, where again you may see the clinician or the IVF clinic thinking they could be a donor, is in the context of frozen embryos for whom the clinic has lost contact with the couple. We have a number of embryos in storage currently in that kind of situation. Is it possible that the IVF clinician or the clinic might see themselves, then, as legitimate donors of those embryos rather than having to discard them? I think there's room for some precision there.

The second point I'd like to speak to very briefly is what information should be disclosed to those from whom consent is requested. I think something very positive and innovative has been done with the regulations. They have asked for written documentation confirming disclosure with respect to the purposes for which the embryos would be created or the material would be taken, and also disclosure with respect to the rules for withdrawal, and that is separate from the consent document. That's an innovation that I think is well warranted and important.

The only caution I offer in my remarks is that one not unwittingly perhaps contribute to the mistaken perception that those are the only two required elements of disclosure. Disclosure is far more complicated than those two aspects, and I just worry that one might think that's all that is needed to be disclosed prior to moving on to the consent stage. Again, I applaud that move. I think it's an important set of documentation to ensure that there really is informed consent.

The third point is, when should consent be requested? This is the point that I probably feel most strongly about, and if you will permit, in order that I don't make a mistake, I will actually read that one part of the presentation.

● (1600)

I say here:

> Issues of critical importance with consent to the research use of in vitro embryos are: i) the timing of the original consent; and ii) the need to reaffirm the original consent at the time of anticipated research use (owing to long delays).

This is a key aspect of the 2002 CIHR guidelines, which are incorporated into the legislation. They were introduced specifically to give positive effect to the right to withdraw. This does not appear to be reflected in the draft consent regulations.

Recently, debate has centred on the research use of fresh versus frozen-thawed embryos. In discussing the withdrawal of consent, the draft consent regulations foresee the future research use of cryopreserved embryos. Therefore, there are repeated references to the beginning of the process of thawing—this is in regulations 12 and 14—but further clarity is required on this point.

My colleagues and I have argued that the research use of embryos should be limited to frozen-thawed embryos or fresh embryos not suitable for transfer. This is because donating healthy, fresh embryos created for reproductive purposes to research is not in women's self-interest. If there are further IVF attempts, donating fresh embryos to research can, one, decrease the chance of pregnancy and child-bearing; two, increase the psychological stress experienced as a result of IVF; three, increase the number of risky or painful procedures; four, increase the social disruption that IVF causes; and five, increase the financial burden of infertility treatment. Moreover, donating fresh embryos to research is not in women's other regarding interests.

The important point here is that in 2005 the CIHR guidelines were changed. The original presumption was that non-transferred healthy embryos typically would be cryopreserved for later reproductive use. Instead, the guidelines explicitly endorsed the research use of fresh embryos. This change was made despite evidence documenting the fact that it is easier to derive human embryonic stem cells from frozen-thawed embryos than from fresh embryos.

In the 2002 CIHR guidelines—and this is important because it is the 2002 guidelines that are incorporated into the act—it was understood that if embryos were truly being created for reproductive purposes, as required by the act, then typically, embryos not transferred in an initial cycle would be cryopreserved for such future use. Therefore, embryos available for research would be cryopreserved embryos.

Here I want to quote to you from the Ethics Committee of the American Society for Reproductive Medicine:

> Using only frozen embryos for research ensures that time passes between the creation of embryos for conception and their donation for research. Still, it is reasonable to expect questions eventually to arise about the donation of fresh but supernumerary embryos. Donation of fresh embryos raises the possibility that a physician might induce a patient to allow insemination of extra eggs so that they may be donated for research. Moreover, this increases the chance that decisions will be made quickly and later regretted by couples. Without evidence that fresh embryos are significantly preferable to frozen embryos for ES cell use, it is appropriate to use only spare embryos that have been frozen.

The draft consent regulations address the issue of research involving fresh versus frozen embryos only indirectly in the discussion of withdrawal. More clarity is needed on this contentious issue. Consistent with the 2002 CIHR guidelines, embryo research should involve the use of frozen-thawed embryos. The draft consent regulations should also require a reiterated consent at the time of anticipated research use owing to anticipated long delays between the time of original consent and research use.

Below there—and I'll leave that for you to look at later—I've just made some suggested rewording that would be consistent with the recommendation.

I'll move very quickly and briefly to my last two points on who should request the consent. I find that the consent regulations are silent on this matter and that it would be helpful for there to be some direction, largely because there's the potential for conflict of interest between the perspective of the clinician and the perspective of the research scientist.

● (1605)

Finally, I would like to turn to the point already addressed by Mr. Caulfield: what should be the limits on the right to withdraw? Unlike Mr. Caulfield, I actually am pleased with the section on withdrawal with respect to embryo research, or items 12(c)(v)(A), (B), and (C). In here it says very clearly that in fact one can withdraw up until "the latest of the following occurrences". And the latest of those occurrences is, in here, "the creation of a stem cell line".

That does mean that up until the point at which the stem cell line has been created, the person who has provided the embryos or the reproductive material retains the right to withdraw. I do think it would be very difficult to make the claim that one could withdraw one's gametes or one's embryos once they don't exist any more by virtue of the fact that a stem cell line has been created.

That said, I am pleased with the withdrawal requirements with respect to research. I actually do find them to be problematic with respect to the use of third parties for reproductive purposes. Very briefly, the regulations there require that up until the point at which the person provides a written statement to the effect that the materials have been designated to them, the donor loses the right to withdraw.

My recommendation or suggestion is that this is far too early in the process. The right to withdraw needs to be protected to a later stage in that process. At the very least, it ought to be protected until such time as the materials have been received, later than the point at which they may have been designated.

The example I provide here is of a woman who may be willing to donate her eggs to a sibling. She couldn't withdraw this if she had already accepted a written document saying they had been designated to her sibling. That to me seems deeply problematic in the context of the material perhaps not even being in existence.

The last point I would like to make is that there's very little data available about the incidence of withdrawal from embryo research. However, what data there is suggests that with time and distance from IVF clinics, many women do not act on their original consent to donate excess in vitro embryos to research. This is a significant empirical finding that underlines the importance of providing women and couples with time to reflect on the options before the disposition of embryos.

Klock et al. reported that 88% of couples who initially decided to donate their frozen embryos to research changed their minds. More recently, in a 2006 survey here in Canada at one of the IVF clinics, Nisker et al. reported that 45% of couples who had specifically designated their frozen embryos for donation to research changed their minds.

My point is that people need the time to make the decision, and they need to reiterate that consent. If they don't, that's the time at which they're telling you, with that distance from their infertility treatment, that they really don't want to participate in that research. I think it's absolutely important that we protect that right to withdraw.

Thank you.

The Chair: Thank you very much. You've created even more questions.

Let's carry on with our next witness.

Dr. Lalonde, the floor is yours.

Dr. André Lalonde (Executive Vice-President, Society of Obstetricians and Gynaecologists of Canada): Thank you very much.

This presentation will be brief. I represent obstetricians, gynecologists, and family physicians in Canada. Our members are responsible for the care of the majority of pregnant women in Canada.

The Society of Obstetricians and Gynaecologists of Canada, or SOGC, is committed to promoting free and informed choice. We consider that consent and the right to withdraw consent should be the operative principle at all times and in all issues of gamete and embryo donation.

The SOGC endorses the requirement for two written documents in relation to the consent process. The first document should be a disclosure document attesting to the fact that there was full disclosure about the current options for the use of human reproductive material and human in vitro embryos. It should also include the rules for withdrawal of consent. A second document should be a consent document used to record consent, setting out the specific consent of individuals involved.

The SOGC is of the view that the withdrawal of consent must always be possible and believes the donors of human reproductive material should be allowed to change their minds, including where a third party acknowledges in writing that the material has been designated for their reproductive use.

The SOGC is concerned that there is a possibility that donors will be unable to withdraw their consent. General principles of consent to treatment require that physicians recognize that withdrawal of consent is a legitimate request at any time. No physician would force the woman to continue with ovarian stimulation. The SOGC believes clinicians should honour a woman's choice to withdraw her consent and should not ignore her revocation of consent.

In this document we do not comment on the debate around fresh and frozen embryos, as we believe this issue will probably come up in another part of the regulations. We feel that today is specific to consent.

In conclusion, the SOGC continues to support the Assisted Human Reproduction Agency of Canada as well as the Assisted Human Reproduction Act. The SOGC remains in agreement with the proposed regulations.

Thank you.

● (1610)

The Chair: Thank you very much. We'll move on to Dr. Buckett for his presentation.

Dr. William Buckett (Chair, Government Relations Committee, Canadian Fertility and Andrology Society): Thank you.

I'd like to thank the committee for inviting me here. I'm speaking on behalf of the Canadian Fertility and Andrology Society. The CFAS provides the leadership, we believe, in reproductive health. We include physicians and laboratory staff, nurses, psychologists, and counsellors, as well as patients, patient support groups, and so on. Therefore, we represent the stakeholders who are the providers of infertility care, as well as the recipients of infertility care.

With regard to the current proposed regulations, without reiterating what Dr. Lalonde, Dr. Caulfield, and Dr. Baylis have all said already, we broadly agree with the proposals. We feel that they reflect current best practice in IV centres and ART centres in Canada at the moment, and therefore, with the exception of some concerns about the language of what is actually written, we tend to support these.

Thank you.

The Chair: Thank you very much.

Just for the committee's information, Ms. Françoise Baylis has to be out of here by five o'clock, so if we have questions for her, we would want to do that as soon as possible. Also, at the end of the committee, we'd like to go in camera for some quick business on childhood obesity.

With that, we have Ms. Fry for ten minutes.

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

I just want to ask one question. Does anyone, and can anyone, answer why choosing the members on this board is taking such a long time? I understand there is a meeting happening in Vancouver very soon and you don't have members of the board ready for the meeting. So perhaps someone has some answers for that.

Secondly, on the issue of reiterated consent, while in theory I agree with it, how practical is that? If a couple had years ago given their consent, and then, as you say, later on they decided not to bother, they adopted some kids, and they don't even want to be involved in this anymore, they may actually say, “No, I don't care, throw it away, I don't want to reiterate my consent”, because they've moved away and they've moved on, and they don't want to be reminded of that time. So while I understand your theory behind it, what are the practical ramifications of that reiterated consent that could occur a long time after?

Dr. Françoise Baylis: I think that's an excellent question, and Dr. Nisker and a number of his colleagues at the University of Western Ontario have in fact done a study. I referenced that. It's reference 14. It was published this year, in 2006. It involves a scenario whereby, in conjunction with their research group, they sent questionnaires out and letters explaining that this was a research project. They wanted to know if these people were still willing to have the embryos they had previously said could be used for research purposes.... I don't have all the numbers in my head for you, but what I can say is that 55% of those who responded said, “Yes, we really stand by the consent that we've given you, and it's fine, go ahead, use those embryos for research.” Forty-five percent said, “No, we've changed our mind. We don't want you to do that.”

So does it require an effort on the part of the clinic? Absolutely. Is it important in terms of making sure that people are not subtly, and I do mean subtly, coerced into saying yes? I think that's important, because IVF is a very emotional endeavour for people who participate. In that context, it's clear that there is lots of documentation about the psychology of this. People are trying to please their clinicians. They are dependent on their clinicians for access to treatment, and they do say yes when, with sober reflection or no longer being in the program, at least 45% are willing to change their mind.

● (1615)

Hon. Hedy Fry: Did the 45% who said they would change their mind, or who changed their mind, give you the reasons for changing their mind, and did they understand what would happen to the frozen embryos if they have changed their mind, that it would be discarded, destroyed, etc.?

Dr. Françoise Baylis: Yes. There were very detailed documents. I was not part of that research, but I did see drafts of those documents and they were quite detailed in terms of explaining the consequences of the different decisions. It was in fact to find out whether this is doable, and if so, what kind of response rate you would get. This is a clinic that has a number of embryos in storage because they've not been using them for teaching or research purposes in other contexts. It is doable, and it's recent Canadian data.

The Chair: Professor Caulfield.

Mr. Timothy Caulfield: That is obviously an excellent question. I actually have the study before me and would be happy to leave it with the committee. It's a valuable study, done by Jeff Nisker and his colleagues. I do want to clarify what it was: 45% was a non-response. So we don't know what they would have said. It was kind of like a survey. Still, I think Professor Baylis's points are important.

In some respects, you answered your own question by saying that people move on in their life. Their perspectives may change. That, in many respects, is the very reason you need to go back and reconsent.

I think, really, if you look at other ethics contexts, it's standard practice to reconsent in these kinds of situations, whether it's biobanking or other kinds of clinical research. So I think it can only increase trust and increase certainty in the consent process.

The Chair: Go ahead, Dr. Lalonde.

Dr. André Lalonde: I tend to put, as we say in French, a *bémol* on this issue, because, as he said, 40% of the people could not be reached. When people move from province to province, etc., we know that in relation to cervical cancer and other issues, it's nearly impossible to reach them. If we put this into the law, it is going to add to the cost of IVF, and at what difficulty? How are physicians going to reach somebody who moved eight years ago?

I have some questions on that. I think the regulations, as they are, are better; it's a more general regulation.

Hon. Hedy Fry: Thank you.

The Chair: Madame Gagnon is next.

[*Translation*]

Ms. Christiane Gagnon (Québec, BQ): Thank you for having studied this issue, Ms. Baylis, Mr. Lalonde, Mr. Caulfield and Mr. Buckett.

I would like to ask Ms. Baylis a question, but you may all share your thoughts on the subject with us.

Do you not think it would be easier, rather than analyzing one regulation in isolation, like section 8, to consider all of the regulations together? You say that in section 8, the user is not defined clearly enough. We would have to take a more comprehensive look at it. Why are we only studying section 8 today? The associated regulations do not give us a general view of the intentions. If the rationale is not clearly set out in section 8, would it not have been preferable to study all of the regulations together?

Dr. Françoise Baylis: Everyone would like to have an overview, but several of us are still aware of the fact that there have already been long delays. From what I understand, those working on the drafting of the regulations must do so as quickly as possible. If we had to wait until everything was ready before moving forward, we would have to wait for years and years to come.

I understand very well what you are saying, and in theory, I agree. However, for practical reasons, we cannot wait. We really must move forward and make sure that we are respecting the intentions expressed by Parliament when the law was enacted in 2004.

Dr. André Lalonde: I agree with Ms. Baylis and I would add that if the agency had really been launched and the people appointed who should have been, much more progress would have been accomplished in these areas. The people from the Department of Health have done a lot of consultation with the associations, ethics groups, etc. These documents are the subject of a broad consultation. The methodology is good.

On the other hand, to answer Ms. Fry, I would say that it is rather urgent that the agency be able to start its work.

● (1620)

Ms. Christiane Gagnon: If I understood clearly what you said, Ms. Baylis, a high percentage of people withdraw their consent as far as gametes or embryos for research are concerned. I would like to understand what their motivations are.

I can understand that this exercise involves a great deal of emotion and that people do not necessarily have the same perception before as after. Would one of the reasons why people withdraw their consent perhaps be that the context from which they gave it and the context in which they withdraw it are not the same, and that furthermore, that consent has become the subject of discussions? According to the clinician or doctor, is a rather moral approach not taken? We know that not everyone agrees on research involving embryos. Is it possible that the clinician's personality has an influence on these events?

Dr. Françoise Baylis: I think that everything you just said is quite correct. It depends on the people concerned, whether it be the two partners in the couple, the clinicians, or yet again on the spirit of the times. The scientific possibilities have changed, and permission is no longer granted for the research. We're talking about stem cells and we want to say yes to the research. It can work both ways. All we know—and this is very well documented—is that over time, people change their minds as to what the definition of an embryo is. At the outset, perhaps it was considered as tissue, perhaps later on, it is perceived as an unborn child, in a frozen state, which could be the brother or little sister of the child that is already born. Perhaps there are other factors that are taken into account, but what we know very well is that people change their minds, and the problem is that when you get the first consent, when the period of treatment is just beginning, it is highly unlikely that the couple can be told what the goal of the research will be.

One of the comments I make in my brief is that it is not enough to talk about research in general, because the participant may want to help advance research on infertility, and will agree that their embryos be used for such research or even for stem cells. But if told that the objective is to do research on abortion, participants may very well decide that they do not want their embryos to serve for that type of research. Therefore, very often, it is the objective of the research that will determine whether the person will support the project or not. If we look at the current guidelines on research involving humans, not only embryos, it states very clearly that the person must understand the goal of the research before granting his or her consent.

In this context, participants cannot give their consent unless they agree with the project, accept the goals of the project ,and donate their embryos. That is why I am emphasizing the fact that when the first consent is given, where research is concerned, the information available is insufficient. Whereas in the other cases, if the intention is to donate the embryos to another couple, the person understands what that means, she understands the objective. Things are different where research is concerned. That must be specified, in my opinion.

Ms. Christiane Gagnon: But how could we specify that?

[*English*]

The Chair: Mr. Caulfield would like to answer as well.

Your time is up, but we'll allow Mr. Caulfield to answer.

Mr. Timothy Caulfield: I'd again like to endorse the idea that this consent should be as specific as possible. I agree with Professor Baylis on that point. But the question is on whether or not section 8 is the appropriate place to talk about the substance of consent.

I would like to read from the study, because Dr. Nisker's study has received a lot of attention here today. Let me read exactly what the conclusions were.

Of the 40 couples contacted, only 22 agreed to donate embryos to stem cell research. One couple no longer wished to donate embryos to research, so that was one explicit “no”. One package was returned as non-deliverable. There were no responses received from 16 couples, and we don't know what was behind those 16 couples.

Dr. Nisker does a good job of explaining why he thinks they can read some interpretation into those 16 couples, but I think you also need to be careful not to over-interpret the data. It's an interesting study.

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

Mr. Steven Fletcher (Charleswood—St. James—Assiniboia, CPC): Thanks, Mr. Chair.

Thank you to all the witnesses for coming today.

One observation is that we are here to talk about section 8 and section 8 alone. I'm getting the sense we may be drifting a little away from that.

A concern was raised by Ms. Gagnon, and I can assure you that the department is moving as fast as possible in a very difficult area.

It's the same as the concern you raised, Dr. Fry.

My first question is to Timothy. I understand the amendments to the CIHR guidelines were made to clarify that both non-frozen and frozen embryos could always be used in stem cell research provided that consent practices are followed. Are you satisfied this does not constitute a change in the consent provisions of the act?

● (1625)

Mr. Timothy Caulfield: As was also highlighted earlier, I think there's a very interesting conflict with the 2002 guidelines, which are explicitly referenced in the act. I believe it means the 2002 CIHR guidelines are the guidelines that are relevant to the legislation. It creates a very interesting legal dilemma because you have a set of guidelines that were created by a relatively ad hoc committee, which both Françoise and I sat on, and became incorporated into law without the knowledge that it was in fact what was going to happen.

In the document that we both participated in, we said it was a living document and that they may be changed in the future. Nevertheless, the legislation explicitly references 2002. If you move forward to the amendments that occurred, it clearly seemed to try to clarify that you can use fresh embryos.

I was not closely involved in the amendments, but they seem to be a clarification on the use of fresh embryos. Is it appropriate? Is that what you're asking me?

Mr. Steven Fletcher: I want to get your view on the fact that there has not been any change to the consent provisions of the act as they constitute or reflect the CIHR guidelines.

Dr. Françoise Baylis: I think I can speak to that on two points. There were the 2002 guidelines that came out. The guidelines were updated in 2005. They were also updated in 2006. In 2006, they returned to some of the text of 2002 and explicitly acknowledged that it is because it is a 2002 guideline that it had been incorporated into legislation. So there is a recognition on their part that at least some of the changes they tried to introduce would not be consistent with what would be required legally. So there have been changes in both directions.

On the point you're making with respect to fresh and frozen, there is, in my view, now an inconsistency that has been introduced into the CIHR guidelines. They still require a reiterated consent, which doesn't make sense in the context of taking fresh embryos. I've also suggested that there's data from other countries suggesting that there is no obvious reason to do that, and I have other documentation here that shows it's actually harmful to women to have made this change. I'm actually disappointed in the change, but there is no course of law for it.

Mr. Steven Fletcher: I'll have to take exception to the point.... It's my understanding, and that of the government, that CIHR has put systems in place to ensure that the research it funds meets the highest ethical standard, and certainly the 2002 stem cell guidelines, as they're commonly known, meet that high ethical standard. You're nodding your head, so I assume you agree with that.

Dr. Françoise Baylis: I'm in full agreement with the 2002 guidelines. I have problems with the changes that have been made since then, from an ethics point of view.

Mr. Steven Fletcher: Okay.

Dr. Françoise Baylis: But I'm in full agreement with the 2002 guidelines, and in fact I'm suggesting a return to that. I'm suggesting that it be clear with respect to that, that the assumption was that you would take cryopreserved embryos because all fresh embryos would either be transferred to a woman, because doing so would be in her best interest, or cryopreserved for her best interest.

Mr. Steven Fletcher: That's from an ethics point of view, but the law and ethics are sometimes not consistent, and ethics depends on who you talk to, but the guidelines are—

Dr. Françoise Baylis: That's not the case with respect to the 2002 guidelines. With respect to the 2002 guidelines, which are referenced in the act, there is the presumption that you're using cryopreserved embryos. In 2005...which is not referenced in the act, there is an explicit statement that you can use fresh and frozen.

● (1630)

Mr. Steven Fletcher: Okay.

Dr. William Buckett: Excuse me. Can I just make a very quick point?

The Chair: Make it a quick point.

Dr. William Buckett: There are certain cases in which you may have embryos that are not good enough to freeze—in other words, they're not going to survive being frozen and thawed—but they are not going to transfer either. Therefore, the idea that it's in the best interest of the patient to either transfer the embryos or freeze them is not actually the case. Yes, we transfer the fresh ones—one or two or three or whatever—and freeze some if we can, but there are still going to be other embryos that would otherwise be destroyed.

The Chair: Okay, fair enough.

Ms. Priddy, you have five minutes.

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

I want to go back to what you said was the original consent percentage. So it wasn't really that 45% of people did not change their mind; it was, if you will, that there was a non-return.

Mr. Timothy Caulfield: That's correct.

Ms. Penny Priddy: That was not my first understanding of it. Thank you.

Secondly, in the area of who should request consent—which does cause me some particular concern in terms of who actually requests consent—do you have a recommendation? It says here that members of the research team are.... One would suggest the members of the research team have a bias. That's fair enough. They're researchers. But would anybody want to comment on whether it should be some more neutral third party?

Mr. Timothy Caulfield: I think this is a very interesting question and again one that has immediate relevance. The interesting question is whether it falls under our section 8 analysis. Having said that, I'd be happy to offer an opinion.

I actually think the clinician who is uninvolved with the research may be an appropriate party. Certainly, legally, I think they're an appropriate party, because the consent will be obtained in a clinical setting over which the clinician has legal responsibility, whether that is for research or clinical activities. It's important to note that the clinician should not be the researcher in that sense.

The other reason a clinician might be a good person to play this role is that they have other obligations toward the patient. They have fiduciary obligations that exist for the exact purpose of dealing with potential conflicts of interest.

One could argue that in other research settings, be it cancer research or other clinical research settings, the potential conflicts may be even more profound. I'm not saying there aren't issues in those contexts, but in those situations, we let the clinician get consent. Some would argue that they're the appropriate person to get consent because they know the patient well and they have these other legal obligations.

Ms. Penny Priddy: I think I asked this question the last time, but I got an answer I didn't understand, so I'm going to try again. It may sound like a foolish question, but when there's a request made for organ transplants, or organ donation, if you will, is there any connection between that and...? In many circumstances, if people are dying, embryos would not be appropriate for donation, but in some cases they might be. Is there any connection between asking around organ donations and asking around embryos? Are they part of that?

Dr. Françoise Baylis: My understanding is that it's dealt with in part 2 of the regulations. The expectation there is that you would have similar kinds of expectations in terms of proper disclosure, full understanding of the rules with respect to withdrawal, and very clear mechanisms as to how the withdrawal would have had to take place prior to it being acted upon.

Ms. Penny Priddy: Right, but is it separate from the organ donation?

Dr. Françoise Baylis: That's my understanding. It would be specified, because you actually have to have a written statement that you've been told about these five possible uses and that you understand these specific rules for withdrawal. It would be a separate consent. It wouldn't be what you sign on the back of your driver's licence, such that it would pick up your gametes.

Ms. Penny Priddy: Thank you.

Lastly, who makes the determination, and how would the determination be made, or by how many people, that an embryo is not feasible for either freezing or implanting, but that perhaps it is suitable for research? I'm trying to look at what the backups are for that to ensure that it's used properly.

● (1635)

Dr. William Buckett: That decision would be made primarily by the embryologist, who studies the quality of an embryo in a laboratory to determine whether it would be able to survive being frozen and thawed. The embryologist, in consultation with the clinician and the couple whose embryo it is, will then make a decision as to whether that embryo should be frozen, if that's what they really want, even though they're aware that it might not survive being frozen and thawed, or whether it should be destroyed or be considered for research.

Ms. Penny Priddy: The professional recommendation comes from the clinician and the embryologist.

Dr. William Buckett: Yes.

Ms. Penny Priddy: Thank you.

Dr. Françoise Baylis: If I can add to that, one of the things that's absolutely true—and there are a number of us funded to do research around the concept of the healthy embryo, what constitutes a healthy embryo, and what is an embryo that is or is not suitable for freezing or transfer—is that we find that because it is too much dependent on the expertise of the clinician or the embryologist, etc., you do get variety in terms of how you go about thinking and scoring when you're not looking at a genetic anomaly but are looking at some metabolic or other considerations.

One other important thing is that there was a study done by Tekpetey, presented in 2003. If I'm not mistaken—and you might know this—I think he won the prize that year, showing that what would be described as ugly embryos—morphologically, they're not very nice—turn out to make beautiful babies. He actually showed that some of the criteria that are used to make those determinations may not be as tight as we might have thought.

Ms. Penny Priddy: That's the part I was worried about.

Thank you.

The Chair: Thank you very much.

Mr. Batters for five minutes.

Mr. Dave Batters (Palliser, CPC): Thank you very much, Mr. Chair. I want to thank all the witnesses for being here today to shed some light on this important, amazing, and somewhat controversial topic. We certainly appreciate all their expertise.

I have two questions, Mr. Chair. One is fairly short, and one is a little lengthier. I'm going to ask both my questions and give all the witnesses a chance to respond if they so wish.

First, at this time, how is consent obtained from gamete and embryo donors? Is there a standard procedure in place across the country?

The second one is a multi-part question. Are you satisfied that you were given an opportunity to comment on the proposed regulations under section 8? Were your comments or concerns addressed?

I'd like you to use the five minutes. For those of you who feel changes need to be made to section 8 of the assisted human reproduction regulations, this is an opportunity for you to reiterate the need for certain changes.

Thank you, Mr. Chair.

Mr. Timothy Caulfield: We're actually in the process of doing a study on how consent is obtained in the context of embryonic stem cell research. I can't speak to how it's obtained more broadly, but we tried to explore exactly how consent has been obtained in the past for those researchers and those clinics that are actually involved in embryonic stem cell research. Generally, what has happened—I know Françoise can speak to this too—has been relatively ad hoc. In part, that's because the regulatory environment has been in flux and the regulations have been in flux, and I think a lot of the research community is still learning about what's going on.

Having said that, it's a relatively small research community. This is a small, qualitative study that we've been doing, and we were actually surprised how few researchers are actually involved in embryonic stem cell research in Canada. Counting principal investigators, you're looking at three or four individuals. You're not talking about a big community. Those individuals are very closely tied with the entire process, and they seem to be relatively sensitive to, particularly now, the consent processes.

Though we have variation in what has been going on, it's our impression from what is very preliminary data—and I probably shouldn't be referring to stuff that hasn't been published yet, so I put that major caveat on it—that the consent obtained to date has been done to a high ethical standard. Having said that, there's variation; therefore, one of the benefits of a regime like this is that it will create a standard.

Mr. Dave Batters: So this section 8 will create this standard procedure across Canada for consent?

Mr. Timothy Caulfield: As I said earlier, and as is recognized in some of the Health Canada background documents, there are a lot of consent norms out there. The consent norms in the context of research are tremendously high. Justice Picard has said it's the most onerous duty imaginable. Having said that, I think these guidelines will help to ensure and also create a form of monitoring that will allow us to know what is going on in the—

● (1640)

Mr. Dave Batters: Thank you, Mr. Caulfield. I just want to give everyone an opportunity with the time that's left.

What changes need to be made to section 8?

The Chair: Ms. Baylis wanted to answer as well, so let's do that.

Dr. Françoise Baylis: I did just want to say that we had completed a study. It's referenced in number 5. It was published in 2005 and it looked at the consent process for embryos for research. We found only two clinics that did the same thing, and that was because they used the same form and were partnered clinics. In other words, every clinic does its own thing, and there is a wide degree of variation that hopefully will be reconciled by this.

Dr. William Buckett: I would just quickly concur. From a clinical point of view, I would say the same thing. In other words, there is a wide variation in the way we obtain consent for all parts of the AHR. However, in principle, this is the right sort of thing that most people do, and this will help to standardize it across the country.

Mr. Dave Batters: On changes that need to be made, for any of you who have any big objections, this is your opportunity.

Dr. Françoise Baylis: I have said that we need clarity with respect to whether or not you can get consent—because that's what we're talking about—for the research use of fresh and frozen embryos. It does need to be addressed, because there are references to the timing of withdrawal having to do with the thawing of the frozen embryos. This suggests that you're imagining that you're going to be thawing embryos.

Given that there is inconsistency with respect to that view, and given that Canada's first two stem cell lines come from fresh and not previously frozen embryos, this is something that needs to be really clear. My understanding is that it needs to be consistent with the 2002 guidelines, which presume that they are cryopreserved—something the regulations seem to presume as well—but it will be contested, and it needs to be clear.

Mr. Dave Batters: Thank you for that, Madam Baylis. That was an excellent summary.

Are any other changes needed, though?

Dr. André Lalonde: No, I think we're satisfied with the general intent of this. As someone mentioned awhile ago, it's supposed to be a living document. There are going to be changes every two or three years. It's in the law that you have to come back in front of this committee every two to three years. The more we try to be precise now, the more we're going to have delays. So we're happy. It's a good start.

Mr. Dave Batters: Do I have time for one more?

The Chair: Your time is gone. Actually, you're over.

I do want to follow up, just for the committee's information.

Françoise, you said the two stem cell lines that were created in Canada were from fresh, not frozen. Is that through CIHR?

Dr. Françoise Baylis: That's correct, but it depends on what you mean by “through CIHR”.

The Chair: That's right.

Dr. Françoise Baylis: It was not CIHR funded.

The Chair: We asked that question, and they said it was only frozen. That's why that struck me as misinformation.

Dr. Françoise Baylis: No, the first two stem cell lines were created using fresh embryos. That research was not funded by CIHR. That research was also announced and made public immediately after the CIHR guidelines were changed in 2005, permitting both fresh and frozen.

The Chair: Okay. That's very good information. Thank you.

Ms. Dhalla.

Ms. Ruby Dhalla (Brampton—Springdale, Lib.): Thank you very much for coming down and sharing some very insightful information.

I wanted to touch upon Dr. Baylis' information, which you passed around to us. You stated in your report that according to the 2002 CIHR guidelines, they were amended in ways that perhaps were inconsistent with women's reproductive interests.

Could you perhaps expand on that a little bit?

Dr. Françoise Baylis: Yes, I'd be happy to expand on that. That is a specific reference with respect to this issue that we keep returning to, whether or not you should be approaching women who are creating embryos for their reproductive purposes and encouraging them to donate them to research when it's in their best interest that they be frozen for their own reproductive use.

I would agree, however, with what Dr. Buckett made clear a minute ago, which is that there are some embryos that are not suitable for transfer. If it were the case that they were not suitable for transfer, they're presumably not suitable for freezing in the context of pursuing a reproductive project, and I would allow that it would then make sense that they would be available or eligible for research.

But that is not in fact the constraint that is put on the fresh embryos; therefore, in theory, healthy fresh embryos that could otherwise be used for reproductive purposes would be available for research purposes. And that's the part later on where I talk about how this is contrary to women's interest. If they truly want to get pregnant, it's better for them to freeze their embryos. If they don't want to have to pay to be hyperstimulated again, it's better for them to freeze their embryos. If they don't want to take the risks of hyperstimulation again, it's better for them to freeze their embryos.

All in all, if you're deeply committed as a clinician to doing what's best for your patient, you ought not to be approaching them and saying, “By the way, there are some other options here. Instead of freezing them for yourself, would you like to give them up for research?” I'm saying that's something that ought not to happen, and I can happily report that in most clinics it does not happen.

Ms. Ruby Dhalla: Good.

The Chair: Mr. Caulfield.

Mr. Timothy Caulfield: I'd like to comment on the fresh and frozen embryo. I think this is perhaps an area where this committee can do some important work. I think you probably sense that not everyone in the community agrees on this. I'm one who feels that perhaps it's appropriate to use fresh embryos. I think we need to be careful in presuming what is in the woman's best interest, and perhaps if we have an appropriate informed consent process, they can decide for themselves what is in their best interest.

But it is a contentious issue. I think it's one that this committee may want to tackle in a transparent manner. I also think we need to be careful about the science around here. There are obviously some scientists who feel that working with fresh embryos is valuable and important, and it might be worthwhile to have some of them before you.

● (1645)

Dr. Françoise Baylis: I'd just say that scientists should not be acting on their feelings; they should be acting on the data. The published data say very clearly that you do not get an advantage from using fresh embryos as opposed to frozen and thawed embryos. If somebody can show me data that says otherwise, I'd like to see it. All of the published data do not support that feeling.

Ms. Ruby Dhalla: I can tell that there's a wide variance in terms of opinions, and I believe Mr. Lalonde also touched upon the fact that there's also a wide degree of variation in terms of consent forms.

How has not having the board in place right now impacted on that variation, and in terms of timelines and so forth, how imperative is it to have the board put in place immediately to ensure there is some sort of consistency?

Dr. William Buckett: I missed the beginning part of your question.

Ms. Ruby Dhalla: Mr. Lalonde had spoken about the fact that there's a wide degree of variation in terms of the consent form and how that's obtained. In regard to the delay we've seen in terms of the implementation of the board, how is that impacting on the industry and the area?

Dr. William Buckett: I would hope that most clinics consent patients roughly in the way the proposed regulations have laid out. Of course, I can't speak for every single clinic everywhere. When we have discussed these proposed regulations as a group with all the directors of all the IVF clinics, we have not found that people have come back and said, “Oh, but we do this”, or “We do something differently.”

In terms of the safety to Canadians, I don't think things are terrible at the moment. However, I think it would help if we had standardized legislation. Then it would be the same everywhere.

The Chair: Okay. Thank you.

We have Ms. Davidson. You have five minutes.

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

This is some very interesting information we're hearing this afternoon. I have a couple of questions.

We've talked about the 2002 guidelines, and I think, Ms. Baylis, you said that you favoured most of the things that were in those 2002 guidelines.

In 2005 there was the introduction of fresh embryos. Is that correct?

Dr. Françoise Baylis: That's correct, and please, I want to be explicit. Both Mr. Caulfield and I were involved in drafting the 2002 guidelines, so my support of them may be biased.

Mrs. Patricia Davidson: Okay. What process was followed to come up with these amendments? How did this amendment arrive? We've heard a lot about the 2002 process, but how did the amendment come about?

Dr. Françoise Baylis: The 2005 amendments were made on the basis of recommendations from the stem cell oversight committee and some recommendations from the CIHR governing council. They would then have been approved at the level of the governing council within CIHR. They then would have been taken to the other councils, NSERC and SSHRC, for their approval, because all the councils work together on that, and then they were announced in June of 2005. Shortly thereafter, Canada's first two stem cell lines were also announced.

Mrs. Patricia Davidson: Was there a comparable or a lesser degree of consultation than in the 2002 process?

Dr. Françoise Baylis: The 2002 process did have a public consultation. That public consultation was criticized for not being broad enough; however, there was a consultation. There was no consultation for subsequent changes; consultation is in fact not required, so their actions were consistent with what would be expected within the organization in making changes to their guidelines.

Mrs. Patricia Davidson: One of the things I was a little confused about was the information that 45% of the couples changed their minds when it came to it, but then once we had more discussion on it, that wasn't exactly the way it went. They were—

Dr. Françoise Baylis: I will stand behind what I said. I work very closely with Jeff Nisker. He's a PI on a project I have that is funded by CIHR. I am working with him looking at healthy embryos. I saw drafts of the documents sent out to those couples, and these were not returned as not deliverable. That's different. It's not that they didn't reach the place and the post office sent them back. It was made very clear that if we did not hear back from them, our understanding was that we were not to act on the consent and that we would not act on that consent. That is why I made the statement that it can be interpreted in that way.

● (1650)

Mrs. Patricia Davidson: So there was a directive on the information that went out that if it wasn't returned, it would be deemed to be negative?

Dr. Françoise Baylis: It was explained that we would make that interpretation. It is still possible that they did not agree with how we explicitly said we would understand or interpret that behaviour, but I did want to specify that it was not a case of not getting a response because Canada Post returned it as not deliverable.

Mrs. Patricia Davidson: Somebody—it might have been you, Mr. Caulfield—said that perhaps we could come up with an appropriate informed consent process so that donors could give consent for a fresh embryo. Was it Mr. Buckett?

Mr. Timothy Caulfield: I don't think that was me.

Mrs. Patricia Davidson: Okay. Do any of you have any idea of what an appropriate informed consent process would be?

Dr. William Buckett: I'll answer.

This is not pertaining to stem cell research, but perhaps it pertains to other research in which one may look at, for example, freezing embryo techniques, which is embryo research to improve care. Our current practices are first to obtain the patient's consent to the principle of embryo research using fresh embryos. Then, if they have checked that little box and signed for that, they get approached by a researcher, who would then discuss the particular research project that had already received its ethical board approval. Then, if the couple are happy to sign the consent form for that specific project, they would do that.

Dr. Françoise Baylis: That's the reiterated consent described in the 2002 guidelines.

Mrs. Patricia Davidson: Okay.

You've talked a little bit about how these regulations are going to affect the Canadian public and the AHR practices, and you've talked about getting standard procedures in place. Are other things going to benefit from this?

Mr. Timothy Caulfield: Do you mean from the regulations?

Mrs. Patricia Davidson: Yes.

Mr. Timothy Caulfield: As I said, the standardization and the ability to monitor is a benefit. As well, there is the ability to create a culture of consent. It may sound trite, but I think it's important. It is going to create an awareness that there are specific consent rules in place.

Because it's going to have that impact, I think it's very important to ensure—and again, this is important work that a body like this could do—that the rationales for that regime are clearly articulated. I think they need to be consistent to some degree with long-held research ethics and norms that apply to other areas of research.

Mrs. Patricia Davidson: Thank you.

The Chair: Thank you.

Madame Demers is next.

[*Translation*]

Ms. Nicole Demers (Laval, BQ): I missed your presentations. However, last week, I asked a question of an ethicist who was here regarding the concerns he had about the direction the committee was headed in, regarding everything that has been done up until now. He was not able to answer me. However, he told me that Mr. Caulfield would certainly be able to do so.

Therefore, I would like you to tell me if you have any concerns with the direction the committee has taken, about the way in which the consultations have taken place up until now and about the direction our work has taken.

My question is also directed to Mr. Lalonde.

[*English*]

Mr. Timothy Caulfield: *Merci*, and I apologize that I am unable to respond in French.

I get the sense that you're asking me whether the process that has surrounded this committee has been appropriate. I do think there has been an unfortunate delay in the undertakings of the agency and in the regulations. Whether one is for or against the regulatory process and the legislative regime that's been developed, I think it's worthwhile getting it up and running and getting the regulations established. That's one concern I have.

A second concern I have is somewhat minor, because I know this happens with many processes like this one. It's the degree to which the community at large has been aware of the consultation process and has participated in the consultation process. I know that is always a challenge, but given the controversial nature of this area, I think it's important to get as much consultation and input from as varied a group as possible. And I have a sense that perhaps that hasn't happened, particularly around the regulatory development, as well as it could have.

● (1655)

[*Translation*]

Ms. Nicole Demers: Thank you.

Mr. Lalonde.

Dr. André Lalonde: I have no concerns regarding the process. For five or six years, our society has participated in consultations, in one-day, two-day or week-long meetings. Things were published in the press. This issue was discussed in great detail. I think we have to start somewhere. The consensus we have in Canada is the best that we can possibly have. In fact, we will never have unanimous consent on this issue. So, let us begin the process, let's move on. We begin with what we have and we can build on it afterwards. Therefore, researchers and ethicists will come with other aspects and we will be able to make changes over the years, but we must first launch the process.

Ms. Nicole Demers: Thank you, Mr. Lalonde.

Mr. Chairman, I'm going to share my time with Ms. Gagnon.

Ms. Christiane Gagnon: We are currently working on the consent form. In fact, officials from Health Canada are taking care of that. Have you been asked to work on the drafting of the consent form? If not, would you have any direction to give them?

[*English*]

Mr. Timothy Caulfield: I can comment.

Are you referring to the creation of a general consent form template?

In March of next year, as part of my Stem Cell Network project, we are convening an international workshop to consider research ethics issues, including many of the issues we are talking about today. As part of that, we anticipate developing some specifics that would be appropriate for both the consent process and the consent form. Again, that's in March of next year.

[*Translation*]

Dr. André Lalonde: When we have received the regulations dealing with the right to practice that type of medicine, documents will be tabled, but I have not seen a document entitled "consent form".

[*English*]

Dr. William Buckett: Again, my understanding was that this was going to come later on in the process, but I've been happy with the consultation process so far.

Dr. Françoise Baylis: Yes, I would say that so far I've been quite pleased with the consultation process. I think it has been open to hearing different perspectives and responding to them. And I'm also aware, in terms of the initiatives going forward.... I would be quite certain, for example, that the ethics committee at SOGC would be actively involved in looking specifically at what one would want to provide the members with, in terms of a general orientation, that would satisfy the legal standards expected of them.

The Chair: Thank you.

Go ahead, Mr. Fletcher.

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

Again, just focusing on section 8, and given that it is, as you say, a living document and can be revisited over time—and if I understand the committee, it's better to have the regulations there than not—would everyone on the panel agree with the statement that the regulations should be passed as presented with the knowledge that they can be revisited in the future?

Dr. Françoise Baylis: I would have to say that I would prefer to see a bit of tweaking, nothing major in terms of the orientation, but I wouldn't be able to say wholeheartedly “passed as worded”. I think my main comments have to do with the issue around withdrawal. It says only at the point at which the material has been designated for... and I would suggest that it be a later period in the process for the withdrawal.

I would also like some clarity around whether or not one can be asked to provide a consent for the use of fresh embryos.

Mr. Steven Fletcher: Have you been consulted in the past on this issue?

Dr. Françoise Baylis: I have been consulted in the past on this issue.

Mr. Steven Fletcher: Okay.

And the other panel members, would you agree with my statement?

Dr. William Buckett: In the view of expediency, yes, I think we would be happy simply to pass it down.

Dr. André Lalonde: I think we feel that we should go ahead with the regulation now, because I understand if we start making amendments to it, this will be another delay.

Mr. Steven Fletcher: That's right.

Dr. André Lalonde: I don't think we need that. We have the basic document that our members can agree with, and there will be guidelines put out by the professional societies—CFAS, SOGC—and universities on all of these issues for years to come. So I think we have a strong basic document. Let's go forward.

Mr. Steven Fletcher: Mr. Caulfield.

Mr. Timothy Caulfield: I agree with those comments. I'm taking my hat off as a law professor and putting on a more practical hat. In that regard, I would agree.

I actually hear the comments made by Professor Baylis, that we should push the right to withdraw back as far as possible. That, to some degree, addresses some of my practical concerns, but I still think we might want to revisit the rationales behind that so that they're clearly articulated.

● (1700)

Mr. Steven Fletcher: Mr. Chair, I'll just make an observation. Everyone has been consulted. It's not a perfect set of regulations. I'm not aware of any regulations that are perfect from everyone's perspective, but the committee will be well advised that this is a step forward. It's better than where we would have been, and we should move forward.

Thank you.

The Chair: Thank you.

Before Ms. Baylis has to leave, I have a couple of quick questions.

First of all, Mr. Caulfield, with yours, you suggested that we move it back, the consent to withdraw. To what place...? You didn't specify that.

Mr. Timothy Caulfield: I didn't specify that. I was trying to escape having to answer that.

The Chair: Yes, I realize that.

Mr. Timothy Caulfield: One could make strong arguments that it should be even after the stem cell line has been created, and I would like to see that revisited.

Now, to be fair, virtually every other guideline that has explored this has said that the right extinguishes either at the creation of the blastocyst, when it's been assigned for research, or when the blastocyst is destroyed for the production of the stem cell line. So I think the position is relatively consistent within the international guidelines, but I think there are some strong arguments as to why individuals may still have a right of control over a stem cell line once it's created.

I'm afraid that right now is not perhaps the appropriate time to go into this.

The Chair: But you would say at least to the stem cell line.

Mr. Timothy Caulfield: At least to the creation of the stem cell line, which is—

The Chair: Further than what actually the regulations are suggesting.

Dr. Françoise Baylis: The regulations do actually allow it up until the stem cell line use.

The Chair: Okay.

Dr. Françoise Baylis: That's 12(v). It's worded that up until the point that the stem cell line is created, you cannot withdraw, and the reason behind that comes from an old philosophical perspective in political philosophy having to do with law. You've mixed your labour with it, and therefore, in fact, you have some property rights in the stem cell. The stem cell didn't exist, but for you as the scientist doing a certain amount of work...and in fact, what was donated is no longer there to be retrieved. So what you gave me as an embryo, I can't give back to you. It doesn't exist anymore. That's part of the reason for saying that this would be a reasonable point at which it cannot be returned to.

The interesting thing, then, is in the context of not doing stem cell research, but donor gametes.... I've given you my eggs. At what point can I say no, give them back to me? I would say until you've taken them and transformed them into something else, until you've made them into an embryo, well, then you can say back to me, “Mrs. Baylis, I'd love to give you back your eggs, but I don't have them anymore. They've been made into an embryo. You can't have them back.”

The problem there is with the way it's worded. It says that you can withdraw up until the third party acknowledges in writing that the human reproductive material was designated for that use. I'm saying “was received”. That puts it just a little further down. I understand the problem, then, is who receives it. So it's not an uncomplicated issue.

The Chair: The comments about individuals who give consent and then change their mind later...for some of us who were around the table and listened to testimony when this legislation was drafted, it shouldn't surprise many of us, because people will walk over cut glass—pardon the expression—to have a child when they're trying to conceive. Once they conceive, looking back a year or two later, they might have a different perspective on how precious the embryo is and have a different take on giving it up for research. I don't think that should surprise many of us in the field.

The data on the Nisker study is interesting. You said something about 88% of those—

Dr. Françoise Baylis: That's another study that was done in the United States, with a very small sample size. If I were being critical of the study, I would say it's an extremely small sample size. You can't really generalize from it.

The problem is there is just so little empirical data. People are not collecting the data such that it can be presented. That's why the study by Jeff Nisker is important, because it's Canadian, it's recent, and it was done with a certain degree of thoroughness. But the criticism could be that it's one clinic.

We just don't have a lot of data, but we do know people change their minds, and I'm asking that people retain that right to the last possible moment.

The Chair: Okay, and I think the committee is well advised to consider whatever changes on that side of the issue.

I want to thank you for coming in, and I thank the committee for their questions. We will take your advice under advisement, I'm sure, as we consider these regulations.

Thank you very much.

We'll take a quick pause and then we'll move in camera.

[*Proceedings continue in camera*]

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