House of Commons
CANADA

Standing Committee on Health

HESA • NUMBER 040 • 1st SESSION • 38th PARLIAMENT

EVIDENCE

Tuesday, May 10, 2005

Chair

Ms. Bonnie Brown

Standing Committee on Health

Tuesday, May 10, 2005

● (1120)

[*English*]

The Chair (Ms. Bonnie Brown (Oakville, Lib.)): Good morning, ladies and gentlemen. It's my pleasure to welcome you to the 40th meeting of the Standing Committee on Health.

This morning we have two items on our agenda. The first is an update from the assisted human reproduction agency. You'll recall we had a lot to do with that bill before it passed. It's now been about a year at least, and we want to find out what's happening with the establishment of the agency. Part two of the meeting will deal with Bill C-28 in clause-by-clause review.

We'll begin with human reproduction, and I will invite one of the representatives from the Department of Health to tell us where they are on that particular project. Ms. Weber.

Ms. Caroline Weber (Director General, Policy, Planning and Priorities Directorate, Health Policy Branch, Department of Health): Thank you, Madam Chair.

I have an opening statement. Would you mind if I read it?

The Chair: No, we'd be happy to hear it. We hope it will tell us what we want to know.

Ms. Caroline Weber: I hope so also, and I look forward to your questions afterwards.

Thank you for the invitation to appear before the committee today to provide an update on the progress the department has made in implementing the Assisted Human Reproduction Act.

I am Caroline Weber, director general of the policy, planning, and priorities directorate within Health Canada.

[*Translation*]

I am delighted to have been invited once again to appear before the Committee to discuss this matter.

I would like to introduce my colleagues: Bill Maga, Director of the Assisted Human Reproduction Implementation Office; Francine Manseau, Manager of the Policy Development Group; and Rodney Ghali, Senior Policy Advisor. Both of them are also with the Assisted Human Reproduction Implementation Office.

[*English*]

Since 1994 the government has worked towards establishing a comprehensive legislative framework to address the complex issues raised by assisted human reproduction. The Standing Committee on Health has a long and important history in this development. Most notably, since 2001 you've played a significant role in shaping the legislation we have before us today. As we move towards full implementation of the act, your important role will continue.

[*Translation*]

As you know, barely a year ago the legislation received Royal Assent and key provisions were implemented.

At the same time, the department has continued to work towards the full implementation of the Act, which essentially involves developing the components of the regulatory framework and creating the Assisted Human Reproduction Agency.

● (1125)

[*English*]

During this time we have also been active in related support activities, which include a redesigned website as a focal point for our public involvement process in regulatory development, planning for the health information registry, and the launch of a pilot project on altruistic gamete donation. I will elaborate on these activities further in just a few moments.

I'd like to start with the work completed today on the act's supporting regulations. Policy development in this area has been divided into eight distinct yet related themes. These are consent, reimbursement of expenditures, embryo research, pre-implantation genetic diagnosis, clinical and laboratory practices, counselling, health reporting information, and, finally, administrative issues related to the licensing and enforcement framework.

[*Translation*]

In 2004, the public consultation process was launched as part of this strategic work. Last fall, departmental representatives went across the country to meet with their provincial counterparts, key stakeholders and members of the public, to provide them with technical information about the legislation and talk about action to be taken in the coming months with a view to developing the regulations and creating the agency.

In all, they held 16 meetings in 11 different cities. The department also organized workshops on counselling and reimbursement of expenditures for stakeholders. Those workshops brought together experts and other interested parties and were aimed at collecting important data in order to move the policy development process along.

I believe copies of the counselling report have been distributed to Committee members. We will soon be releasing the report on reimbursement of expenditures.

[*English*]

Also in the fall of 2004 we undertook our first national consultation on specific regulatory policy proposals related to consent under section 8 of the act. Once again, I believe a copy of this consultation document was submitted to the committee.

As you know, draft regulations under this act must be laid before both houses of Parliament before promulgation. We're nearing completion of the draft section 8 regulations—those are on consent—and intend to pre-publish them this summer and have them available for your review by the end of this calendar year. These regulations will likely come into force sometime in 2006.

The remaining public consultations on regulatory proposals are anticipated for later this spring and into the fall and winter, with most draft regulations being pre-published in the *Canada Gazette* in 2006, followed by a review by this committee in 2006 and in 2007. It is anticipated that the entire regulatory and licensing framework will be in operation in late 2007 or early 2008.

[*Translation*]

As regards the creation of the new agency, you are probably aware of the statement made by the Minister recently with respect to the choice of Vancouver, British Columbia, for the agency's head office. We will soon be starting a recruitment process with a view to staffing the board of directors of the agency and filling the position of president. This will occur as part of a public, open and transparent process.

[*English*]

The board will be comprised of up to 13 members reflecting a range of backgrounds and disciplines, which will ensure broad representation and varied perspectives on AHR-related issues. An announcement regarding appointments to the board of directors is expected to coincide with the creation of the agency on January 12, 2006.

You will recall that three years following this date there is to be a legislated parliamentary review of the provisions and operation of the act. That's in section 70 of the act.

[*Translation*]

In the meantime, we are working on the agency's administrative and regulatory mechanisms, including drafting administrative regulations relating to the operation of the board of directors and human resources plans that will allow the agency to begin its activities more quickly.

As I already mentioned, I would now like to briefly address the other related tasks we are currently engaged in. Health Canada recently released a request for proposals with respect to a pilot project on altruistic gamete donations. Because it is aware of the impact of the ban on the purchase of gametes from donors, Health Canada will be collecting quantitative and qualitative data on recruiting gamete donors through an altruism-based system through this pilot project, with a view to supporting the implementation of the Act and helping assisted human reproduction clinics recruit altruistic donors.

● (1130)

[*English*]

Work is also under way on developing the health information registry. A needs assessment is being conducted, and infrastructure requirements, including the important issue of privacy protection, are being examined.

Committed to an open and transparent regulatory development process, we have redesigned our website to become a user-friendly and integral tool in consulting with Canadians. On the site we will ensure all of our consultation documents are readily available to the public, and we have provided a public e-mail address to ensure that if members of the public have questions related to this initiative, they have direct access to departmental officials.

Thank you again for this opportunity to provide an update on our work, and I'd be pleased to answer any questions you may have.

The Chair: Thank you very much.

We'll begin the questions with Mr. Merrifield, I believe, and then Mr. Ménard.

Mr. Rob Merrifield (Yellowhead, CPC): Thanks for coming in and giving us an update.

This is a sort of blast from the past. It's interesting to see how these regulations are coming together.

I do have a couple of questions because of some of the things I've seen happen as of late internationally as well as domestically with regard to this piece of legislation since it was passed, and I was trying to put it together. First, I have to have a better understanding of exactly what went on at the United Nations with regard to your role and how we voted at the United Nations on the cloning motions that were put forward there. We voted against the motion that would have reflected the views of this piece of legislation. I don't know how that happened and what your input to our voters at the United Nations was, but I'd like your input on that.

Ms. Caroline Weber: What was finally presented at the UN for a vote didn't really coincide with this legislation exactly, but I'm going to ask Rodney to elaborate on it because we did send him to the UN to participate in those discussions.

Mr. Rodney Ghali (Senior Policy Advisor, Assisted Human Reproduction Implementation Office, Health Policy Branch, Department of Health): If I could, I'll begin with just a bit of context around the negotiations at the UN.

As you are probably aware, the negotiations started back in 2001. What was certainly clear from 2001 up until this winter was Canada's position on human cloning. We've made consistent statements of full opposition to all forms of human cloning, and we made those statements very clear at the UN during those negotiations.

What we also made very clear during that time was our desire to have a consensus resolution, because we and a number of other countries believed the only way to have a truly universal instrument was to have the full buy-in of all countries. Appreciating a number of societal and cultural differences...it certainly became clear during the last round of negotiations that a consensus resolution was not possible. While we worked towards the final document that eventually was voted on, there were unfortunate—

Mr. Rob Merrifield: I just want to get clarification on what you just said. Is that the first motion, where you abstained from the vote and we lost it? Is that the one you're talking about?

In the motions that were brought forward at the UN, you said you were looking for consensus but you could see you couldn't get consensus. I understand Canada abstained from the first motion that was brought forward, and we lost that because it was a tie vote.

Mr. Rodney Ghali: I think you're talking about the vote that took place in 2003.

Mr. Rob Merrifield: That's right.

Mr. Rodney Ghali: The situation with the document that was being discussed at that time was that there was a draft resolution that was attached to the document. That resolution created a number of significant policy and legal implications for Canada at the time. Certainly, while on the surface it appeared to be consistent with Canada's position, which was a full ban on all forms of human cloning, in fact a careful examination showed the document went further in other areas that did not have anything to do with human cloning. As a result, we were not in a position to support something that was not reflected in—

Mr. Rob Merrifield: Exactly, so why didn't we vote against it? We abstained. It makes no sense.

Mr. Rodney Ghali: As I said, the other objective we had during those negotiations was to have a consensus resolution, and we felt that because we could not find that consensus resolution, we were in a position to abstain at that point.

● (1135)

Mr. Rob Merrifield: Okay. That's a hard one to understand.

Now let's go on to the 2004 one.

Mr. Rodney Ghali: Okay. During the last round of negotiations, as I was mentioning, some unfortunate language was introduced into the draft document that added an element of imprecision and vagueness to the actual scope of the draft resolution being negotiated. Although we were clearly trying to negotiate an instrument against human cloning, language such as “life sciences” and “genetic engineering” was introduced, which clearly expanded the scope of the draft declaration and went into other areas of human reproduction and research.

We were not alone, certainly, in our concern with respect to that language expanding the scope of the declaration. There were a number of other countries that tried unsuccessfully to remove that language from the declaration. In the end it didn't work as it should have, and we, along with a number of other countries, in the end had to vote against it because of that.

To provide a concrete example of what I mean by that language, if —

Mr. Rob Merrifield: That's what we need to get into: what kind of language are you having a problem with?

Mr. Rodney Ghali: If we look at the declaration that was eventually adopted by the UN, in the operative paragraphs of that document—“the operative paragraphs” mean those are the critical pieces of the declaration that a country should abide by—the words “human cloning” only appeared once, whereas the words “life sciences” appeared three times, and the words “genetic engineering” appeared once. So it was clear that the scope of this document was not reflective of what the original negotiating mandate was. We were unclear—and couldn't get a definition of—what was meant by “life sciences”. Cloning certainly could be a component of life sciences, but there are great amounts of other sorts of research activities that are included in life sciences, and we were not in a position to negotiate an international instrument on other areas of research.

Mr. Rob Merrifield: Is it because, then, you thought it was going to allow things that this piece of legislation would not, or the other way around?

Mr. Rodney Ghali: What it looked like was that it could capture activities that would be permitted in Canada. An example would be pre-implementation genetic diagnosis. That's an activity that is going to be a regulated activity under the act. Parliament judged that activity to be acceptable, and the declaration that was eventually signed at the UN could be interpreted to actually prohibit that activity. It raised a significant policy and legal concern for us, and therefore we weren't in a position to support it.

Mr. Rob Merrifield: That's a difficult one to explain in an international arena, where these aren't necessarily binding; they were showing the intent of the nation. The intent of the nation, and the message that was coming out of that vote in the way Canada voted, was that we were open to cloning.

Mr. Rodney Ghali: No, we were actually very clear during those negotiations and made two public statements in New York of our full opposition towards all forms of human cloning. We expressed our regret at being unable to support the document that was eventually adopted.

I think it's also worthwhile to point out that Canada wasn't alone in its opposition to that document. If you look at our OECD partners, the majority of OECD countries—

Mr. Rob Merrifield: Wasn't the vote 132 to 37, or something? I can't remember the exact numbers, but wasn't it something like that?

Mr. Rodney Ghali: I believe it was 84 for, 34 against, and 37 abstentions, and there were over 40 absent countries. So looking at the numbers, it was actually the minority of countries that supported that document.

Mr. Rob Merrifield: It becomes disturbing to me, because when I see what we did on the first vote.... Maybe I'll put it to you this way: if you could have that first vote back, would you still abstain? Would you have voted for or against it?

● (1140)

Mr. Rodney Ghali: It's very difficult to speak in the hypothetical —

Mr. Rob Merrifield: That's not hypothetical. If you could have it back, would you have done it? Your explanation of what went on in 2003 with that motion doesn't make any sense to me at all, and for us to abstain from it rather than.... If we had problems with it, we should have voted against it. To abstain makes absolutely no sense, if you're using the same logic that led you to say no to the one that was to ban all forms of human cloning in the last one. I'm just looking for consistency in how you instruct our team to vote over there.

Mr. Rodney Ghali: I think it's also worthwhile to point out that where we were back in 2003 was very different from where we were in 2004 because—

Mr. Rob Merrifield: Oh, no. It's the same piece of legislation. I don't think the position changed.

Ms. Caroline Weber: Oh, no, but what was going on internationally changed a lot.

I think the other thing that might have changed.... We were still trying to get a consensus, truly. At that point we had an odd document on the face of which looked like it was completely consistent with our domestic legislation and, frankly, that we wanted to support. There were these other riders that were being attached to it that kept raising questions about what they were really talking about here and where this was really going.

In our interest to drive to a consensus, we decided to abstain on that in the hopes that this was coming back and we could work towards a consensus. Frankly, that never really emerged. We worked towards achieving a consensus, but as events continued to unfold, even on the declaration in principle, it just got worse and worse, honestly. This has been a very dynamic environment. We welcomed a convention that would mirror our domestic legislation. It has never emerged.

As you know, this is a very divisive area. I don't see a consensus emerging internationally. In fact, it's probably fragmented more than it was a couple of years ago.

The Chair: Thank you, Mr. Merrifield.

Mr. Ménard, go ahead, please.

[*Translation*]

Mr. Réal Ménard (Hochelaga, BQ): Thank you very much for again appearing before the Committee. At one point, I had the sense that we were almost part of the same social circle, since we would see each other every week.

I have the feeling that things have not been going quite as well as we might have liked but since the Bill only received Royal Assent a year ago, we shouldn't be too tough on you, even though we are disappointed that the government has yet to appoint a board of directors. However, that responsibility falls not to you, but to the Governor in Council.

However, I want to talk about two decisions that I find strange. The first was to establish the head office of the agency in British Columbia. That surely has something to do with the home province of the current Minister of Health, but I must say I see few other rational reasons for putting it there. Also, the fact that members of the board of directors have yet to be appointed is also worrisome.

Having said that, I have two major concerns. First of all, you may recall that I had put a lot of questions to your legal counsel—I don't recall his name—with respect to the legality of the bill. History has proven me right, insofar as Quebec is challenging certain provisions of the bill in front of the Quebec Court of Appeal and, according to a number of analysts, it will win its case because you do not have the legal jurisdiction, other than through the criminal law, to intervene in matters relating to assisted human reproduction, which is not enough.

Also, although the provisions of the Act relating to prohibited practices are in effect, the inspection regime is not. I have met with a number of women's groups who have concerns in that regard. I have been told that eggs are being sold on the black market, and that some clinics have extremely dubious practices.

How can you ensure that the provisions of the Act with respect to prohibited practices are effectively enforced, if you have no tools to implement them?

Ms. Caroline Weber: Thank you, Mr. Ménard.

[*English*]

I'm going to ask Bill Maga to respond since it really is a question about inspection and enforcement. Your comments were on a couple of different issues. That's a question you'd like addressed.

Mr. Bill Maga (Director, Assisted Human Reproduction Implementation Office, Health Policy Branch, Department of Health): First of all, right off the bat, I'd like to make it clear that any suspected criminal activity that we become aware of would be referred to the RCMP or any other police force for investigation and follow-up.

Let me just outline briefly the type of compliance policy we'll be following. It's a policy composed of a number of different components, starting off with what could be described as responsive monitoring, followed by a range of possible actions. First of all, there's the basic education to make sure that all involved understand the responsibilities under the act. We've also got promotion of voluntary compliance, through which we work with the clinicians and researchers and those involved to facilitate their voluntary compliance. It then increases in severity from there with things like written notices, and it even leads up eventually to seizures and prosecutions.

● (1145)

[*Translation*]

Mr. Réal Ménard: I see.

Secondly, feminist groups, particularly the Planned Parenthood Federation of Canada and the four or five groups who have a more specific interest in your project, are concerned that development of the regulatory framework is taking an inordinate amount of time because you are holding consultations on only one or two sections at a time.

Are you still aiming to have the agency up and running in 2006-07 with a budget of some $10 million? This morning, can you provide some reassurance to us, assuming that the government is able to take its fingers out of its nose, with respect to the board of directors? And if directors are appointed, do you continue to believe that a fully operational agency and regulatory framework will be in place by 2006-07?

[*English*]

Ms. Caroline Weber: I'm going to ask Bill to respond again.

[*Translation*]

Mr. Réal Ménard: I would like to hear from Ms. Manseau; this lady never speaks. Also, she worked very hard on this legislation; she was here every week. Give her an opportunity to speak. Don't act like the whip here.

[*English*]

Mr. Bill Maga: If I could just understand the question....

[*Translation*]

Mr. Réal Ménard: If anyone understood the question it was certainly Ms. Manseau.

Ms. Francine Manseau (Manager, Policy Development Group, Assisted Human Reproduction Implementation Office, Health Policy Branch, Department of Health): For everything to be in place, our timeframe is more like 2007-08. We have about three years to develop the regulations. The agency will be put in place first, but we estimate that all the regulations will be ready by 2007-08, including the licensing process.

Mr. Réal Ménard: But the documents released by Health Canada talked about a fully operational agency in 2006-07.

Ms. Francine Manseau: Yes, the agency will be in place and will be able to begin setting up its operations and hiring staff, because many of these processes have to be in place in order for the agency to issue licences. When the regulations are ready, we may have to provide guidelines for clinics. The regulations are still highly legalistic; they really look like a series of small bills. So, we will need to develop guides to help people understand the processes they have to follow in order to be issued a licence, for example. The agency will be able to begin that work. Also, it will need a good year to hire staff, develop inspection protocols, and so on.

While the agency is getting prepared, at Health Canada, we will be developing the regulations. We will then put the two pieces together. The goal is for everything to be in place by 2007-08.

Mr. Réal Ménard: The issue of informed consent is a major part of this legislation. The Committee spent a great deal of time on it. When will that regulation be enacted?

Ms. Francine Manseau: Informed consent is, indeed, an important part of the legislation. It underlies a number of its components.

We have been working on the first component. We held consultations and are currently developing the regulation, which should come to you by fall or in late 2005.

Consent in relation to section 8, which is a prohibition, has to do with using human reproductive material to create an embryo or using an embryo to…

Mr. Réal Ménard: Or taken from a cadaver.

Ms. Francine Manseau: This has to do with the authorization to obtain gametes from a person after his or her death, with a view to developing an embryo.

Next fall, there will be consultations held with respect to this kind of use, which is fairly narrow in relation to the other regulations on informed consent, which are really dealt with in section 14.

There have indeed been consultations on this first component. We are now developing the regulation. We should be in a position to publish it in Part I of the *Gazette* this summer.

Mr. Réal Ménard: Thank you.

[*English*]

The Chair: I think you're finished, Mr. Ménard.

Ms. Dhalla.

Ms. Ruby Dhalla (Brampton—Springdale, Lib.): Thank you to all of our witnesses for coming.

Obviously the area of assisted human reproduction is quite complex in nature, and I think there is a complex number of issues with regard to the social, health, and ethical aspects of it. There's a tremendous diversity in terms of opinions for all Canadians.

During the regulatory process and the development of what's going to be coming out, how do you intend to reach out to diverse Canadians and the number of differing views we have across the country?

Ms. Caroline Weber: Thank you very much for your question.

I'll again turn to Madame Manseau to respond to that.

● (1150)

Ms. Francine Manseau: As you say, it's a very complex field. I think the challenge we have is also the fact that right now there aren't that many guidelines or standards that exist in this field. Even the professionals out there.... Counselling is an example of where there's not even an organization in terms of the professionals coming together.

So in this instance, we had a first meeting with counsellors. We tried to identify them, brought them together, got them to start discussing, and tried to tell them what the regulations would mean in terms of what would be required so they could start formulating the qualifications for counsellors.

What is meant by counselling? There's fertility counselling, and there's also genetic counselling in this field.

There is a lot of work to do, because nothing is out there. We do certainly look at the international scene because there is experience in other countries. We even had a meeting where people from other countries just happened to be here in Quebec City at an international meeting. We had them meet to inform the Canadian counsellors about their experiences, what was working and what wasn't.

So it is very complex. We're using different tools. Certainly the website is one that any Canadian who wants to have information can use. All the documents that have been prepared, the results of any workshop discussions, are always made available so people can have access to them. They can even e-mail us, and the turnaround time for a response is usually quite fast.

We sometimes have to bring together people just to gather information so we can go further and develop some policy options. That's the second phase. We did that for section 8. There are policy options out there, and we get comments from the individuals and then start drafting regulations.

So it is complex, and the fact that there's not that much information available makes it even.... The regulatory process itself—there are policies of the government that we have to follow—assumes that it will usually take about two years to develop a regulation up to the point of having it gazetted. We're trying to do all the regulations in about three years, which is itself a—

Ms. Ruby Dhalla: In terms of your interaction with stakeholders, what has been the level of involvement?

Ms. Francine Manseau: There's been quite good interaction. I think for a while some of the stakeholder groups were not supportive of the legislation. I think that has changed quite a bit. We are working with them, I would say, very well.

Again, it's a small number of people. We have to be mindful of that too when we get them involved, because sometimes it can be very demanding for them. So we also have to judge that. But we are working well together. Sometimes they are challenged in the way we need to be developing regulations, the way they need to think and organize, and why there are some professional guidelines.

Sometimes, on some issues, there's a lot of education that needs to be provided, so they understand how to develop regulations and the types of issues and questions that we need to address. It's a very interactive process. It's very demanding. But certainly I think we're trying to get the tools, and even to get staff trained to understand. It's very complex legislation. I know that some of your members here have been through it . Writing regulations is like mini-legislation. So the challenge is there and we're going ahead.

Ms. Ruby Dhalla: I have one last question. With regard to informed consent, which one of my colleagues brought up, it's obvious that the requirements and technologies are changing at a very rapid pace. I know with regard to informed consent you try to provide the individual with as much information as possible in terms of the risks. How do you intend to disseminate the information in a manner that the consent will be uniform across the country?

Ms. Francine Manseau: In developing regulations you try to arrive at some kind of model in terms of the type of information that would be required. It's true what you're saying; it's evolving very fast. A good study was done that enabled us to know what the literature was saying in terms of the risks associated with those different procedures. Again, any regulation has to be justified.

Ms. Caroline Weber: Can we just clarify a little bit there? It seems like the question gets into consent for procedures.

Ms. Francine Manseau: The legislation is not about consent for the procedure, you're right. It's more about informing individuals about the risks and safety issues pertaining to it. It's true that it's not consent to undergo a procedure. It's more that consent is about using gametes to create an embryo and the risks that are involved, and everything the legislation says about how it's going to be done.

● (1155)

The Chair: Mrs. Crowder.

Ms. Jean Crowder (Nanaimo—Cowichan, NDP): I apologize. I'm not prepared.

The Chair: Thank you.

Mr. Lunney.

Mr. James Lunney (Nanaimo—Alberni, CPC): Thank you, Madam Chair.

I'm hoping the interpreters will be able to pick up what I'm saying and that none of you picks up what I'm dealing with.

One of the controversial issues in the bill had to do with the use of embryos for stem cell research. Currently, it has been a year or so since this legislation was enacted. We're still waiting for regulations. Is research currently occurring on so-called surplus embryos for the purpose of stem cell research, and if so, to what extent?

Can you comment on that?

Ms. Caroline Weber: Before I hand it over to Francine, because of the regulation and promulgation, if that is that okay—or Rodney on research—I just want to clarify for everyone that it's research involving the use of the in vitro human embryo, not necessarily only for derivation of stem cells. Stem cells are one possibility, but stem cells are not actually covered by the piece of legislation, so what we're talking about is regulation of research involving the use of the in vitro human embryo, but not regulation for stem cells or for stem cell research. I know that's always a bit confusing.

Mr. James Lunney: We had an awful lot of discussion about stem cells at this committee—hours—and parts of many meetings were preoccupied with that discussion. We certainly know that the purpose of this, and one of the controversial issues, was the use of so-called surplus embryos for experimentation and with embryonic stem cells . That's particularly what I'm asking about.

Ms. Francine Manseau: Maybe I'll ask Rodney, who is part of the team. He is leading the work we're doing on this file.

Mr. Rodney Ghali: Sure. Your question asked if we are aware of any projects that are currently under way using excess embryos. We are aware of a couple of publicly funded projects that are using those embryos, but we don't have exact numbers because it's certainly not Health Canada that is funding any of those projects—the department, I should say.

Mr. James Lunney: In the absence of regulation, under what authority would they be doing that research at the present time?

Ms. Francine Manseau: Right now some sections of the legislation have been proclaimed, and in particular section 71, to control activities, has been proclaimed. These have been proclaimed at the end of April. It says that only individuals who were doing a controlled activity in the year prior can continue to do so. As you know, the Canadian Institutes of Health Research already had a series of guidelines that were developed for the funding of research projects, and through that process, we understand, some projects have been approved, but again, the fact that they needed to have done that in the year prior is also a condition. As you know, the stem cell guidelines have also been referenced in our legislation. As we are developing the consent regulations and so on, we are also guided by them. They would be—in terms of policy intent—where we are also going with the regulations.

Mr. James Lunney: Do the current regulations limit the number of embryos produced in the fertility process?

Ms. Francine Manseau: The details are not yet—

Ms. Caroline Weber: We don't have the regulations yet. We don't have regulations until you see them, so those regulations haven't come through part I of the *Canada Gazette* or to this committee. We're in the process of developing all of those, but we don't have regulations yet.

Mr. James Lunney: We've had great advances in the ability to freeze ovarian tissue, for example, and to freeze gametes. It's certainly not a problem, and it's not a problem disposing of gametes if it's decided they won't be used at a future date. Of course, those are some of the ethical questions we certainly were very much concerned about at this committee.

Leaving that for a moment, the other issue you mentioned was a pilot project on the recruitment of altruistic sperm donors. We know there was certainly some concern about the availability of sperm, and there is certainly concern around this committee table, among those of us who were on the committee last time, about the importation of sperm from U.S. sources. The actual origin, because it is not identified, might concern us if it came from prisons, and so on.

Would you further elaborate on what's happening with these programs to encourage altruistic donation here?

● (1200)

Ms. Caroline Weber: Francine has been working on the pilot project.

Ms. Francine Manseau: The pilot project has been released. I think the objective of the pilot project is certainly to provide us with, first of all, more information on different strategies being used to try to get donors who would be donating without being paid, and also I guess to enable us to gather some information, qualitative and quantitative information, about the impact of those strategies to inform the process as we implement the legislation.

That has just been released in terms of research for proposals. We are expecting proposals to be coming in by mid-June right now. The objective is to get the clinics working together. It's really a national initiative in the sense that what we are asking for is a clinic to come forward, but to come as a team, so that at least three regions in Canada will be represented, with one of the regions undertaking the pilot in French. We want them to try to come in as a group and to be able to develop some new strategies, or even use old strategies in some way but refocus them, and for us to try to get good, sound analysis and information to be able to continue to develop the policy in this area. So this is what's been announced recently.

The Chair: Thank you, Mr. Lunney.

Mr. Thibault.

Hon. Robert Thibault (West Nova, Lib.): On the question of the agency, what year did you say you'd have the agency in place, the board?

Mr. Bill Maga: The agency will be established in January 2006, and we expect that the announcement of appointments to the board would be shortly after that.

Hon. Robert Thibault: So how do you go about recruiting people for this board? How do you achieve a mix that is representative?

Mr. Bill Maga: It's a long, lengthy, laborious process that is likely to take up to about eight months, but the act provides some guidance. A section in the act stipulates that the board's profile should reflect the interests and expertise required for the act, so we have a little guidance there with respect to that.

The next big challenge is to get out and make everyone aware that in fact this process is occurring, and we're working on a process to do that right now. I say we still are working on it, so I can't elaborate, but we hope to make an announcement soon.

Hon. Robert Thibault: So we have an act in Parliament. We will have regulations governing it, and we've got an organization, the agency, to administer it. What exactly does the board do?

Mr. Bill Maga: Well, the board is responsible for the administration of the agency and ultimately, in particular, the decisions surrounding the licensing system.

Another big responsibility of the agency—

Hon. Robert Thibault: But will the board be reviewing the applications? Will the recommendations for licensing be done through the board, which will decide who gets or who doesn't get a licence?

Mr. Bill Maga: That's correct, and they would be reviewing reapplications or potential suspensions. They will be responsible for overseeing the licensing process.

Hon. Robert Thibault: Okay, sorry, I interrupted you. So they do the administration of the agency, the licensing—

Mr. Bill Maga: The administration, the licensing, and they'll be providing advice to the minister, in particular, with respect to AHR and how the agency does its business. Of course, there's health reporting information that the agency will be collecting, so the board will be responsible for overseeing how that's handled, etc. There are a number of key functions, of course, that the agency will have to play, as well as its role within the health portfolio.

Hon. Robert Thibault: The board is created by Governor in Council or by cabinet.

Mr. Bill Maga: That's right.

Hon. Robert Thibault: Does it answer to the Minister of Health? Would that be its reporting link to Parliament?

Mr. Bill Maga: Indeed, it reports to Parliament through the Minister of Health.

● (1205)

Hon. Robert Thibault: And the administrative functions, would those come under the department under the deputy minister's umbrella, or would they be an independent agency?

Mr. Bill Maga: Actually, the agency's going to operate separately from Health Canada. Although the agency will report to Parliament through the minister, it will have a president who is analogous to a deputy minister. It would report through the president to the board.

Hon. Robert Thibault: But when it comes to areas like seeking funding and those things, will they be coming under the umbrella of the Department of Health? I presume they will.

Mr. Bill Maga: In seeking funding, no. There will be a separate departmental corporation that will have to submit its own Treasury Board submissions, for example. But we have to make a distinction. The department will still be responsible for the overall policy as well as changes or new regulations under the act.

Hon. Robert Thibault: I see.

The act makes it illegal to sell sperm, or ovum, or eggs. I have two questions. Do you see a shortage coming? Do you see it as being a problem in reproductive medicine, in the demand? Are you starting to get an idea about whether there will be an altruistic supply of gametes?

Mr. Bill Maga: I think we can refer that to my colleague, Francine Manseau.

Ms. Francine Manseau: On the issue of recruitment of donors, whether it should be in a paid or unpaid system is always a challenge. The demand is much higher than the supply. Certainly when you are making changes, which are very important changes, as is this one going from a paid system to an unpaid system, there's always a period of adjustment. There's no doubt about that. Other countries that went through this process also witnessed, in the short term, a reduction in the supply, after a while coming back to, I would say, an acceptable level.

As I said, paid or unpaid, there's always a shortage. But, yes, there will be an adjustment period. I think through the pilot project we're hoping to be able to support some kind of a move to a more altruistic system.

Hon. Robert Thibault: Is there a shortage now, I think was the last point?

Ms. Francine Manseau: Yes, there's always a shortage. Even in a paid environment, there's always a shortage.

Hon. Robert Thibault: Thank you.

The Chair: Thank you, Mr. Thibault.

Mr. Carrie.

Mr. Colin Carrie (Oshawa, CPC): Thank you very much, Madam Chair.

I would like to question you on the registry. In 1993 the Royal Commission on New Reproductive Technologies called for a standardized and centralized record-keeping. How is that going? How do you foresee the information gathered being used?

Ms. Caroline Weber: I'll ask Francine. She is working on the health information piece.

Primarily we won't actually be implementing that until we have the agency up and running. I say this as an opening remark on that.

Anyway, there are two functions basically that had been articulated in the legislation for that information.

Ms. Francine Manseau: Yes. The legislation called for a registry to be set up and for information to be gathered by the clinic and then provided to the agency. We see maybe not two registries but two major components of that. One would be a registry with information about people donating to a third party, the family using it, and the children born from it, so that you can have a control on the number of children who are born per donor. You would keep very important medical and genetic history, gather that, and make it available.

Another kind of *volet* to the registry is one of providing information on the outcome of the procedure. So when an individual goes in, they will be provided with information about the outcome of those procedures, what is the success rate.

We have started the work in terms of trying to develop what would be those components. First of all, there's the question of when you develop the regulation, what type of information should be collected. All of it has to be based on the rationale of having health and safety concerns, and how much risk is involved in some procedure to then justify the amount of information you'll be collecting. We started to do the work on that.

Another *volet* is also the whole infrastructure of the system that would need to be put in place to be able to manage that information and to be able to report back. With that we've been doing a lot of looking at experiences of other countries that have been in this business for a while, what are the lessons learned, and so on.

So those two initiatives are under way. We expect to have a policy option consultation document available in the fall.

● (1210)

Mr. Colin Carrie: Has there been any resistance from the stakeholders in the implementation of registries?

Ms. Caroline Weber: There have been concerns expressed about personal health information. But again I think there's a bit of a misunderstanding there because the most extensive amount of information really, at the personal level, is for the registry for gamete donors, for third-party donors. But we're imagining more aggregate level information for the successive procedures.

There's more concern that every time they go to a clinic for a procedure their personal information is going to have to be registered, but that's not the case. I think the concerns expressed have been more of that kind of nature coming out of this confusion than anything else.

Mr. Colin Carrie: I was thinking more along the lines too that if somebody is conceived in one of these ways, and, as we now know about AIDS, down the road there's disease, they'd be able to get access to medical history and stuff like that.

Do we have a baseline that we're starting with in collecting data, or is it just wide open right now?

Ms. Francine Manseau: Right now there is some information that's been collected by the clinics. The extent to which the information that is collected is being made available is certainly limited, but there has been an effort on the part of the clinic to collect information. How far they are following up on children is another issue too. You might have the information when a child is born about if it was a low-weight birth or if there were some problems, but to be able to follow a child, you need to have a lot of evidence that there's a lot of risk so as to also require that. As I said, this is something we looked at in terms of what the literature is saying what the risks are, so that you can justify up to what point you can be collecting information.

Ms. Caroline Weber: But the system needs to be in place, and these data need to be protected, so we're not doing that. We haven't started collecting that baseline.

We saw the sector start to migrate a bit because we know there is a lot of variation out there in terms of information collection, and they started to talk to each other more across the country about what kinds of information they're collecting and to think about standardizing that a bit.

So I think there has been movement to do a better job with more consistent performance across all the clinics, but we don't have the information registry yet. We're still working on that infrastructure approach, the data element. We need to consult on that, and we want the agency in place to be responsible for the data.

Mr. Colin Carrie: I see this as so important because more and more kids are conceived this way. The sooner the better I'd like to see that.

Another question I had is in regard to prevention—

The Chair: I'm sorry, Mr. Carrie. You're over five minutes.

Madame Demers is waiting.

I'm sorry, Madame Demers, I forgot about you and went back to the Conservatives.

[*Translation*]

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

Mr. Maga, earlier you answered my colleague with respect to the possibility of non-compliance with sections 5 to 9, saying that when you are made aware of a case, you refer it to the RCMP.

But if you have no inspectors, who is giving you this information? Who is making you aware? How many cases have been brought to your attention since March of 2004?

[*English*]

Mr. Bill Maga: Thank you.

What has happened in the past.... As a matter of fact, we've had two instances where it's been brought to our attention that there have been questionable practices, and that was in particular with respect to two websites that were advertising for egg sharing.

It was brought to our attention, and in both instances we sent letters to the clinics to have them correct that practice, and those practices were in fact corrected.

It's an example of perhaps the first two aspects of the compliance policy that I mentioned. One is simply providing education. In that respect, the letters inform the clinics of the requirements of the legislation and the responsibilities of the clinician, and then suggest that it would be an appropriate measure for them to refrain from advertising on their website. Of course, they complied with those instructions.

[*Translation*]

Ms. Nicole Demers: Those were cases where the problem was highly visible. It had to do with an Internet site; anyone has access. But if we're talking about cases where it's hidden, less visible, how can you find out that regulations are not being followed, since you have no inspectors? This is quite a concern for me.

I also want to ask you about sub-sections (1) and (2) of section 65, which read as follows:

> 65. (1) The Governor in Council may make regulations for carrying into effect the purposes and provisions of this Act and, in particular, may make regulations:
>
> (2) exempting controlled activities or classes of controlled activities, generally or in circumstances prescribed by the regulations, from the provisions of this Act, subject to any terms and conditions prescribed in the regulations.

Can you give us an example of a situation where such an exemption would apply?

● (1215)

Ms. Francine Manseau: I will try to answer Ms. Demers' question.

That option was clearly put in the legislation in anticipation of situations involving activities that did not involve the protection of people's health and safety.

For example, people may want to inseminate themselves at home using the sperm of a potential donor. Our aim is not to get involved in what takes place in people's private lives, in their homes. The Act states that the manipulation of sperm for the purposes of creating an embryo is an activity that will be regulated. That is the generic approach taken in this legislation.

However, if an individual obtains sperm from someone and inseminates herself in her own home, we should not necessarily be regulating that kind of activity.

Ms. Nicole Demers: It is regulated, but you could exempt it from the regulations and at the same time say that you are enforcing the regulation.

Ms. Francine Manseau: Yes, it would be possible for there to be exemptions.

Based on the wording of the legislation, the manipulation of sperm for the purposes of creating an embryo is a regulated activity.

Ms. Nicole Demers: However, if we ended up with a government that does not approve of these practices, it might decide that there would be no exemptions. In that case, someone who had done that in her own home could be convicted of an offence.

Ms. Francine Manseau: All draft regulations are subject to consultations. We also have to provide appropriate rationale for the regulations going that far. There is a whole process whereby actions have to be warranted for reasons that really relate to health protection. I don't know whether all those yardsticks will be accepted.

Ms. Caroline Weber: As well, all regulations have to be reviewed by the Committee.

Ms. Francine Manseau: Yes, exactly. And we have to provide the rationale, because after all, regulations are a pretty coercive instrument. We have to be in a position to provide reasoned analysis.

Ms. Nicole Demers: Yes, but since I did not have an opportunity to attend all the meetings my colleague has attended, I need clarification in order to have a proper understanding of the situation.

Thank you very much.

Mr. Réal Ménard: It was one of the finer moments of my life.

Ms. Francine Manseau: Really?

Ms. Nicole Demers: Thank you.

Thank you, Madam Chair.

[*English*]

The Chair: Thank you, Madame Demers.

There are a couple of things. I think it could be difficult for the newcomers to follow this, but people who sat through two years of it, I'm sure, are following it easily. For the purposes of the newcomers, I'll say there are essentially two licensing systems. One is a licence to do research on embryonic stem cells, on embryos; that is one set of licences this board will be responsible for. The other set of licences has to do with running a fertility clinic and dealing with infertile couples, donors of gametes, and all that sort of thing. There are two full sets of activities.

Ms. Weber, you said something that bothered me when we were talking about informed consent. You said it wouldn't have anything to do with informed consent for a procedure. Why? Are you thinking that's just going to be done by the medical doctors?

Ms. Caroline Weber: It's currently covered now under provincial jurisdiction. Actually, we've been researching the provincial frameworks on consent for developing our consent regulations also.

Again, I'll ask Madame Manseau to—

The Chair: If that's the case, the doctors are going to be getting the informed consent?

Ms. Francine Manseau: It's just that the consent to have a doctor perform something on you is a decision that concerns the doctor and the patient.

The Chair: I understand that, but we were concerned about that.

Ms. Francine Manseau: The information—

The Chair: No, not the information; it's the actual consent. The piece of the puzzle I'm most concerned about is this. I'm not concerned about the infertile couple; they are essentially the primary customers of that doctor. What I'm concerned about is that while that doctor is the one getting the consent from the young female to extract her eggs in that very intrusive procedure, that doctor has an interest in helping his primary clients, who are the couple. Granted, we've taken the money out of it, but even so, I think everybody involved, from the sperm donor to the egg donor to the couple, should have to go through this counselling.

● (1220)

Ms. Francine Manseau: It's obligatory now in the legislation. Before you obtain any gametes from anybody or do any procedure, they have to go and have counselling provided to them.

The Chair: So the definition of that counselling becomes even more important. I can see you'd probably be under pressure from the medical profession, which always did that counselling—well, they called it counselling but it wasn't—instead of people who are specialists in counselling.

I would refer you, Ms. Manseau, back to that wonderful person we had from the University of Western Ontario clinic, who to me covered all aspects of it, keeping the whole person in mind.

Ms. Francine Manseau: When we did the consultation, as I mentioned, we brought together everybody we could identify who was doing professional counselling in Canada. There were about 30 or 35 of them gathered.

As you say, it's important to try to define what we mean by counselling, because with the regulations you want to ensure the people have the right qualifications and that there's the same understanding of what we mean. Counselling could be different for a donor, for an individual going through...and so on. So the requirements could be different, but we are working with professionals involved in the field to develop those.

Ms. Caroline Weber: I'll to try to address your question directly, Madam Chair. There are lots of procedures one can talk about in assisted human reproduction. My comments were referring to what I thought was a more general reference to techniques. I think your concern is really about obtaining gametes, and certainly the legislation covers that and requires the consent forms. While that has to be collected at the clinic, we are going to be regulating and examining those and the process by which consent is obtained.

The Chair: Thank you.

I'd just like to compliment the gentleman who was on CBC Radio explaining all this. Mr. Ghali, you did an excellent job.

Sometimes I wonder why we're so busy trying to recruit donors when we don't even have the regulations in place. It would seem to me that clinics are quite capable of maintaining their own activity level. They might want some assistance and some united force doing it, but I found those people to be very aggressive when they were here. Of all the things we should be taking care of...it's getting the regulations in place they have to abide by, not helping them do their work.

In any case, I thought you explained the philosophy underpinning the bill extremely well.

Mr. Rodney Ghali: Thank you.

The Chair: I'm worried about responsive inspections. We have other experience with that with regard to adverse reactions to pharmaceuticals. First of all, how well publicized is the phone number where you make a complaint? How many people are there waiting for it? And then how many inspectors are ready to rush out and inspect? I don't think we have the best record in that.

Ms. Caroline Weber: This is a temporary situation, Madam Chair. Establishing the agency and moving that forward in its stages of development is—

The Chair: But will it still be responsive?

Ms. Caroline Weber: No, not at all. This is really our temporary approach to this until we have the agency. No, it's not the policy direction here; it's not the intended way of managing this.

The Chair: I understand. Thank you.

Mr. Merrifield.

Mr. Rob Merrifield: I just have a couple of quick questions. First of all, you say you'd like to have the agency up on January 12, 2006. What's the budget for 2006 for the agency?

Mr. Bill Maga: For 2006-07 it will be $10.2 million.

Mr. Rob Merrifield: And then after that it will be what?

Mr. Bill Maga: It's the same the year after that.

Mr. Rob Merrifield: What is your timeline on the regulations that are yet to come? Where I see a problem is that you're going to have an agency up without the regulations, and I think they're going to be in a bit of a vacuum for a while.

● (1225)

Ms. Caroline Weber: But we've tried to avoid that a little bit. As to the timeline, we have tried to take this in a staged approach, so we're working on the consent regulations; we're hoping to have the consent regulations close to being done by the time the agency is created. They need to hire staff and do a lot of work in terms of infrastructure.

Mr. Bill Maga: Yes, you're quite right about that. We don't want to bring the agency into force, into fruition, too early. That being said, we have this parallel track going with the regulations, with their development on one side and the agency on the other.

The agency will have a lot to do once it's established. We expect that just the staffing process is going to take at least 18 months. The agency is going to have to look for some pretty specialized expertise with regard to inspectors and the licensing experts, etc. At the same time, they're going to have to start to develop their own management systems, their HR systems—

Mr. Rob Merrifield: Is that because they're the ones who are going to be on the...? You're looking for recruitment for the board. Is that why you're looking for that expertise?

Mr. Bill Maga: It's not only for the board but for the agency itself, the people who are going to be doing the inspection and doing the licensing. That's a specialized trade. We have a number of things going on with regard to developing the systems for the agency—HR systems, financial systems, inspection systems—and all this is going to take time. The way we're trying to run it is that they'll coincide; the regulatory development and the operationalization, if you will, of the agency will coincide late in 2007 or early 2008.

Mr. Rob Merrifield: Yes, I can see some significant stresses on that agency for the first while. You have a dilemma ahead of you on that.

Ms. Caroline Weber: Honestly, we share your concern. We tried to stage the development of the regulations so they'd have something to work with, and then we're bringing more in as they're staffing and figuring out how they're going to make their organization work.

Mr. Rob Merrifield: Actually, one of the things that surprised and offended me, in some ways, was that this piece of legislation was drafted opposite to the way this committee recommended. When we first looked at it this first year, as the chair rightly said, this was two years.... Well, actually she was wrong. It was three years and two lifetimes that we worked on it. We looked for an agency that sat from a judge aspect, rather than an expertise aspect, but you came in with more of the expertise aspect. I think that's probably going to cause you more trouble in the long run.

Ms. Caroline Weber: Expertise is part I think of what we're looking for, but there is also interest in the area. Again, we're trying to recruit people for the board from a wide range of backgrounds. The comments Bill is making about the expertise level really pertain more to the staff within the agency.

Mr. Rob Merrifield: That's fair enough. That's wisdom, in the sense that you look for the best expertise around the country, but not necessarily that you have to have it on the board. You just have to have the ability for the board to get that information. Fair enough.

Ms. Caroline Weber: Exactly. Yes.

The Chair: Thank you very much, on behalf of my colleagues, to the witnesses for coming.

Now that my mind is working its way back into the intricacies of this project, let me just say I'm glad you're handling it and not me. It is like keeping many balls in the air at once as you move forward. Those of us who were on that committee just want to encourage you to be strong against the forces that are trying to make you weaken things and soften things up so that the industry, as they call it, can carry on unfettered. We tried to put a stop to that, and we have, through the bill, so it will be a matter of making the regulations equally tough.

Thank you very much.

● (1230)

[*Translation*]

Mr. Réal Ménard: Madam Chair, the information we've been given is that the government will not be presenting amendments to any of the clauses. Is that correct?

[*English*]

The Chair: That's what I understand. There are no amendments coming forth from any source.

Just to remind you—you know how we always start with clause 2, because we do the title later? There is no title, because this bill just amends another bill, so we can start with clause 1.

Looking at Bill C-28, ladies and gentlemen, shall clause 1 carry?

Those people who agree with the clause had better say it out loud, because all I heard were two people saying no.

Ms. Nicole Demers: There were three saying no.

The Chair: Okay. There were three saying no.

(Clause 1 agreed to on division)

The Chair: Shall clause 2 carry on division?

[*Translation*]

Mr. Réal Ménard: Madam Chair, on a point of order. I simply want to ensure that we have a clear understanding of how things are going to work.

We do not want to see this bill pass, but if it does pass, the six clauses it contains will carry on division. However, that does not mean this bill will carry at the end of our work. At that point, we will vote on the bill as a whole. Is that correct?

[*English*]

The Chair: Yes, okay. That's fine.

(Clauses 2 to 6 inclusive agreed to on division)

The Chair: Shall the bill carry?

Now we need a vote.

[*Translation*]

Mr. Réal Ménard: I would ask for a recorded vote.

Ms. Nicole Demers: It's important that people know exactly how MPs voted on this. They certainly won't…

Mr. Réal Ménard: It is a bad bill.

Ms. Nicole Demers: It's a very bad bill.

[*English*]

The Chair: Madam clerk, the vote on the bill.

(Bill C-28 agreed to: yeas 8; nays 3)

The Chair: Shall the chair report the bill to the House?

Some hon. members: Agreed.

The Chair: Thank you very much, ladies and gentlemen. Bill C-28 is carried, and I will report it on your behalf to the House.

The meeting is adjourned

Published under the authority of the Speaker of the House of Commons

Publié en conformité de l'autorité du Président de la Chambre des communes

Also available on the Parliamentary Internet Parlementaire at the following address:
Aussi disponible sur le réseau électronique « Parliamentary Internet Parlementaire » à l'adresse suivante :
http://www.parl.gc.ca
