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## Thursday, November 17, 2005

## Chair

**Ms. Bonnie Brown**

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● (0910)

[*English*]

**The Chair (Ms. Bonnie Brown (Oakville, Lib.)):** Good morning, ladies and gentlemen. It's my pleasure to welcome you to the 54th meeting of the Standing Committee on Health.

According to your agenda, the first item is an update on the study on prescription drugs. The clerk has attached a motion that suggests an amount that will cover the costs of any witnesses we might call. We all know this may never come to pass or may only barely get started. However, we still have to be sure, in case we do go forward, that we have equipped ourselves with the resources to cause things to happen properly.

There's a motion that the proposed budget for the prescription drug study, in the amount of $39,900, be adopted. Would someone like to move that?

**Mr. Colin Carrie (Oshawa, CPC):** I so move.

**The Chair:** Mr. Carrie moves that. Is there any debate on it?

(Motion agreed to)

**The Chair:** Thank you.

The second thing about the prescription drug study is, if anybody would like to suggest witnesses who they know would have something to say about it, I would ask you to get your names into the clerk. The clerk has a number of names based upon people we thought were rather outstanding in the previous hearings, but as you know, we only dealt with about half the issues in our first report. So we would be asking these witnesses to focus on those areas that we're looking at this time.

Yes, Mr. Merrifield.

**Mr. Rob Merrifield (Yellowhead, CPC):** As I understand it, next Tuesday we're into a report coming back from.... It's Bill C-420, right?

**The Chair:** Next Tuesday is Bill C-420. We'll have Mr. Waddington brief us on his progress, and then we'll do clause-by-clause, as an earlier motion suggested.

On the Wednesday we're going to have a meeting at 3:30 to follow up on our concerns about tobacco and cigarette smuggling, as raised by Mr. Ménard. Apparently, officials are coming from Health, Finance, Revenue, Border Services, and the RCMP to brief us on what it is they're doing.

Then on Thursday, we hope to begin the prescription drug study. We have one witness confirmed, but quite a good one—Dr. Joel Lexchin from the Medical Reform Group.

The following Tuesday we have the Minister of Health for supplementary estimates.

The next few meetings are set, but I just want to be prepared, in case we go longer than that, to make sure we have the money.

**Mr. Rob Merrifield:** So what you're saying is next Thursday's looked after. It's beyond that we want witnesses for.

**The Chair:** Yes. Well, next Thursday we only have one witness.

**Mr. Rob Merrifield:** Okay. As a suggestion, I know the Baker-Norton group did an international study. They're the group that actually did the study on adverse events within facilities.

**The Chair:** Where are they based?

**Mr. Rob Merrifield:** I think out of Toronto, but I'm not 100% sure.

**The Chair:** If you can get a phone number to the clerk, maybe she could try them.

**Mr. Rob Merrifield:** You've got it.

**Hon. Robert Thibault (West Nova, Lib.):** I would happily provide the committee with a list of suggested witnesses. Also, there are participants who participated in the COX-2 inhibitor study whom it might be worthwhile to consider inviting to meet with us at that time.

**The Chair:** Okay. Good.

Mr. Fletcher.

**Mr. Steven Fletcher (Charleswood—St. James—Assiniboia, CPC):** Yes, Madam Chair, on the prescription drug study, because issues of supply and price seem to be of concern, I wonder if we can include witnesses who can touch on that area.

**The Chair:** I think we should get an update on that, Mr. Fletcher, yes.

Okay. I think those are the issues.

Oh, there's the whole thing about travel.

**Mr. James Lunney (Nanaimo—Alberni, CPC):** Madam Chair, before we leave the issue of witnesses, can I just add one?

**The Chair:** Sure.

**Mr. James Lunney:** From the Vancouver area there is a woman who is very concerned about the anti-depressants and what they're doing to people, and particularly the adverse effects related to teenagers. Anyway, her name is Joan Gadsby. Just for the record, that we would—

**The Chair:** We heard from her the last time we were in Vancouver.

**Mr. James Lunney:** You did. She would be interested in appearing again, I'm sure.

**The Chair:** Now, on the whole issue of going abroad on this study, do you think it's a moot point or shall we...?

**Hon. Robert Thibault:** Madam Chair, my intention is to vote in favour of the government in any confidence motion, to continue the work of the House and the committee so we can get on with our committee.

**The Chair:** Let's not get into this.

**Hon. Robert Thibault:** That's the only opinion I can give you. Perhaps other members could think otherwise.

**The Chair:** I think everybody asked their whips if they could get out of town. Did anybody's whip say no?

Yours did?

[*Translation*]

**Mr. Réal Ménard (Hochelaga, BQ):** I think that, realistically speaking, we should not commit to too much. The next two weeks will be decisive. The official policy of the Bloc Quebecois is not to authorize any travel from now to the end of November. In any case, let us be honest. The thing is not to make people work for nothing. If the government is going to fall, it will happen over the next two weeks. If the government does not fall, there are two possible scenarios: either we carry on, or the government prorogues. There is a nasty rumour making the rounds, which the parliamentary secretary must have heard, according to which there will be a prorogation. If that is not the case, we will in any case find ourselves here at the beginning of December and we'll be in a position to plan for January at that time. I believe that for the moment, no opposition whip will authorize any travel.

● (0915)

[*English*]

**The Chair:** That's the answer, so we don't have to worry about travelling.

That was the last question.

The corollary to that is the possibility of replacing that travel week with a week of an intense number of meetings, but I think we'd better get through the next two weeks first. Then we'll look at that question.

**Mr. Rob Merrifield:** As long as we get the schedule for next week, then we'll know.

**The Chair:** Okay, item two on the agenda is a motion we deferred earlier, and it's back in front of us. You have the motion attached to your agenda. It's Mrs. Crowder's.

Mrs. Crowder, you'll remember we didn't vote on this last time because we thought we might want to hear more and think about it a little more. Do you have anything you would like to bring to the committee today?

**Ms. Jean Crowder (Nanaimo—Cowichan, NDP):** Thank you, Madam Chair. There are a couple of items.

One of them is that it seems we've had some difficulties in getting additional information. For example, the assistant deputy minister sent out a letter indicating that now she's seeking a legal opinion on whether or not she can release the chair's notes from the meeting on March 22 or...when the scientific panel met. The Public Health Agency is now the owner of the 1996 cohort study, but when we approached Minister Bennett, she wasn't aware that the Public Health Agency was the owner. When we sent her the testimony from the committee informing her of that, she said she would look into it, and we've heard nothing.

It seems there is some difficulty in getting information, and I'm wondering if there's some barrier to getting information—for example, a confidentiality agreement that's been signed that we're not aware of. When I checked on the website yesterday, I couldn't find anything about confidentiality. I found information about conflict of interest.

Before the committee looks at this motion, could we ask Health Canada to provide us with any confidentiality agreement they might require people to sign, so that we can determine whether there are some barriers to our getting additional information? I would suggest we table this motion. I would ask the chair to write the letter and just table this motion until we get that information.

**The Chair:** Ms. Dhalla.

**Ms. Ruby Dhalla (Brampton—Springdale, Lib.):** At the same time as we request the confidentiality agreements, we can also request the agreements signed with the individuals sitting on the expert panel. I'd be very interested to see those. We can move ahead and further examine to see what conflict of interest guidelines were in there. Also, as an additional request, can we possibly get those for our next meeting?

**The Chair:** Thank you.

Are there any other suggestions?

Mr. Thibault.

**Hon. Robert Thibault:** Madam Chair, as was stated last time, the Department of Health is making all the necessary arrangements to provide the information on the question of the abstracts.

Also, the minister will be here on the 29th and he'll be happy to answer any of these questions. I trust he will have expertise with him to assist him.

**The Chair:** Thank you, Mr. Thibault. You don't object to our writing this letter suggested by Mrs. Crowder?

**Hon. Robert Thibault:** No, but the only thing you should realize is...number one, I don't know the answer to it, but there are things that are confidential in the way they're processed, without there necessarily being a confidentiality agreement. When applications are made by companies before the department as part of the regulatory process, there is some protection of information as material that is the property of the company making the application. It's protected from public disclosure in some instances, at least until the device or the drugs are approved. That information can best be answered by response to that letter or by the minister when he appears here.

**The Chair:** Yes. I think if we could see some of the forms they use, it might also be interesting for us as part of our prescription drug study, if you know what I mean.

**Hon. Robert Thibault:** Yes.

**The Chair:** I think some of this will translate from the implants to the drug study. I don't think it would hurt us to be informed.

Mrs. Crowder.

**Ms. Jean Crowder:** I wanted to be clear. I'm interested in any confidentiality agreements that may have been signed with the scientific panel, or the people who were on the expert panel in September, people who are directly related to making recommendations to the minister. I want to see what kind of confidentiality agreements...the template they may be required to sign.

● (0920)

**The Chair:** I wouldn't use the word “template”, though, Mrs. Crowder. We may get a generic one as opposed to the real one.

**Ms. Jean Crowder:** Yes, I want the real one. I assume they have a template that they use, which is the real one that they sign. I want the real one. I want the one they actually signed.

Thank you.

**The Chair:** Are there any other comments?

Ms. Dhalla.

**Ms. Ruby Dhalla:** Madam Chair, once again, may we stress...in view of the nature of the environment that we are in right now, perhaps we could—

**The Chair:** Speed is essential.

**Ms. Ruby Dhalla:** Yes, please.

**The Chair:** Thank you for reminding me.

Are there any objections to this plan? Thank you.

We will consider Mrs. Crowder's motion still on the table. It can be resurrected at any time, but we will not be voting on it today.

Let us move now to the next motion, which is Mr. Ménard's on assisted human reproduction regulations. Mr. Ménard, would you like to talk about this?

[*Translation*]

**Mr. Réal Ménard:** Madam Chair, first of all, I would like to thank you for holding this meeting. As is probably the case for several other committee members, I have had representations from women's groups and other citizens concerned with the regulations on medically assisted human reproduction. You will recall, Madam Chair, that the regulations are more important than the act, because they will determine the important conditions for the preservation of reproductive materials as well as the prohibited practices. Basically, the implementation of the act is set out in the regulations. We worked on this legislation for two years. Three different ministers succeeded one another before this bill reached its final form. The committee worked very hard.

I was somewhat surprised to learn certain things from a background report that was published in the papers. I don't know if it was published in English Canada, but in Quebec, Ms. Hélène Buzzetti from *Le Devoir*, the journalist who wrote this background article, was informing people of the fact that the final regulations will not be available until 2008. I was under the impression that they would be available in 2006. It concerns me to have to wait until 2008 for a piece of legislation that was passed in 2004. I am told that sperm banks are having difficulties in terms of availability. Obviously, this is not only a regulatory issue. I know that there are campaigns that have to be carried out. Perhaps we as a committee should ask ourselves what we can do to conduct an awareness campaign. I would really like us to study this, because it appears to me to be a problem. I do not know why. Is it because of a lack of officials? When we have to wait from 2004 until 2008, that is worrisome.

[*English*]

**The Chair:** Yes. Seeing your motion, I asked the clerk if she could arrange for this briefing, and actually, she has people here today. So would you like to move to yours now?

**Hon. Robert Thibault:** Yes, please.

Madam Chair, it's my understanding—

**The Chair:** Does that make you happy, Mr. Ménard?

**Mr. Réal Ménard:** I'm very happy. I would like to kiss you and the clerk—not at the same time.

**Voices**: Oh, oh!

**The Chair:** Mr. Thibault would like to comment, and then we'll invite the witnesses to come to the table.

[*Translation*]

**Hon. Robert Thibault:** I would first of all like to thank the Bloc Quebecois health critic for having given the committee advance notice of his request. Because of that, the clerk's office and the department were able to get organized so that we have specialists here, this morning, to respond to our questions. I believe that the regulations on consent will be ready in 2006, but the departmental officials will be able to tell us right away.

[*English*]

**The Chair:** Do we need to vote on this motion now? I don't think so.

Could we have the officials from the Department of Health come forward, please?

Welcome, Mr. Maga and Ms. Manseau.

Ms. Manseau is an old friend of ours who saw us through the study on assisted human reproduction, and Mr. Maga is a new person in that particular section of the department.

The floor is yours, whichever one of you wishes to begin. Please begin.

● (0925)

**Mr. Bill Maga (Director, Assisted Human Reproduction Implementation Office, Health Policy Branch, Department of Health):** Thank you.

If I could start with a short presentation, I thought that while we're here we could give you an update with respect to all the activities we've been undertaking at the assisted human reproduction implementation office.

Again, 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.

My name is Bill Maga. I am the director of the assisted human reproduction implementation office, or AHRIO, as we call it, and with me is Francine Manseau. Francine is the manager of the regulatory policy development group within our office. You may recall that Francine and I were here as part of a team last May to provide you with a similar update.

To get right to it, this committee has certainly been a key player and has had a significant role, most notably since 2001, in shaping the legislation that we have today. As we move forward towards full implementation, that important role will continue, and perhaps we'll touch on that again a little later.

It has been 18 months since the act received royal assent and key elements came into force. The department has continued to work on two main tracks with respect to implementing the legislation. Of course, the first is the development of the regulatory regime under the act, and the second is the establishment of the Assisted Human Reproduction Agency of Canada.

Today we'd like to outline what we've done over the last six months, since our last visit, and what we intend to do over the next six months or even a little further into the future.

I'd like to start with the work completed to date on the act's supporting regulations and then follow up on the activities related to the agency. I'll ask Francine, as manager of the regulatory group, to elaborate on the development of our regulations.

[*Translation*]

**Ms. Francine Manseau (Manager, Policy Development Group, Assisted Human Reproduction Implementation Office, Health Policy Branch, Department of Health):** Good morning.

I will give you a summary of the activities we have undertaken. In the fall of 2004, we began a series of national consultations regarding the specific policies and regulations on consent, pursuant to section 8 of the act.

Moreover, in November 2004, we made public a report on counselling which was distributed to committee members when we were last here, in May.

We also made public the report on the workshop on the refunding of expenses for egg and sperm donors. I believe you received copies of that report this morning.

Last September, the department pre-published, in part I of the *Canada Gazette*, the proposed regulations for section 8. These draft regulations were intended to ensure that, among other things, the written consent of the donor was obtained before the use of human reproductive material for the creation of an embryo, as well as the consent of the donor for the use of an in vitro embryo for any purpose. I believe that a copy of the proposed regulations and the summary of the impact study on the regulations were distributed to the committee this morning.

As you know, the draft regulations for this legislation must be tabled with both Houses of Parliament before they can be promulgated. Following the 75-day comment period as far as the draft regulations for section 8 are concerned, which will come to an end at the beginning of December, we will make the appropriate amendments to the regulations following the comments we will have received, and the proposed regulations will be presented to Parliament so that they can be studied by this committee in the new year. We hope that these regulations will come into effect in the spring of 2006.

We have also undertaken wide-hanging consultations with stakeholders in order to allow for the drafting of regulations on the pre-implantation genetic diagnosis. The pre-publication of the draft regulations for this section of the act should appear in part I of the *Canada Gazette*. This is planned for 2006.

The department must plan to hold consultations in 2006 on various issues such as clinical practices, laboratory practices, counselling and research on embryos, to name but a few, and the overall regulatory framework and granting of licences must be implemented for the end of 2007 or the beginning of 2008.

As you are perhaps aware, the department is subject to federal government policies on regulations. Under this policy, it generally takes at least two years to draft and adopt new regulations. This timeframe does not take into account the parliamentary review of these proposed regulations.

As you know, in the legislation we have before us, there are many areas for which regulations must be drafted. They have been organized under eight themes which overlaps, and we intend to produce all of the regulations in some three years.

As you also know, there are currently very few standards or guidelines in Canada on the subject for which we must create the regulations. Because of this, we must undertake extensive and rather comprehensive consultations in order to ensure that the objectives of the regulations will be reached without imposing an undue burden on Canadians.

Moreover, over the past six months, health Canada launched a request for proposals regarding a pilot project on the altruistic donation of gametes. As it is well aware of the impact of the imposed ban on the purchase of gametes from donors, Health Canada has gathered, within the framework of this project, qualitative and quantitative data on the recruitment of gamete donors within an altruistic system, in order to support the implementation of the legislation and to help assisted human reproduction clinics to recruit altruistic donors. The winning proposal was selected, and we are now in the final stages, which consists of negotiating a contract. Once we have finalized this process, we will launch the pilot project; this will no doubt be done by the end of this year.

I now give Bill the floor. Perhaps he will be able to tell you more about the establishment of the agency.

● (0930)

[*English*]

**Mr. Bill Maga:** Thanks, Francine.

As for the establishment of the agency, last June we launched the recruitment process for the board of directors of the agency, and that includes the chairperson and the president, who are both members of the board. This process is a public, open, and equitable one. The board will be comprised of up to 13 members reflecting a range of backgrounds and disciplines that will ensure broad representation and varied perspectives on AHR-related issues. As you'll recall, that requirement is actually in the act.

We made an announcement with respect to the competition in June of this year, and we expect that appointments will be made early in 2006 after the establishment of the agency. This is an important date, because when section 21(1) goes into force establishing the agency, the clock starts on the three-year review of Parliament of the operations of the agency and the provisions of the act.

In addition, we've made good progress on building the critical infrastructure for the agency that will allow it to be up and running as quickly as possible once it's established. The goal is to present a series of policies and systems that would facilitate the early operation of the agency but allow the board of directors the flexibility to choose at their discretion from a number of options for the provision of corporate services. This will maximize the agency's autonomy.

Many of the systems and tools that the agency will need we already have in place, or their development is well under way. For example, we have the financial systems just about set up. These are the systems the agency will need to manage its budget, to make financial transactions, to ensure its accountabilities. We've done this in collaboration with Public Works and Government Services Canada. They should be ready to go by January.

With regard to the agency's staff, we have job descriptions—they've been written—and classification rationales have been produced for the agency's proposed 44 positions. In addition, we have a human resources strategy document in draft that will be presented to the president and the board to facilitate the early staffing of the agency. And of course there's a suite of administrative policies and guidelines we've prepared that will guide the agency's staff in the early days. We've even gotten to the stage of producing some draft bylaws that the board of directors will be allowed to vote on early to get into operation. These bylaws will eventually be presented for Governor in Council approval. Public Works has also been helpful in our search for accommodations for the new agency, to be located in Vancouver. It looks like a permanent location is not going to be available until later in 2006, so right now we're looking for some temporary space as well.

With regard to communications, we've worked on the agency's website; we've developed a new agency title and word mark for registration under the federal identity program; and we've also worked on a communications manual for the agency.

Concerning enforcement, we have developed a memorandum of understanding with the inspectorate of the health products and food branch of Health Canada to provide compliance and enforcement support through in-house inspection staff. We have six inspectors who will be designated under the Department of Health Act, along with three of our own staff who will be participating in providing direction and advice with regard to compliance and enforcement.

Inspectors will carry out the research and information dissemination and collection activities will be starting this winter, possibly in January and into early 2006. Should the need arise, investigations in response to alleged infractions will be carried out.

● (0935)

The compliance philosophy that we have is one of participation, education, and being in partnerships with the regulatees. We intend to work during the first year or so, prior to the regulatory regime actually coming into force, with the clinics and the labs to ensure that they understand why we're there and what is expected of them.

So you can see that we're working on a number of fronts and that things are certainly coming along. We'd all like to see things proceed a little quicker than they have, but we've got a good team assembled at AHRIO and are in fact progressing as quickly as we can.

Thank you.

**The Chair:** Mr. Merrifield, I believe, is going to begin.

**Mr. Rob Merrifield:** I want to thank you for giving us the update.

I was quite concerned about what you had presented this spring when you came forward. You had said the regulations would be gazetted in early fall and started on, and the agency early in the new year. I think that's what you had said, so you have confirmed that.

So September 17 is when the first part of the regulations were gazetted. Is that correct?

**Mr. Bill Maga:** That's the first part of the first set of regulations.

**Mr. Rob Merrifield:** Yes, I realize that's only one little part, but is it enough? Is it enough to give direction to an agency. The agency is going to be struck early in the new year. Under what criteria is it going to run, and what is its mandate? What's its first order of business?

**Mr. Bill Maga:** Well, the first order of business is—

● (0940)

**Mr. Rob Merrifield:** What will it be working under? Those regs would have to come back to this committee, I understand, before anything would really happen.

**Mr. Bill Maga:** Well, the first order of business—

**Mr. Rob Merrifield:** I see a dilemma.

**Mr. Bill Maga:** I don't think it's a dilemma. The first order of business for the board of directors, once they're appointed, is to get organized. Certainly it's going to be a very busy time for the president. We're starting from scratch here; this is a new agency.

The president is going to have to hire, first of all, that first tranche of senior management, and then it will fall down from there. There are a vast number of things that the agency can be doing until the time the regulatory framework comes into place. Staffing is just one. They have to get their systems in order, and one of the big things will be a communications and consultation strategy.

**Mr. Rob Merrifield:** Yes, I can understand the job he's got to do. I appreciate that. What I don't understand is what criteria the agency will be working under until this first part actually gets through the committee and into, and passed as, regulations. Is there enough just in the first part to give appropriate direction to an agency that is supposed to follow the mandate of the bill?

**Mr. Bill Maga:** Well, certainly the bylaws being drafted right now for the agency are going to guide its initial activities. In combination with the prohibitions that are already in place, that's where the.... I think you're actually referring to the business of the agency with respect to monitoring the licensing and ensuring that the prohibitions are respected.

**Mr. Rob Merrifield:** Right.

**Mr. Bill Maga:** Those are all part of the initial operations of the agency.

**Mr. Rob Merrifield:** I suppose that's why Réal brought forward the motion here, because we are a little concerned about the speed of the regulations, so that the council or this agency can be ramped up and be given direction other than just by the Minister of Health. That was one of the concerns we had with the bill, that the Minister of Health could actually supercede some of what would be offered by the regulations. When you say it's going to be working under order in council, that gives me a little discomfort.

**Mr. Bill Maga:** But the agency has most of its direction contained right in the act. The act outlines its responsibilities and what it's supposed to do, its functions, etc. So that's laid out for it. In combination with the bylaws, that will give the agency its marching orders and its modus operandi.

What they will have to wait for are the regulatory components in order to begin to fully operate.

**Mr. Rob Merrifield:** Okay, let's get into what happened this summer.

It concerns me a little bit when the CIHR is changing its rules to allow fresh embryos for research. Can you tell me whether that would be complying with the regulations? It certainly was not the intent of the bill. I understand that it's only for reproduction purposes that this research is allowed, and yet, can you tell us if what CIHR is doing is actually for that kind of research, or is it for other research?

**Ms. Francine Manseau:** What the legislation does, basically, is constrain the reasons why an embryo can be created. That's already enforced, and that would be the prohibition under section 5, where the three reasons you can create an embryo—in paragraph 5.1(b), if I recall—would be to create a human being, to improve assisted human reproduction procedures, and for training. So these are the only three reasons.

**Mr. Rob Merrifield:** Can you tell me if the CIHR is—

**Ms. Francine Manseau:** We're talking about the creation of an embryo here. I think what the CIHR was dealing with was the use of an in vitro embryo for research purposes. What the legislation allows are the reasons an embryo can be created. The legislation would allow the use of an in vitro embryo for research if there was consent from the people from whom the embryo was created, once the agency is set up. It would also allow the agency to be convinced that there is a need to use an in vitro embryo for the purpose of research. And there could be other regulations attached to it, also.

**Mr. Rob Merrifield:** I think I understand what the bill is saying. What I'm wondering is whether the research the CIHR was doing this summer would comply with the bill, once it's fully operational and the regulations are passed. Or are they working outside the bounds of the bill at the present time, or do you know?

**Ms. Francine Manseau:** Once all the regulations are in place, I guess what will be important here is the consent that's been provided by the people from whom the embryo was created. That would be one of the rules attached to it, that the embryo has not been bought, and so on and so forth. The law does allow supernumerary embryos that are not used for reproductive purposes to be used for research. But you need to have the consent of the individual to be able to do that. Once the agency is created, the agency will have to be—I don't think I'm using the right word—convinced of the necessity of using an in vitro embryo for research.

● (0945)

**Mr. Rob Merrifield:** So if I'm reading you right, whether what the CIHR is doing at the present time is appropriate would be at the discretion of the agency.

**Ms. Francine Manseau:** Whatever research is going on in Canada using in vitro embryos, the agency will have to allow a licence for individuals to be able to do research using an in vitro embryo.

**Mr. Bill Maga:** Can I just make one point of clarification? The act doesn't make any distinction between fresh and frozen, so under the act, it doesn't really matter. We're still talking about an in vitro embryo. So it would appear that the research is compliant with the act.

**Mr. Rob Merrifield:** Okay, that was my question. I understand that if it's for reproduction, they can do the research at the present time. I'm asking if CIHR's research, to your knowledge, is just for reproduction. Or is it for research other than for reproduction? And are they subject to the act as it is now?

**Ms. Francine Manseau:** Nothing in the legislation right now restricts the purposes for which an in vitro embryo can be used for research. What it does restrict are the purposes for which you can create an in vitro embryo, and you cannot create an in vitro embryo for research.

**Mr. Rob Merrifield:** So you're saying it can be created for a certain purpose and used for something else.

**Ms. Francine Manseau:** No, no. They are supernumerary embryos. Those embryos that you don't require anymore for reproductive purposes could be used, if there's consent.

**Mr. Rob Merrifield:** You can't take a fresh one and say, gee, I'm going to fertilize all of these without the intent of their being for reproduction. They would die in the petri dish prior to your saying that you would have to inject it for reproduction into a donor.

**Ms. Francine Manseau:** The purpose for which an embryo can be created is very clear in the legislation.

**Mr. Rob Merrifield:** My concern is whether CIHR is actually complying with the law at the present time. That's my concern. And from what you've told me, I'm not sure that you really know.

**Mr. Bill Maga:** Can I make a clarification? There's an overlap between the act and the activities of CIHR, and that's in the use of an in vitro embryo. So when a research project uses an in vitro embryo, that project comes under the auspices of the act. The most popular, or at least the most broadly known, research right now with respect to in vitro embryos is the derivation of stem cells. When you use an in vitro embryo to derive stem cells, that comes under the act. The derivation.... Pardon me?

**The Chair:** At the very first moment you create an embryo, it comes under the act, not later on.

**Mr. Bill Maga:** No, but the overlap between CIHR's act—

**The Chair:** What does that mean, an overlap? Are you talking about their guidelines for embryonic research?

**Mr. Bill Maga:** Yes.

**The Chair:** This supercedes them. My understanding is that the act supercedes their guidelines. It's an act of the Parliament of Canada. They have to conform to this act. We don't have to conform to their guidelines.

**Mr. Rob Merrifield:** So that's the question. Are they conforming?

**Ms. Francine Manseau:** If I may add something about the guidelines of CIHR, there was an amendment done in Parliament where the guidelines of CIHR are now attached to the legislation in the area of consent. If you look in section 3, we define consent, and it has to also be in line with the guidelines of the CIHR.

As well, in section—

**The Chair:** That's hoping they synthesize.

**Ms. Francine Manseau:** Yes, well, I would say hoping, and really they are now attached to the legislation. Consent has to be developed in a way to reflect also the guidelines that have been done by CIHR.

● (0950)

**Mr. Rob Merrifield:** But surely the CIHR guidelines wouldn't supercede the act, then?

**Ms. Francine Manseau:** The act is the act, but what I'm saying is that there was an amendment in Parliament that now attaches the CIHR guidelines to the consent provision in our legislation and also to the licensing, in subsection 43(1). That was a decision taken in Parliament.

**The Chair:** Yes, Mr. Thibault.

**Hon. Robert Thibault:** I didn't mean to interrupt, Mr. Merrifield. I think it's an important line of questioning. I'll just make a suggestion, and he can put it toward the question—or Mr. Merrifield can.

I think what this is all trying to get at is whether CIHR is subject to this act and whether the agency will be responsible for monitoring and reviewing the work of CIHR. I don't want to waste your time, but I think that—

**Mr. Rob Merrifield:** I put that question there twice. I didn't get a real clear answer.

**The Chair:** The other thing is, how are the food inspectors that they're going to use going to have the clout to go to the CIHR and say, no, no you can't do this? I don't understand that...not the food inspectors, but the inspectors you talked about, going up against Dr. Bernstein and the best scientists in the country and saying, well, you know, these are the rules, and you people....

It's not going to work. This agency should have its own inspectors, not somebody else's inspectors who don't know anything about it.

**Mr. Bill Maga:** If I could respond to that, the idea is the same. The MOU with the inspectorate is the same idea as the early provision of the corporate services to get the agency up and running. It will be up to the board of directors to look at their options with respect to enforcement. What we're going to do is present the directors with the option for the inspectorate, and they might choose to take that on as a temporary measure until they get their own staff up. But they will have that option. It's just the same as what we're trying to do with the other corporate services. But we do need some enforcement capacity right now, because the prohibitions are in place.

**The Chair:** For the one regulation we're going to have soon?

**Mr. Bill Maga:** No, we have a number of prohibitions in place already—for example, the prohibition on cloning or using techniques to determine the sex of an in vitro embryo. So we do need some capacity for that right now, and the MOU with the inspectorate is going to provide that.

But I would just like to say that a researcher who is seeking CIHR funding, once everything is up and running, is going to have to go to the agency to get a licence to do research that involves the use of an in vitro embryo. It's very clear they won't be able to perform that research without the licence and without doing it in accordance with the regulations, whether they're getting CIHR funding for not.

**The Chair:** But they're funding now, before the agency is up, before the inspectors are in place. So CIHR is implicitly saying, it's okay, go ahead, don't worry about this other bunch that's coming along soon.

**Mr. Rob Merrifield:** Yes, and would that be grandfathered once the agency is up? That's also something in the act that concerns me a little bit, because—I'm just playing devil's advocate—they could accelerate whatever they want in research right now, and I believe, under the act it would be grandfathered into it.

Is that right?

**Ms. Francine Manseau:** The grandfather provision says that you can do an activity that you've done in the year prior to the coming into force of those sections of the legislation on April 2004. So you can continue to do a controlled activity until such time as the agency or the regulation sets a date at which you will require a licence.

As long as you were doing a controlled activity in the year prior—that means from April 2003 to April 2004—you would be able to continue to do so until such time as the licence scheme framework is in place and the licence is issued.

**The Chair:** Thank you, Mr. Merrifield.

It's Mr. Ménard's turn.

[*Translation*]

**Mr. Réal Ménard:** Thank you, Madam Chair.

[*English*]

**The Chair:** You're very patient, Mr. Ménard.

[*Translation*]

**Mr. Réal Ménard:** You also worked very hard when you sat on the committee. This is something that concerns us.

At the time when Allan Rock introduced the bill, he said that one couple out of every five in Canada was infertile. That is what is important. I don't think that infertile couples were expecting it to take four years for the regulations to be drafted. I would like you to give a written description of the drafting team to the committee. How many officials are there? Have these people been seconded to Health Canada from the Privy Council or the Department of Justice? Why did it take four years to draft the regulations?

I'm not worried about section 5. I understand that the regulation applies for the six prohibited practices. That is not our concern. I also understand that section 8 is fine. What I find troubling are sections 6 and 65. Section 6 involves surrogate mothers. This committee decided to prohibit the general practice of compensating surrogate mothers. You and Hedy Fry introduced amendments to compensate surrogate mothers under certain conditions. I would like you to explain that. Is it true that, at this time, there are donor shortages throughout Canada and infertile couples are having trouble accessing reproductive material, since there are fewer donors? We are told that there is a relationship between the number of donors and section 6. I would like you to expand on that. I will come back to section 65.

I would like to know, therefore, who is working on this, how many officials there are, and why it will take four years. Could you also give us an update on the effect of section 6 on fertility clinics in Canada.

● (0955)

**Ms. Francine Manseau:** Bill will answer the question relating to human resources, and I will deal with sections 6 and 7 of the act.

You are correct in saying that sections 6 and 7 are already in force. It is therefore against the law to compensate a surrogate mother, just as it is against the law to pay a sperm or egg donor. Section 12 of the act relates to the reimbursement of donor expenses incurred by the surrogate mother. That section is not yet in effect. In answering Mr. Merrifield, I mentioned section 71, which allows people to continue with most of the controlled activities. Section 12 has not been implemented because we were well aware that very few clinics were in the habit of paying the expenses of a donor who submitted receipts. There is a transition period so that clinics can begin to do so. Until the section comes into force,no lump sum can be paid to a donor.

**Mr. Réal Ménard:** It will come into force when the regulations have been drafted.

**Ms. Francine Manseau:** I mean that section 12 can become operative before section 71; it will state that only those who have reimbursed a donor who has submitted receipts for expenses will be able to continue to do so until either the regulations or the proper authorizations have been issued.

**Mr. Réal Ménard:** Is that why there are few donors in some parts of Canada, as was mentioned in the *Le Devoir* article that I spoke of?

**Ms. Francine Manseau:** I do not want to discuss the cause. I think it has always been a challenge to find donors, whether or not we have a system of compensation for them. What they are doing should not be taken lightly: they are creating a child. When such an important change takes place, namely, when we move from a process where donors were paid to a system where only the costs are covered, then clinics must adopt a different approach. That is what we were trying to accomplish with the pilot project that will soon be announced. We are currently negotiating with the people who were determined to have these initiatives, particularly so that they could create an awareness of the existing need.

**Mr. Réal Ménard:** Let me understand this.The committee felt that, generally speaking, a sperm donationshould be an altruistic gesture. We realized, as we examined the bill, that we had gone too far. I clearly remember what my colleague Hedy Fry had to say: she felt that someone who took a day off work should be paid and people should be compensated for their travel costs. I thought the regulations would take that into account. Hélène Buzzetti from *Le Devoir* wrote a very extensive article on this subject, at least for Quebec. The sperm banks are running low. I thought it was important to reimburse certain expenses. What will we gain with a pilot project? Why is this section not yet in effect? Is it because the regulations have not yet been drafted?

● (1000)

**Ms. Francine Manseau:** No lump sum can be paid at this time. However, it is possible to compensate a donor for certain expenses. Once the regulation comes into force, it may be possible to broaden or limit the compensation fields. But at this time, there is no set limit. A donor can be reimbursed for transportation or other costs.

The bill states that a donor can be reimbursed for expenses that are incurred if a receipt is provided. As to paying someone who takes leave from work, that is prohibited under section 12 of the bill.

Currently then, a clinic can reimburse a donor's expenses.

**Mr. Réal Ménard:** Why are there no regulations yet for these sections?

**Ms. Francine Manseau:** We have had consultations, and policy proposals for the possible application of the regulation in this area will be published early next year.

**Mr. Réal Ménard:** Has your department been made aware of the fact that there is a drop in sperm bank donations? Has someone made this known, to your knowledge?

**Ms. Francine Manseau:** Indeed.

**Mr. Réal Ménard:** How do you interpret that? Does this have anything to do with the slow progress in drafting the regulations? Why is it taking so long? Do you have a staffing shortage? What is happening?

How do you explain that in areas as complex as employment insurance, for example, regulations can be drafted in six months, when for something that is complex, but less so, it takes four years? Explain what the problems are, generally speaking. We will not take you to task. We know that it is complex, but try to see it from our side. We work on a bill for two years, and you take four to draft the regulations. This is something that a legislator has a hard time understanding.

**Ms. Francine Manseau:** There is more than one regulation. There are regulations; for example, subsection 65(1) includes paragraphs (a) to (z), and even (z.1) and (z.2).

**Mr. Réal Ménard:** I know, I read it last night.

**Ms. Francine Manseau:** Therefore, there are a series of regulations for each one.

With respect to compensating gamete donors, once the regulation is in place, compensation will have to be authorized. That will possibly be one way to limit the type of expenses that will be reimbursed.

A donor can be reimbursed at this time. So it is not the lack of a regulation or authorization that would currently prevent a clinic from trying to recruit donors and pay their expenses. This situation is not caused by the absence of any regulation. It is more closely related to the change that has been brought about by the act. Previously, a donor was given a lump sum, and with the new act, the expenses will be reimbursed.

This is a totally different way of seeing things. What we probably need is an awareness campaign, and new donors might be different from the ones who applied before. This is a complete change. However, the regulation is not what is holding things up. I believe that the sperm banks and the clinics should take new initiatives. Moreover, the pilot project is intended to bring about this change.

**Mr. Réal Ménard:** I would now like to ask you a few questions about the staff.

[*English*]

**Mr. Bill Maga:** Perhaps I can just address the more general question with respect to both the regulatory process and what we have to go through to come up with these regulations.

You mentioned the unemployment act. There's a situation where we have an established program—the act has been in place for a long time, the regs have been in place for a long time—but here we're starting from scratch, with something that is very complex, very interrelated. These are fundamental questions, and it's going to take some time. We have a number of regulatory analysts working on that, and we have three or four Justice lawyers working on that, but the department is committed to the federal regulatory policy, and that has certain requirements and expectations associated with it. Probably the most important is public involvement and public participation.

There's a document being distributed today, an issue ID piece, on pre-implantation genetic diagnosis. This is the first part of how we begin our regulatory process. Because of the newness of these issues, and because we in the office don't know everything, we want to make sure, through documents like this, that we've got everything covered, that we know what all the issues are. We have to go out and do that a couple of times.

● (1005)

[*Translation*]

**Mr. Réal Ménard:** There are six people—lawyers, legal specialists—who work full time drafting regulations. How many full-time staff do you have working on these sections? Yesterday I reread section 65, which includes 26 subjects.

I simply want to know why it is taking so long. I understand that it is complex. I have been a member of Parliament for 13 years and for two years, I sat on the committee that examined this bill. But four years! Why so long? How many people are working on it? Perhaps the committee should pass a motion to hire more employees. Why is it taking so long to draft this?

**Ms. Francine Manseau:** There are about 12 people working on it at this time.

[*English*]

**Mr. Bill Maga:** Yes, a dozen. And we have access to three or four counsel from Justice Canada.

**The Chair:** What we're trying to find out is how many person-hours per week this is being worked on.

**Mr. Bill Maga:** In Francine's group there are about 12 full-time people dedicated to the development of the regulations, but what we're trying to do is address the eight clusters all at once. It's a lot of work for those 12 people and for the Justice lawyers involved.

**The Chair:** You really scare me when you talk about Justice lawyers, because most of us see that as a prescription to slow everything down. Could we not hire our own lawyers who are not in the Department of Justice?

**Mr. Bill Maga:** I think you'd have to talk to a Justice official about that.

**The Chair:** No, I'm asking if the health department, which is responsible for this, couldn't hire outside counsel. Do you always have to go to the Department of Justice for your legal help?

**Mr. Bill Maga:** It's the current policy, yes.

**The Chair:** Okay.

The other thing that concerned me, Mr. Maga, is that you said you don't know much about this and therefore you have to consult.

**Mr. Bill Maga:** Well, we don't know everything about all the issues, that's true.

**The Chair:** Not everybody is present here today, but this committee spent two years thinking of nothing else but this and hearing all this, which is why we put these things in. This book really worries me, because it sounds to me like you're going out to ask people again about something we've heard about over and over and over again and decided about. The decision has been made. Why do we have to keep consulting people? Why can't we simply draft a regulation based upon the clause in the bill?

**Mr. Bill Maga:** We could do that.

**The Chair:** Good.

**Mr. Bill Maga:** We could do that. I don't know if that's the preferable way to go.

● (1010)

**The Chair:** Well, the people on this committee are totally aware of the pressures you will be under should you go the route of all these consultations and all these questions, such as, "What do you think about these things?", and they all write in.

There are some very powerful interests out there. Some of them are attached to the potential money they can make in what is described by themselves as an industry that was supporting their lifestyles and that we came down hard on when we did this bill. This gives them the opportunity to rise up again, to try to turn reproductive technology into the industry that it had developed into, that we were trying to squelch through this bill.

Then you will have the infertile community that want freedom to do what they want in order to have babies. You can't blame them. It's a natural thing. But they are very powerful and very persistent. Then you have the third group, who are the scientists who want the freedom to do what they want to do.

Every time you open this up to consultation, consultations that this committee has held twice—the same people came twice—we as people who represent all parts of the country and all political parties had to make those painful decisions. We made them and they are reflected in this bill, with the exception of a couple of amendments that were made in the House by a couple of mavericks on the committee.

In fact, most of this bill reflects our hard decision-making. That's why I don't know why you're going out and opening up what could be a can of worms for all these people to come back out and yell at you.

**Mr. Bill Maga:** We're used to that.

No, we appreciate the huge amount of work the committee put into the act, and it's standing the test of time. As a matter of fact, we continue to get compliments from other jurisdictions about the comprehensiveness of the act and its importance. But what we're trying to do is to take it from the level of the legislation down to the minutiae of regulation. That's a difficult thing to do sometimes, and that's why we have to be able to specify and show to clinicians exactly what they can and cannot do.

We have to bring those basic principles associated with the legislation down to the reality of day-to-day operations in the clinic. That's where it gets very complicated and that's where we actually do need advice from the clinicians who actually perform the procedures, because I'm an economist by training and I don't know a lab from anything else.

We do need that assistance in order to ensure that we get it right the first time. That's why we have to go out. Because the department's committed to the federal regulatory policy and participation of Canadians—that is why we need to get out and ensure that we do have it right the first time.

**The Chair:** We put in that the regulations had to come back here, because we want to go through them with a fine-tooth comb.

The fact is that of the 25 or 26 areas that we designated to be regulated in the bill, it looks to me that one is on its way and a second one is being developed. For 25 areas, this could take until 2015.

**Mr. Bill Maga:** No. We've got a very ambitious schedule coming up on a number of fronts, starting in the spring. Would you like to hear what we've got planned for the next six months in terms of regulatory development?

Francine, would you like to go through the list?

**Ms. Francine Manseau:** There has been a lot of work to understand how the field is working in detail.

PGD is an example. The law is certainly very clear that you will need to get a licence before you can do that activity. Would the regulation exactly determine the purposes for which it would be allowed on a case-by-case basis? It is in the details now. How will you go about doing that? How prescriptive are you going to be, and so on? That is only an example.

But to answer Bill, there has been a lot of background work.

If we look only at labs, we need to understand what is required right now by every province for a fertility lab. This information has never been regulated. Counselling is another one. What do you define? Who is qualified? There is nothing in Canada that qualifies a fertility counsellor. We have to go through all the jurisdictions to understand what the requirements are. A lot of background work has been done.

It's the same thing if you want to put some limits in the regulations on how you do something. You need to have the information to justify imposing those limits. There is a very good paper that we have people working on, looking at the health and safety risks and at what the picture is telling us. As you know, this scale is moving very fast. We've done a lot of background work.

In the new year, we are going to start consulting and ensure that we understand it well so that we can start saying this is how it should be done, we got it right, and the standards are or are not in use. We are going to be consulting in February on the licensing scheme, as well as the laboratory and clinical practices. We are also going to be consulting on health reporting information, counselling, and embryo research.

A lot of background work has been done to get us to the point where we can understand exactly how and when we are going to impose some of those limits and what impact that will have. We have to be able to provide all of that information as we are proposing regulations.

**The Chair:** Thank you.

Ms. Dhalla, and then Mrs. Crowder.

**Ms. Ruby Dhalla:** Thank you very much for coming.

I can understand the frustration of some of my colleagues around the table. I know that they've put a lot of time and energy into putting through the legislation, and they've spent two years on it. When they hear that it's going to take four years to do the regulations, they're naturally going to be frustrated.

I think one of the important things to remember is that when Bill C-6 was assented to in March 2004, this was the will of Parliament. From my reading of it, I think they've very clearly laid it out, identified the parameters, and set up a great framework.

You've now identified that one regulation is on its way. If we consider this as a possible consideration for a second one, you've identified six or seven feature initiatives. How long is it going to take to get the other 15 regulations?

● (1015)

**Ms. Francine Manseau:** There is one that I gave you.

**Ms. Ruby Dhalla:** Yes, you identified about six of them.

**Ms. Francine Manseau:** Yes, but I would say that they involve a lot of subsection 65(1). When I name one, there could sometimes be six or seven subgroups within that one. When we talked about those eight clusters, we basically took subsection 65(1) and grouped them within those teams, if you like.

When they go out to consult on licensing, clinical, and laboratory activities, it involves about six or seven groups of the subject matter under subsection 65(1).

**Ms. Ruby Dhalla:** Is four years for the drafting of regulations a normal timeframe within the departments?

**Mr. Bill Maga:** May I respond to that?

When the act received royal assent in March 2004, we got the go-ahead to start to operate at full speed. Because of uncertainty prior to that, we couldn't really get started.

So in March 2004 we started to staff up and we started to get operating. So that's one thing. There's a little bit of a time requirement there. In terms of the typical length of time of doing regulations, two years is quite typical to go through the regulatory process, with all the public consultations requirements under the federal regulatory plan.

We can't do everything at once. So what we're doing is concentrating on some of the key initiatives like licensing and the laboratory practices that are going to take a very large amount of work. Things like PGD and some other of the clusters we'll do along with the major ones, but we can't do everything at once. So we have to pick which ones we chase at any particular time.

So when you're looking at doing a set of eight clusters of regulations, in terms of a timeframe I would think that three or three and a half years is in fact somewhat ambitious.

**Ms. Ruby Dhalla:** If you need any help from the health committee in terms of having extra resources.... And I realize for you that may seem like a very ambitious timeline, but for people sitting around the table, the process is obviously extremely slow in comparison to some of the other legislation that has been dealt with in the past. Is there anything at all the health committee could do to perhaps push it forward at a faster timeline?

**Mr. Bill Maga:** Not that we can think of right now.

**The Chair:** We could pass that motion and have it approved by the entire House of Commons, like we did on the silicone gel breast implant thing, to hurry this up. We have a motion right now that the House of Commons has completely approved on something else Health Canada is doing.

**Ms. Ruby Dhalla:** Even in reading the piece you've put out on the questions page for individuals to respond, it says in the opening line right at the end, “Further consultation will occur at a later date”.

**Mr. Bill Maga:** That's right.

**Ms. Ruby Dhalla:** Reading that in itself, though...consultations can take anywhere from a year to two years, three years or four years, and nothing ever gets done in the end.

● (1020)

**Mr. Bill Maga:** Remember, as I said, this is an early issue identification piece. As you know, part of the regulatory process is the part 1 requirement. That is just one part of it.

So we have to develop the regulations, produce the regulatory impact analysis statement, get all the approvals necessary—and you can imagine how long that takes—get it into part 1, wait the 75 days for the public consultation, take the comments, incorporate them, if necessary, in revised regulations, and then bring it forward again for part 2.

So it is in fact quite a laborious process, but we're doing the best we can to hurry things along.

**Ms. Ruby Dhalla:** I think all the health committee members want due diligence done in ensuring that the regulations are reflective of what's going on in a very rapidly changing industry, but I think the concern around the table is in regard to the timeline that is being taken. I think the health committee members need to look at any type of motion or something within the House of Commons to try to get this expedited.

No one doubts the amount of work that you yourself and your team has put in, but I think something needs to be done to move the timeline at a faster pace.

My last question is this. How has not having the regulations completed to date hindered your particular work within assisted human reproduction in the industry?

**Mr. Bill Maga:** Our main work and the main function of our office is to promulgate those regulations and to establish the agency. That's our main goal. This is a temporary office that will be wrapped up after those goals have been achieved. That's our main goal, to get these regulations promulgated.

**Ms. Ruby Dhalla:** What about within the industry itself, though? How has not having regulations done to date hindered some of the work that's being done there?

**Mr. Bill Maga:** There are certain concerns with respect to clarity and certainty. They would like to know exactly what these things are going to look like in the end, but at the same time, they want to make sure their opinions and concerns are heard in the development of those regulations. We have to make sure, as we try to speed along with the regulatory development, that all the parties involved, whether they be clinicians, patients, or offspring counsellors, have an opportunity for input into the development process.

**The Chair:** Ms. Crowder.

**Ms. Jean Crowder:** My questions will be brief. They're more on process.

You mentioned the board of directors. What stage are you at in terms of having the board of directors identified?

**Mr. Bill Maga:** As I mentioned, we began the recruitment process in June. It's a multi-stage process. We're through one major stage right now, and we hope to have an announcement early in 2006.

**Ms. Jean Crowder:** Early in 2006. I know the appointment of the chair of that board is by governor in council, but would that come before this committee for approval or recommendation?

**Mr. Bill Maga:** It will definitely come before a committee of the House, and I believe this is the committee that it will come before.

**Ms. Jean Crowder:** Okay. We haven't had a happy history in terms of other appointments, where committees did not approve recommendations and yet chairs were appointed anyway. So I'm just curious about that process.

**The Chair:** [*Inaudible—Editor*]...announcements made.

**Ms. Jean Crowder:** That would be a really good idea. It would be difficult for the committee to read about in the newspaper.

**The Chair:** We have strong opinions on this subject.

**Mr. Bill Maga:** I don't doubt it.

**Ms. Jean Crowder:** I want to come back to the regulations. We don't have a happy history around dealing with Health Canada on regulations. I go back to 1984, where regulations were drafted around reporting requirements under the Canada Health Act and never came to fruition. We're still waiting for those regulations. That was 1984.

The Pest Management Regulatory Agency has developed regulations that, a couple of years later, still are not implemented, and pesticide products are continuing to be approved, although in theory these new regulations are being used as guidelines.

I'm just highlighting those things as a history of a regulatory process that is less than comforting in terms of actually going forward on implementing this.

So I have actually two questions for you, and the chair pointed these out already.

This committee did extensive consultations. They heard from people from coast to coast to coast. Why couldn't regulations be drafted and then taken out for consultation? Surely enough information came forward that would start to shape regulations, rather than someone going out and doing more extensive consultation and then coming back and drafting regulations.

The other thing is, what are the consequences to the heads of this current organization if timeframes are not met in terms of drafting regulations in a timely fashion? You mentioned a timetable. It would be interesting to see the timetable. What are the consequences of not meeting that, for people who are in charge?

**Mr. Bill Maga:** Just to clarify your second question, the agency and people in charge of the agency...?

**Ms. Jean Crowder:** Your agency is in charge of drafting regulations. You've indicated to us that there's a timetable for drafting these regulations. What are the consequences to you if these regulations aren't drafted in a timely fashion?

● (1025)

**Mr. Bill Maga:** Let me deal with that one first.

Health Canada is responsible for drafting the regulations. Health Canada is responsible for the policy around AHR and any legislative and regulatory changes that might have to be made in the future. The agency is there, will be there, to administer that legislation. So in fact it will be Health Canada in the future that changes the regulations.

In terms of what it means to us, there are some people in the office, such as Francine, who have been working on this act for a very long time, working on this file for a very long time. They take it personally and they want to see this legislation in place. They want to see these regulations in place themselves as soon as possible.

We're pushing to do that, but this is a tough task. We'll continue to work at that, but in terms of shaping the regulations, there has been a lot of work. Obviously the committee did a huge amount of work, but as I mentioned before, we have to make sure everyone has an opportunity for input into that so that we get it right, so that—

**Ms. Jean Crowder:** Why can't you draft the regs, then go out and get the input?

**Mr. Bill Maga:** That's part of it. We will do that. That's part of the part 1 process.

**Ms. Jean Crowder:** What's this, then? Are there drafted regs going out for consultation on this?

**Mr. Bill Maga:** No. That's an early piece designed to ensure that we have covered all the issues important to stakeholders in the implementation of the legislation. So if a clinician has a concern about how the general legislative policy is going to be applied in the operations of his or her clinic, he or she can use that vehicle to make sure we know about it.

**Ms. Jean Crowder:** If you will forgive me, it seems that when in doubt, conduct another study. It's very frustrating for us when we hear consistently from people across the country on any number of issues that.... There's a fine balance between appropriate consultation to make sure we get it right, and studying things to the nth degree so that you cover every possibility. It's a question of process or methodology.

It seems to me that oftentimes we have lots of information. What we need to do is present people with a draft product and get some input from them. If I'm understanding what happened with this committee, there was extensive consultation done. It seemed there would be points where regulations could be drafted for input, which would seem to speed up the process.

That's really all I have to say about it. Thank you, Madam Chair.

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

Mr. Thibault is next.

**Hon. Robert Thibault:** Thank you, Madam Chair.

And thanks for coming to the committee.

First, I'd like two very quick answers so we understand. I'm following on Mr. Merrifield's question. We have the act. There are some prohibitions in place. CIHR is granting money to some researchers. Are those researchers currently subject to the act and its prohibitions?

**Ms. Francine Manseau:** The prohibitions are in place. Everybody is subject to the prohibitions.

**Hon. Robert Thibault:** Okay.

Currently, whose responsibility is the inspection or policing of the prohibitions in respect to the researchers granted by CIHR—or anybody and everybody?

**Mr. Bill Maga:** It's Health Canada's responsibility to ensure that the legislation is enforced.

**Hon. Robert Thibault:** Thank you.

I've been listening to the questions, and I do share the frustrations with the speed of getting regulations. I think Mrs. Crowder makes a good point, that at some time you have to put something in the window. You're never going to have the perfect product, and I don't think you're going to have it much easier when you come here. The regulations are going to come here and everybody is going to find some fault, and if you think four and a half years is a long time, it will be ten years when it comes to this committee because it will be difficult getting it out.

We just went through the process of the interim marketing authorizations, modifying that product, that process. In one case we're already applying it, but where we already have the law, already have the regulations, we need an amendment to the regulations to deal with one food group or one product or one new formulation, or new addition to an existing formulation.

The process takes 17 months, typically, to change a regulation. I don't blame the bureaucrats for that. It is the will of Parliament that we have this process of gazetting and that there be public participation. In other instances, agencies are granted that authority. In other countries, agencies can automatically modify regulations or add after they are done. The FDA, for example, has a lot more authority than does our Department of Health. The Department of Health has to go through the gazetting process to change the regulations.

I know it's not your fault, but there seems to have evolved a culture—and a few people have mentioned it, particularly Mrs. Crowder.... I define it like this. We've taken the word “consultation” and we've confused it with consensus, where we think that what we're going to get from people has to be what everybody agrees on at the end, that our regulations or our policy has to keep everybody happy.

A camel has often been defined as a racehorse designed by a committee. If you try to make everybody happy, either you never get there or what you come out with isn't necessarily what you want.

I wonder, therefore, if there's a possibility of having the consultations. Let's hear from the people. I agree with that. We already know what the basic will of Parliament is, and I appreciate that fact of putting it in place. You don't want everything in the court all the time. You need regulations that make sense, that are applicable, and that stand up. But at one point, wouldn't it be better to take a decision based on those two facts, put regulations, then have them go through the gazetting process, which brings public participation and modification, rather than doing too much consultation at the front end? There's still going to be the committee to which the regulations are going to come. That is going to be quite onerous.

So I'd like you to tell me if you think that's a good approach.

The other question comes to what Mr. Ménard was raising as to your ability to do this. In every organization, whether there are a million people in it or only four, typically there's a bottleneck somewhere. I don't know if Justice Canada is the bottleneck. I don't know about that area, but what is it that would stop those 12 people from achieving more? If you put more people in it, would it achieve more, or would that bottleneck still be the constraint?

● (1030)

**Mr. Bill Maga:** First I'll respond to your first comment with regard to process.

Accelerating the consultation process is certainly something we could look at. There are certain givens we can't get around, such as the *Canada Gazette* process. Speeding things up at the front end, I think, is the only place where we might be able to gain some time. Recently, we've been looking at our timelines, because we've been conscious of this for awhile, and we've been working with Justice Canada counsel and our project managers to see where we can make things go a little quicker. We're definitely conscious of this.

We'll go back and look at our front end again to see if we can sort of move things along a little quicker. Of course you realize there are some givens that we have to recognize.

On the bottlenecks, it's a little difficult to say. Certainly finding good regulatory analysts with a scientific background has proven a little difficult. When we talk about clinical and lab practices, getting people on staff who have actually worked in a lab and who also know policy analysis and regulatory analysis has been tough.

One of my major preoccupations and challenges has been simply to keep the place staffed. That's been a problem. Then making sure, perhaps, we're out a little too.... Maybe we need to be a bit more cavalier and move things along with a little more fervour. As I mentioned, we can certainly look at what we can do about moving things along at the front end, but maybe that's a cultural thing that we need to change a bit.

**Hon. Robert Thibault:** Is that it?

● (1035)

**The Chair:** That's seven minutes.

It's Mr. Lunney's turn.

**Mr. James Lunney:** Thank you, Madam Chair.

Just for starters, I want to echo what my colleagues have said about the four-year development of regulations. We don't find that acceptable. I agree with my colleagues. They've already stated this clearly.

As was said by Mr. Thibault just a moment ago as well, you're not going to get a perfect document anyway. We heard from all of these witnesses ourselves, and frankly, just throw something down here that hits the target area. I mean, do your best job, but let's get it on the paper. It's going to come back to this committee for review. There's going to be some controversy generated anyway, and there are safeguards already in place. I just have to state this as well.

Finally, on the same point, according to the legislative mandate for the review of the regulations once the agency is in place, it's within three years. It's not after three years, but within three years. The whole process can be reviewed again if there are significant challenges with it. There are safeguards already in place.

I want to come back to the in vitro embryos. Certainly the intent of this committee in coming up with the legislation was that embryos would not be created for research. That was clearly the indication of the act.

It seems that there is a move to interpret this a little differently, that the reference to supernumerary embryos, I think it's been pointed out to us, did not specify whether they had been frozen already or not—they were created for the purposes of reproduction, and now, all of a sudden, 13 embryos have been created. With the technology of the day when the committee examined this, they were all frozen for use in the future in case it didn't take, or it turned out to be in some way defective, or there was a miscarriage or something, so they could use one of the frozen embryos. Now we're talking about, oh well, they're actually created, and with consent of the donors you can take those right out of the petrie dish, as it were, and use them for research purposes.

If that's happening, it is clearly not the intent of the act, and frankly, it's a loophole that needs to be addressed. Health Canada is responsible for enforcement of the act. It is something Health Canada should be supervising with CIHR or whoever is purporting to do research under those pretexts, which are outside of the intent of the bill as far as this committee is concerned, as a creator of that bill. I wanted to say that for the record. I think we've discussed it fairly well, in detail.

I just wanted to address this issue of the agency's composition and conflicts of interest. We've just gone through this on the silicone breast implants, and that issue isn't over yet. What is it about Health Canada and some of your departments that you don't recognize conflicts of interest? I know when we talked about creating this agency, we wanted a committee of wise people who could hear the issues and protect the intent of the act, not people who are linked to industry, with all the insider information and with vested interests. I'm very concerned that what's being created here is exactly what we didn't want to see.

I don't expect you to be able to answer that now, but I do want to come to something that I would like you to answer, and that has to do with compensation for gametes. Again, the committee, in formulating this and hearing from witnesses, was very clear. We wanted to remove compensation for donors. There should not be the buying and selling of human parts or gametes.

When I look at this document here and your consultation, the workshop you had here, there are examples of compensation for gamete donations, sperm donation. You know, this list is interesting, with all the things we might compensate people for for sperm donation: vitamins and prescription drugs, visual aids, magazines, videos, newspapers, travel—not just taxis, but buses, gas, car rental, kilometres for personal vehicle, flights. Flights, for a sperm donation! Are we talking about flying in Clint Eastwood?

Mr. Ménard is looking for a career after politics.

**Some hon. members**: Oh, oh!

**Mr. James Lunney**: On the female side, when we look at the list here, again, it's lost wages and travel time; honoraria—now, what's that if it isn't another word for the $32,000 fees that we were objecting to when we heard about this—expenditures for an accompanying person; medical and liability.... I mean, it goes on and on—supportive care; complementary therapy, I guess massage, I don't know. Frankly, that's not what we're looking for.

The intention was clear. Going through workshops with all the people we heard from before—and this committee made some decisions in formulating the legislation—to me is creating all kinds of problems for us.

We knew there would be a drop-off once you stopped paying university students for their donations regularly, such as $600 a month or whatever it amounted to for these kids to be able to donate as a career while they were earning their university degrees. We knew it would create a drop-off temporarily, and there are elements within the industry trying to create a furor over how serious this drop-off is. We knew that was coming.

I know you have a workshop coming, but we knew that would happen, because it happened in every country where they went to altruistic donations. What has Health Canada done to help disseminate information to try to mitigate that risk by getting information out to the public, to say, look, we are looking for responsible donors to help meet this need?

● (1040)

**Ms. Francine Manseau:** The report you have there, the workshop, is what we heard. It has nothing to do with what could possibly be allowable in terms of expenses through the regulations. It is what we heard.

We asked people, what are you doing right now? So it doesn't reflect at all what could be part of those expenditures that could be reimbursed through regulations.

**The Chair:** Why didn't you ask these people?

[*Translation*]

**Ms. Francine Manseau:** I beg your pardon?

[*English*]

**The Chair:** We could have told you what they would have said. We've heard these people two and three times. To ask them that question is to open up all over again something that has already been settled.

We could go down this list and say this lady would say this, and this lady would say that, and this man would say not to give him any rules at all. We know these things. Why are you having these workshops? What is the purpose? These people aren't the experts. These people are the people who exploit other Canadians for their own gain, for the most part, with the exception of about four people.

The other thing is that the list is totally out of whack, totally out of balance. The industry money people dominate at the rate of five to one here.

So whoever these organizers are, they don't know what they're doing. It's the same thing we saw with the silicone gel breast implants. Let's bring in all the people who have a financial interest in this and let's hear what they say. These things are about health; they're not supposed to be about people's financial progress. It's supposed to be about health.

So this thing you gave out just absolutely enrages me. The questions you're asking them, raising their hopes that they're going to win...a lot of these people lost the battle. They lost the war when we passed the bill, and now you're opening it up again. Why?

**Mr. Bill Maga:** Let me answer that just in terms of the general process.

This is all part of an open and transparent regulatory process, and you know, frankly we can't—

**The Chair:** We had open and transparent. We don't have to do it year after year after year on the same topic. The taxpayers have some right to expect some forward motion, not wheel-spinning year after year.

This will now be the third time these people have been asked. Then there will be a fourth time, and then when the regulations come to committee, there will be a fifth time. How open and transparent do we need? This is overdoing it.

**Mr. Bill Maga:** All right. I think we've got that message.

If I could make one comment on the conflict of interest, I'm sure you're well aware that in section 26 of the act there's a fairly stringent ineligibility clause that restricts potential licensees or individuals associated with licensees or potential licensees to be on the board. I just thought I'd mention that. It's subsection 26(8).

**The Chair:** The list of people, which is somewhere in these papers you gave us, does not reflect what the committee wanted. We don't want people of such expertise that they lose touch with the general value set of Canadians. We wanted people who represent more about values and philosophy and all that sort of thing. We didn't want all these scientists on this thing.

Anyway, go ahead, Mr. Gagnon.

● (1045)

[*Translation*]

**Mr. Marcel Gagnon (Saint-Maurice—Champlain, BQ):** Thank you, Madam Chair.

I would first like to thank you and congratulate you for clearly stating what all of us around this table are thinking. So far, everything has been said and even repeated more than once. I also agree with Mr. Thibault when he says that there is a difference between consensus and consultation. There will never be a consensus.

I know that it is not easy, since it involves human lives and Canadian have varying opinions when it comes to the meaning of life. Some may feel that it is almost a matter of confidence.

I would like to speak on behalf of some couples that I know. My colleague mentioned that one out of every five couples would like a child but cannot conceive. I personally know some people who, if they don't have children soon, will have to spend the rest of their life childless. I also read the article that was mentioned by my colleague.

Of course, if we wait until 2008, some people will be left out. We can say that one fifth of our young couples are in this situation, since one out of every five is infertile. I agree that we must expedite this work.

If we are seeking perfection, then we might still be waiting in 2015. Madam Chair said that it was useless to consult. People have been consulted numerous times and some will never agree on what should be done, because they have private or personal interests.

I fully support the position of my colleague and the people around the table. In the name of life, and on behalf of couples who believe in posterity, I must tell you that it is urgent. Time is of the essence for the couple who asked me to personally intervene on their behalf. If these people wait too long, they will no longer be able to start a family.

On behalf of the committee—this is what you had in mind—I am prepared to do whatever I can so that this file will progress as quickly as possible. In my opinion, it is the will of the members from all parties at this table as well as that of one out of every five couples, whether they live in Quebec or elsewhere in Canada. It is a pressing issue, and we must do whatever needs to be done.

[*English*]

**The Chair:** We'll go next to Mr. Carrie, and then Mr. Thibault.

**Mr. Colin Carrie:** First of all, I would like to thank you for coming here. This is such an important topic for Canadians. For friends of mine who have used reproductive services, it has changed their lives, and they are thrilled.

I would like to add with my colleagues, though—and I don't want you to take this personally—the frustration of this process. It appears to me it is getting to a point of ridiculousness. There appear to be people at Health Canada who are making a career out of running around in circles. I don't know, you may be a little uncomfortable being here and answering these questions, but I am going to make you a little bit more uncomfortable because I want to talk about accountability.

I want to know the name of who's responsible for the process. Obviously you've replied and said Health Canada is responsible for the process. That's not good enough for me, and I don't think it's good enough for the rest of these people. What I want to do and what I'm going to suggest to the committee is that we go up the chain of command and find out who in heaven's name is causing this to continue to progress as this is progressing. I don't want to hear that it is Health Canada that is accountable. Can you give me the name, please, of your boss or who you report to?

● (1050)

**Mr. Bill Maga:** I report to the director general...well, actually, currently Frank Fedyk is doing two jobs. He is acting director general of the policy, planning and priorities directorate in the health policy branch.

**Mr. Colin Carrie:** And who's his boss?

**Mr. Bill Maga:** Senior Assistant Deputy Minister Ian Shugart.

**Mr. Colin Carrie:** Okay.

I would recommend to the committee that we recommend that there be no more consultation as of today, that we just make a decision and move ahead. I would also recommend that we have these people come before the committee and discuss this with us.

This isn't the first time we've run into this, where senior bureaucrats are making decisions that are not the will of the committee, that are not the will of the Canadian people. As part of a democratic reform process, is it possible that we can ask these gentlemen to come before us and talk about process?

I had all these questions to ask you that I think are important about the registry, accreditation, and licensing, but it doesn't seem to me that it matters, because this is going to go on and on in circles. It could take another five or ten years before we get through it. I don't think the Canadian people expect the bureaucrats to make a career out of going in circles and not making any decisions, and also stopping the decisions that are made by committees.

I don't want you to take this personally. I thank you for coming here to bring the work you've done, enlightening us in the process.

Madam Chair, I would make the recommendation that there be no more consultation on this and that we make a decision to have these gentlemen come forward to the committee so that we can talk to them about the process, because we're all frustrated with it.

**The Chair:** If the committee is agreeable, I certainly wouldn't mind asking Mr. Fedyk and Mr. Shugart to come so that they understand our views about this process. But to say that there could be no more consultation....

I mean, it's possible that they are going to need to ask one or two people what their opinions are about things, but I do think it's been overdone. And although I agree with you, it's too strong that we don't do one more thing, that we just write it out.

**An hon member:** The minister is responsible. We have to have the minister here.

**Mr. Steven Fletcher:** Madam Chair, I agree with my colleague that the bureaucrats should come here to explain, but the ultimate accountability and responsibility is with the minister. I know he's coming next week, but there are a lot of things we'd like to talk to him about. I wonder if we could have him come on another occasion to discuss this area specifically. Maybe we could talk about the breast implants and some of the other—

**Hon. Robert Thibault:** We have witnesses here today. We have an order of questioning, and you jumped onto our side to give an additional one for that side. I didn't object to that, but now we're discussing follow-ups, and I don't think it's the time, when the witnesses are here, to discuss future business.

**The Chair:** Let's wait until after, yes.

And that's true, Mr. Thibault, but I thought you might want to wrap up. That's why I did two on that side and you last. You're now the last speaker.

**Mr. Steven Fletcher:** [*Inaudible—Editor*]...today, Mr. Thibault.

**Hon. Robert Thibault:** Very good, Steven. I understand your points, and we can certainly discuss them after, but I think it's out of turn.

I thank the staff for coming here. It's a very difficult situation. I want to caution everyone, all of us, including the members of the committee.

I think you will take back our desire that it be sped up. We'll certainly be meeting with the minister and we'll make that point also.

I get calls as a member of Parliament. I got a call from a small radio station in my riding last week, and they told me their fees for *les droits d'auteur* were increased without consultation. When their association told me that, I jumped this high. I contacted the minister and asked why we did that without consultation. If regulations that affected my business or my future or my desires or aspirations were done without consultations, I'd jump that high again.

As members of Parliament, when we sit in the House, if we're not on the committee and we find out that some regulations and so on have been done without consultation with the Canadian public or the industries concerned—for example, when we find out that in the negotiations on softwood lumber the industry didn't feel properly consulted—we raise that. As Parliament, we set the laws and the parameters and the frame of what we want to achieve.

I am listening to everybody speaking here today—I'm listening to Mr. Gagnon, I'm listening to our chair, and to all of us—and we don't all want exactly the same points. We want to control the way things are happening, to regulate them, to make sure it's not an industry that subjugates people...and I won't get into a description here, but you could almost say it's slavery. You don't want a manipulation of life, but you want to give parents the chance to have children if they want to have children in a reasonable fashion, using a reasonable method. It's a challenge. We have to have regulations that bring all of that together.

These people who are being consulted know what our end limit is and know that we want to control their game, but we also want to give opportunity to the people who want to have a family. I don't think it is ridiculous to consult these people, I think it is a reasonable way of writing our regulations.

So I would join in saying, please, do it as quickly as humanly possible. Don't wait for perfection. When you come here with an imperfect document, we're going to slam you anyway—it's never going to be easy at the committee—but hopefully by participating and working together we can achieve what is good for the public of Canada and for future generations.

● (1055)

**The Chair:** Thank you, Mr. Thibault.

I think you get the flavour of what we're saying. We understand there is one that has been gazetted; there's another one that's very close to being gazetted. Everyone has to understand that there are 75 days for interested parties to comment once it's in the *Gazette*. So to me that's plenty of consultation. So get as many as you can into the *Gazette* as quickly as you possibly can, and then once you get through that period, maybe they'll be ready to come to us.

We just looked at the list, and it seems that there are at least half a dozen that aren't going to take a lot of questions. Madame Manseau knows this topic so well that she could probably write the regulations for five or six of them this afternoon and get them into *Gazette*. Now, there may be others that are thornier, but the point is that this is not going quickly enough. We're obviously going to tell the minister when he comes that we're not satisfied. So anything you can do to get beyond this round-the-mulberry-bush system, we would appreciate.

On behalf of the committee, I'd like to thank you very much for your time. We look forward to working with you and making progress on this file.

**Mr. Bill Maga:** Thank you for your time. We definitely got the message and will be going back and having a good look at how we can move this thing along a lot more quickly than we have.

**The Chair:** Thanks very much.

**Ms. Ruby Dhalla:** Perhaps I'll suggest to everyone in the committee that we perhaps draft a letter. I realize the minister is coming on the 29th, but if we can do something prior to that by the end of the week or next week—

**The Chair:** If you would like me to, I'll try to draft one and get approval from everybody to send it.

This meeting is adjourned. Thank you very much.

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