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Chair

Mrs. Joy Smith

Standing Committee on Health

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● (1110)

[*English*]

The Vice-Chair (Mr. Lui Temelkovski (Oak Ridges—Markham, Lib.)): Order, please.

I would first like to thank the witnesses for coming in.

We have two panels of witnesses today, so we have to move rather quickly.

Mr. Fletcher will make a few opening remarks, I believe.

Mr. Réal Ménard (Hochelaga, BQ): There's a point of order here.

The Vice-Chair (Mr. Lui Temelkovski): There's a point of order?

[*Translation*]

Ms. Christiane Gagnon (Québec, BQ): Yes.

[*English*]

The Vice-Chair (Mr. Lui Temelkovski): Oh, pardon.

[*Translation*]

Ms. Christiane Gagnon: Thank you for allowing me to speak, Mr. Chair.

I thank the witnesses for being here today. My remarks do not mean that I am not pleased to see them here today.

I am looking at the witness list, and we are missing groups who should have been here this morning. I would like to know how it can be that no one representing the gay and lesbian community is here. I know that attempts to contact them have been made since January, but I have heard that the letter did not arrive. It is important that Gai Écoute be here this morning. These are the people who were approached when these regulations were being developed. They were the ones behind them.

I hope that there will be another meeting because I am not happy with the fact that we will not be hearing some testimony about the impact on the gay and lesbian community this morning. What first caught our attention, in fact, was the discriminatory nature of a section of the regulations.

[*English*]

The Vice-Chair (Mr. Lui Temelkovski): That's a good point of order. I think Carmen, our clerk, will be able to explain what has transpired.

[*Translation*]

The Clerk of the Committee (Mrs. Carmen DePape): Ms. Gagnon, I sent a letter of invitation to Mr. McCutcheon a few weeks ago. I do not recall the exact date; but it was in February, at least two weeks ago. I received nothing back from him. I tried to call him, but there was no voice mail. I could not reach anyone by telephone. I sent a reminder asking for someone to get back to me, but there was no reply to that either.

Ms. Christiane Gagnon: We spoke to Mr. McCutcheon.

Mr. Réal Ménard: On the same point of order. Mr. McCutcheon runs an organization called Gai Écoute. I am in touch with that organization three times a week, so I do not understand how you were not able to reach them. If they are not there, you leave a message on a machine. I am confused as to how you were not able to reach a national association like that.

Like my colleague Ms. Gagnon, I too express my disappointment at having a group of institutional experts before me. We do not question the relevance of what they have to say, but it would have been interesting to have a variety of points of view this morning. Those varied points of view are not available to us. We are very disappointed about that.

[*English*]

The Vice-Chair (Mr. Lui Temelkovski): Monsieur Ménard, I'd like you to give the phone numbers of these groups of witnesses to the clerk. We will make every attempt to make sure they are included. We will have another meeting sometime to make sure we hear from these witnesses.

[*Translation*]

Ms. Christiane Gagnon: I also asked that Mr. Tremblay, from the Canadian Organ Donors' Association, be here. You told us that there would be too many witnesses and that others could not be invited. That was another kind of testimony that we would like to have heard this morning. That is the answer I received when I said that I would like to have had that witness at the table this morning. I am a little disappointed.

I am pleased that you are here. You will be able to answer some of our questions, but you do not represent a community that is specifically targeted by an element of discrimination that can be read in the standards that were developed during the consultations on the regulations.

Thank you.

[*English*]

The Vice-Chair (Mr. Lui Temelkovski): I was speaking with our clerk, and the suggestion is that at the end or the beginning of the Thursday meeting we take some time to do committee business and make sure we agree on a time for them to appear as witnesses at the committee, if that's the choosing of the committee.

An hon. member: Or the steering committee.

The Vice-Chair (Mr. Lui Temelkovski): The steering committee is not operational, because we've done our work already.

[*Translation*]

Ms. Christiane Gagnon: There is something I do not understand. Last week, I asked why Mr. McCutcheon had not yet been contacted. I was told that a letter had been sent to him and that he had not replied. As I understand it, he received an e-mail on Friday. That really was too little time. He could have been reached by means other than a letter. If he could read an e-mail on Friday, he could have... I think that the witnesses were chosen a little sloppily.

[*English*]

The Vice-Chair (Mr. Lui Temelkovski): Thank you.

Mr. Fletcher.

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

First, I'd like to welcome Monsieur Ménard to committee today. It's like old times, when he was health critic for the Bloc.

Colleagues, I want to inform you—the chair is unable to be with us today, unfortunately, so it's up to me to do this—that there is a statutory obligation for Parliament to undertake a review of the 2004 first ministers accord on health, entitled *A 10-Year Plan to Strengthen Health Care*. The Minister of Health has asked that the committee fulfill this mandate.

I'll give you the key paragraph here:

> Given that the Standing Committee on Health is authorized to study and report on all matters relating to the mandate, management and operation of Health Canada, in my view it would be appropriate for the Standing Committee on Health to undertake the review as referenced in the aforementioned legislation.

The letter goes on—I'm sure the clerk will table it or pass it on—but the gist of it is that we need to review this legislation before the end of March.

So when we talk about our agenda, maybe on Thursday, we can talk about how we're going to fit this in. It's probably going to have to be next week. I know that Health Canada officials will be ready to come in and deal with that.

● (1115)

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much, Mr. Fletcher.

We will review that on Thursday and try to fit that into the working schedule as soon as possible to make sure we get a smile out of you.

Now, pursuant to Standing Order 108(2), we'll have a briefing on the new organ donor regulations. Our first witnesses are from the Department of Health: Ms. Ballantyne, Assistant Deputy Minister, and Liz Anne Gillham-Eisen, a unit manager.

We'll start now with your presentation, and then we'll continue with the other panellists. We're short of time, as you can see.

Thank you.

Ms. Meena Ballantyne (Assistant Deputy Minister, Health Products and Food Branch, Department of Health): Thank you, Mr. Chair.

[*Translation*]

Before I begin, I want to thank the committee for providing me and our officials the opportunity to answer your questions about Heath Canada's Safety of Human Cells, Tissues and Organs for Transplantation Regulations.

[*English*]

I'm responsible for the Health Products and Food Branch, which is the arm of Health Canada that under the Food and Drugs Act regulates the safety, efficacy, and quality of therapeutic products, including cells, tissues, and organs.

I have with me today Liz Anne Gillham-Eisen, who can provide more specific information on the regulations themselves and the organ donation process. Ms. Gillham-Eisen is a registered nurse who started working in the field of organ and tissue donation 19 years ago, as a transplant coordinator at the Ottawa Civic Hospital. In 1992 she established the organ and tissue donation program at the Ottawa Hospital, and managed this program for 10 years. As president of the Canadian Association of Transplantation, she participated as an expert in the development of the national standards. In 2002 we were lucky that she joined Health Canada and led the development of the federal regulations around these standards.

I would like to bring three points to the attention of this committee. First, I would like to say unequivocally that contrary to what has been reported in certain media, the regulations do not ban homosexual men and others with identified risk factors from donating organs. No Canadian will be prevented from becoming an organ donor based on gender, race, age, or sexual orientation. Organs save lives, and too many people who depend on their availability are on transplant waiting lists. Some will die waiting.

Second, I also wish to emphasize that the primary focus of these regulations is safety—with the recipient in mind. We have moved a long way since the lessons of the tragic tainted blood scandal. Those lessons must never be forgotten.

[*Translation*]

We have moved a long way since learning those lessons and we must continue to learn.

[*English*]

The prevention of transmission of disease to transplant recipients is the primary focus of these regulations.

The third point I'd like to make is that at the centre of our regulatory framework is sound, science-based risk management, and this is consistent with international practices.

Let me now clarify the fundamental principles that have guided the development and implementation of the cells, tissues, and organ regulations.

Science is always evolving. That is why Health Canada has been, is, and will continue to be engaged with independent scientists, health professionals, standards organizations, and other regulators around the world to ensure that our work is informed by the latest established science.

It was the transplant community that first asked Health Canada for regulations—more specifically, regulations based on national standards. It was also the Standing Committee on Health, in its 1999 report entitled “Organ and Tissue Donation and Transplantation: A Canadian Approach”, that recommended that cells, tissues, and organ safety standards be made mandatory through incorporation by reference into regulations under the Food and Drugs Act.

In response, Health Canada committed to developing a standards-based regulatory framework for the safety of cells, tissues, and organs for transplantations.

● (1120)

[*Translation*]

Experts in the field of donation, transplantation, ethics and transplant recipients were assembled to draft the content of what they felt should be in these national standards.

[*English*]

These experts included representatives from the University Health Network, the Canadian Association of Transplantation, and the Canadian Society of Transplantation.

The Canadian Standards Association was contracted as an independent body to take the outline of these draft standards and transform them into national standards. They formed the basis of the Health Canada regulations.

People in need of cells, tissues, and organs are extremely vulnerable. Their health is compromised. One donor who donates both organs and tissues can be the source of more than 100 transplants. Clearly, the potential impact of a single donor with an infectious disease on the health of Canadians is great.

Donors must be assessed for medical conditions and risks that could result in the transmission of a disease to a recipient. This assessment is made through a combination of a physical examination of the donor, questioning of the donor's next of kin, and testing of samples of the donor's blood. We must keep in mind that in the case of deceased organ donation, all this happens after a donor has been declared clinically dead.

Donors are considered to be at a higher risk of transmitting diseases such as human immunodeficiency virus or hepatitis if they have engaged in certain behaviours, including men having sex with men, intravenous drug use, sex trade work, and certain body piercing and tattooing practices. The men having sex with men risk factor is applied to all male donors, regardless of their sexual orientation.

The Public Health Agency of Canada surveillance data, which we monitor on an ongoing basis, clearly shows that the highest proportion of positive HIV tests among adults in Canada each year continues to be within the men having sex with men group. It's 40% in 2006-07. The next highest incidence is among IV drug users, at 19%, and then sexual contact with a person at risk, at 12% in 2006-07. These three risk factors alone accounted for 70% of the new cases of HIV in 2006-07 and cumulatively have accounted for 85% of positive HIV test results since 1985. All of these risk factors are assessed during the donor screening process.

While testing used for organ donors is sensitive, it is not 100% reliable, and there still remains a slight possibility of a false negative result. This includes a window period during which the donor may be capable of transmitting a disease but will test negative for it. For this reason, screening a potential donor for risk factors remains a critical component of the donor assessment process.

Could we ask a different type of question, such as what type of sexual practice has the donor engaged in? There are differing views on this, but I must stress that the deceased donation often occurs under conditions of intense emotional distress and must be treated as the most generous gift one human being can give to another. It is not the donors themselves who must answer these delicate questions, but their family members at a time of intense grief.

Under these circumstances, some families may be even more uncomfortable and may not wish to proceed with donation. Potential donors themselves may not wish to consider organ donation if they know that their families will be subject to this type of interrogation.

As I indicated at the very beginning, Health Canada does not prevent anyone from being considered as an organ donor. Despite the identification of risk factors based on science, an exceptional distribution provision in the regulations allows the transplant of an organ from a donor considered to be at a higher risk, provided that the transplant physician judges it to be in the patient's best interest and the recipient gives his or her informed consent. The recipient and the people caring for him or her after surgery can then make their own decisions on precautions to be taken and follow-up testing.

It is important to note that donor screening for behavioural risk factors has been practised in Canada and the United States since 1994, long before either country had laws mandating it. Therefore, the coming into force of the regulations presented a status quo situation with respect to donor screening in Canada.

Throughout the development of these standards and regulations, there were numerous consultations conducted in which members of the transplant community and general public were provided opportunity to comment on these risk factors. No comments or concerns were raised during any of these consultations about the inclusion of the men having sex with men risk factor or any of the other risk factors.

● (1125)

[*Translation*]

Any changes to the requirements in the standards will be based on valid scientific data, with, as always, the protection of the organ recipient in mind.

[*English*]

With this, members, I thank you for listening. We'd be happy to answer other questions.

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much, Ms. Ballantyne.

Now we'll move on to the Canadian Standards Association, with Suzanne Kiraly, president, and Marc Germain, chair designate.

Ms. Suzanne Kiraly (President, Canadian Standards Association): Good morning. My name is Suzanne Kiraly, and I am the president of the Canadian Standards Association, or CSA.

I am here today to describe CSA's role in the development and maintenance of Canada's national standards for cells, tissues, and organs for transplantation.

CSA is an independent, not-for-profit, member-based association that serves business, industry, government, and consumers in Canada and around the world. Established in 1919, CSA is one of four organizations accredited by the Government of Canada to develop national standards. Our organization maintains more than 3,000 standards, codes, and information products for safety, design, and performance in a wide range of areas, including health care, the environment, and public safety. We have been developing health care standards for more than 40 years.

As a standards development organization, CSA functions as a neutral third party, providing a forum for committees of experts to work within a rigorous and accredited process. Our technical committees are created using a balanced approach that capitalizes on the combined strength and ensures that no single group dominates. The technical committee that developed the transplantation standards included health care professionals; regulators; general interest members, including a transplant recipient; and an expert on ethics.

When a draft standard has been completed, it is submitted for public review so that any interested person or organization can comment. The draft is amended if necessary and then submitted to committee for formal approval.

Once a standard is published, CSA continues to maintain it and will make amendments as needed to keep it current. Each standard is reviewed at least every five years.

CSA is not a government body and does not have the power to make a standard mandatory. A standard becomes law only if a federal, provincial, or municipal government references it in legislation. For the transplantation standards, Health Canada has referenced specific sections in its new regulations, making those sections mandatory.

Specifically, CSA began its work on these standards for cells, tissues, and organs in transplantation in 2000, at the request of Health Canada. In early 2002, the draft standards were posted on the Internet for public review, and over 1,000 comments were received. The standards were completed in early 2003, and they were approved as national standards by the government.

These standards were created to enhance safety and effectiveness for donors and recipients and health care personnel. They represent the best efforts of the leading experts in Canada, drawing on the combined knowledge and best practices of the top national and international organizations in this area.

The series consists of a general standard that applies to all cells, tissues, and organs, and five additional standards that provide requirements for specific types of transplant materials. These standards set minimum requirements for organizations or individuals involved in all aspects of transplantation. These standards are designed to provide a common management framework. Organizations can use them to develop their policies and procedures, hire and train staff, and manage their operations. The goal is for everyone involved in transplantation to safely manage their responsibilities in a consistent and organized way.

CSA standards are revised to address changing requirements and respond to emerging technologies. The technical committee is currently reviewing the documents, and new editions are slated for 2009. We are committed to maintaining and improving the standards to keep them relevant. We welcome comments and suggestions on the standards from all interested organizations and individuals.

Thank you.

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much.

Now we will go to the Canadian Council for Donation and Transplantation, with Ms. Kimberly Young. We also have Dr. Graham Sher.

Oh, are you following as well?

Dr. Marc Germain (Chair Designate, Technical Committee on Safety of Cells, Tissues, and Organs for Transplantation and Assisted Reproduction, Canadian Standards Association): Yes, I'm going to speak on behalf of the CSA.

● (1130)

[*Translation*]

Good morning. My name is Marc Germain. I am here today as the incoming chair of the technical committee on cells, tissues and organs for transplantation and assisted reproduction. In my regular job, I am also vice-president and medical director of the human tissue division at Héma-Québec. I would like to thank the committee for the opportunity to speak today.

The CSA standards on cells, tissues and organs were developed over the course of several years through a careful and well-defined process, as just described by Ms. Kiraly. I would like to make a couple of specific points related to the standards, in particular with regard to the criteria that are applied to qualify cells, organ or tissue donors.

First, as has already been said, it is important to recall that the goal of these qualification criteria, often called exclusion criteria, is to decrease the risk of disease transmission by transplantation and to make the donated cells, tissues or organs as safe as possible for the recipient.

Second, I must also repeat that, with communicable diseases, the qualification criteria based on the assessment of high-risk behaviours are only one of several ways in which the risk of disease transmission by transplantation is reduced. Other steps that are taken to reduce this risk include, for example, the testing of donors' blood for specific transmissible infections. However, for the reasons previously mentioned, it is important to recall that the assessment of high-risk behaviours remains an essential component of the overall safety of transplanted cells, tissues and organs.

Third, I must emphasize that, when developing standards for the safety of cells, tissues and organs, the technical committee took into consideration existing consensus and best practices in the field of transplantation. In particular, the committee attempted to harmonize with other existing standards and regulations, both nationally and internationally, whenever this was felt to be justified. It should be noted that the exclusion criteria related to high-risk behaviours that were included in the CSA standards are very much in agreement with other national and international standards.

The fourth point has also already been mentioned, but it bears repeating. The CSA technical committee and all other stakeholders recognized from the outset that organ donation represents a unique situation. Organs are and probably always will be in short supply. They can very often be life-saving to the potential recipient. Because of this, the standards allow the retrieval and transplantation of organs obtained from donors who might not meet all the qualification criteria, through a process called exceptional release. This process requires only that the transplantation physician and the potential recipient be made aware of the specific situation in order to be able to make an informed decision about the relative risks and benefits of accepting a transplant from a donor who might not fully qualify according to the criteria set forth in the standards.

In conclusion, I want to emphasize that the selection of the best possible qualification criteria, especially the exclusion criteria based on high-risk behaviours, has been discussed extensively over the last several years. Some of you are already well aware of these discussions. For example, in 2006, there was a meeting sponsored by the FDA in the United States to look specifically at those issues, both from the blood donation point of view, and from the cell, tissue and organ donation perspective. Several international stakeholders attended that meeting, including representatives from Canada such as myself. It is an area of intense scrutiny and I can assure you that the CSA technical committee will continue to monitor the situation closely.

I would like to thank you again for your time. I will be happy to take your questions.

[*English*]

I'll be happy to take your questions in English too.

Thank you.

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much, Dr. Germain. I'm sorry about skipping over you.

Now we'll continue with Ms. Young.

Ms. Kimberly Young (Chief Executive Officer, Canadian Council for Donation and Transplantation): Thank you for the invitation.

I'll begin by introducing our agency and providing disclosure.

My name is Kimberly Young, and I'm the chief executive officer of the Canadian Council for Donation and Transplantation, or CCDT, a federally incorporated not-for-profit advisory organization established by the Conference of Federal-Provincial-Territorial Deputy Ministers of Health to support their efforts to coordinate and improve activities relating to organ and tissue donation and transplantation, or OTDT, in Canada.

According to the CCDT vision, every Canadian who needs a transplant should have equitable and timely access to safe tissues and organs; every Canadian who wishes to donate should be optimally considered and, when possible, supported; and all donation should be compassionate, safe, and efficient.

As of April 1, 2008, the Canadian Blood Services, or CBS, will assume responsibility for some national services for organ and tissue donation and transplantation, which includes a transfer of functions currently performed by the CCDT. For this reason, I would like to introduce Dr. Graham Sher, chief executive officer of the Canadian Blood Services.

● (1135)

Dr. Graham Sher (Chief Executive Officer, Canadian Blood Services, Canadian Council for Donation and Transplantation): Thank you, Kim, Mr. Chairman, and honourable committee members.

Throughout today's testimony, you will be made aware of several challenges facing organ and tissue donation and transplantation in Canada, not just those associated with donor deferral criteria. I would like to impart to the committee that there has recently been some positive momentum on this front. The federal, provincial, and territorial governments indicated that Canadian Blood Services will be given a mandate to begin work on key national services for organ and tissue donation and transplantation in Canada. Based on our existing national infrastructure and service delivery model, our experience in donor recruitment and deferral, our experience in biological product manufacturing and processing, our information systems and registry management, our independent governance structure, and our credibility with Canadian stakeholders and the public in general, the FPT governments have recognized that Canadian Blood Services is uniquely positioned and qualified to deliver those services within Canada's national organ and tissue supply chains.

Our understanding is that the focus of this hearing will be on the exclusionary criteria set out in the new safety of human cells, tissues and organs for transplantation regulations. While Canadian Blood Services was not involved in the development of these regulations, we will soon be operating under them and are therefore a key stakeholder.

We have extensive experience in operating in a highly regulated environment, since blood is subject to similar regulations under the Food and Drugs Act, where difficult decisions about donor eligibility must frequently be made in the name of patient safety. We have an earned reputation for openness and transparency and go to great lengths to include Canadians in our decision-making processes. We are also currently embarked on extensive discussions around the blood-related deferral, similar to the one under discussion today. We trust that this hearing will continue to ensure that the CTO regulations are developed in similar fashion.

I want to leave the committee with the sense that as we work with the donation and transplantation communities across Canada to improve performance in these critical aspects of the health care system, we will continue to engage all stakeholders in the many complex decisions that lie ahead. I am strongly encouraged by the opportunities before us and the sense that Canada can begin to improve upon its current poor performance in organ and tissue donation and transplantation.

Thank you.

Back to you, Kim.

Ms. Kimberly Young: Prior to discussing the regulations, I would like to disclose the CCDT's involvement in the development of the regulations.

First, prior to the formation of the CCDT, individuals who are currently council members or staff formally recommended that Canadian standards be established in this area.

Second, several CCDT council members and staff, including me, have been and continue to be involved in the Canadian Standards Association committees.

Finally, as part of their ex officio capacity, a representative of Health Canada attended CCDT meetings to brief members on the development and implementation of cells, tissues, and organs regulations, and the opportunities for consultation.

With that disclosure provided, I'll now respond to the new organ donor regulations from the CCDT perspective. Both the invitation questions and the controversy highlighted in media reports suggest we are here today to answer two main questions.

First, do the new regulations make sense, and were they developed in a consultative way?

While the CCDT recognizes that the process for developing and implementing the regulation, particularly the exclusionary criteria, is a complicated one with potential legal, ethical, and social aspects, the CCDT will only focus its response from a health system perspective. Our response is based on a number of principles that underpin the need for regulations related to cells, tissues, and organs including that exclusionary criteria. I will highlight a few of these principles.

The safety of transplant recipients is of paramount importance. While regulations must consider the interests of donors and potential donors, their primary purpose is to minimize the potential health risks to Canadian recipients.

Every person should have the opportunity to be considered for donation and provided with an explanation for why he or she is not eligible to donate.

The decision about which organs and tissues are used for transplantation is a clinical and medical decision made in consultation with the patient or their family.

The transparency of the health system and medical decisions is important and can be facilitated through regulations and common practices.

Standards and regulations are an important mechanism of risk management. Government standards and regulations are important to the strong functioning of the Canadian health system and the OTDT system in particular.

Government standards and regulations must be well understood by the public in order to maintain the public's trust in government's ability to execute its fiduciary responsibilities to its citizens.

With the foundation of principles presented, I'll proceed to answer the questions.

First, do the regulations, including the exclusionary criteria, make sense?

Based on the principles outlined, the CCDT fully supports the importance of and need for the federal regulation of cells, tissues, and organs in Canada. In addition to the assurance of safety provided by such regulations, they also contribute to the transparency and standardization of the health system related to OTDT. We believe the regulations are sound and make sense because they are patient-centred, evidence-based, and allow for the discretion of the health care team, in consultation with the recipient, to weigh the risks and benefits of exceptions, that being exceptional release and distribution.

For each of those areas, I'll further describe the basis for the CCDT determination in relation to patient-centred.

Health care decisions are made daily on which treatments will be in the best interests of an individual patient. Medical decisions are the legal responsibility of the physician, in consultation with the patient and the health care team, and are made on a case-by-case basis.

The exclusion criteria in the regulations provide a necessary resource when dealing with donation and have been established to eliminate possible risks to the recipient that may offset the benefit.

The CCDT supports the authority of physicians and the health care team to use professional judgment in making decisions about organs and tissues suitable for transplant, within the confines of legal and regulatory requirements and hospital policies. In fact, the new regulations make room for this decision-making in the form of exceptional release.

In relation to evidence-based as part of the CCDT's mandate, we fully explore issues through background research, environmental scans, and international reviews, and we develop evidence-based consensus recommendations in consultation with experts and the OTDT community. We have successfully developed and published a number of these reports. The CCDT understands that a similar process has been undertaken in the development of the CTO regulations.

Finally, further to the application of the regulations and the exclusionary criteria, in practice, as part of the pre-donation assessment, a coordinator completes a medical and social history questionnaire with the donor or the donor's next of kin. Responses will determine what tissues or organs are eligible for donation. If an exclusionary criterion is identified, it is normal practice for tissues to be deferred.

Current practice for organ programs is to weigh the benefit of the transplant for the recipient against the possible risk of disease transfer from the donor. Due to a greater demand for organs, more attention has been given to that area of acceptable risk. If it is deemed that the benefit outweighs the risk, the transplant surgeon as well as the recipient must consent for the transplant to proceed.

● (1140)

Now to the second question and the purpose for being here. Were the CTO regulations developed in a consultative way?

Their development began in response to requests from the Canadian OTDT community more than a decade ago. Health Canada struck a working group of experts to develop safety standards for CTOs. In 2000, Health Canada contracted the Canadian Standards Association, as we've just heard. They struck a technical committee, with broad representation, that was responsible for the simultaneous development of the general and subset standards.

Prior to the formal development or consultations, Health Canada utilized a directive guidance document to prepare the community.

An international consultation was undertaken to ensure comparability with other jurisdictions. Coast-to-coast in-person consultations were conducted, which we attended. In March 2003 a national review of establishments handling or processing CTOs also occurred to assess adherence to the basic safety requirements.

Throughout the development, the OTDT community was invited to provide ongoing feedback through a website and through publications in the *Canada Gazette*. And a process was established, through the CSA technical committee, to vet that community input.

Therefore, based on the above, we believe these regulations were developed in a consultative way. However, based on recent media reports, it appears that some individuals and groups did not feel informed or consulted. While we understand that Health Canada undertook a broad public consultation, we were not privy to whether direct consultation occurred with populations affected by the exclusionary criteria.

In closing, on behalf of the Canadian Council for Donation and Transplantation, I respectfully submit the following suggestions to the House of Commons Standing Committee on Health.

First, the CCDT suggests that you support the regulations, including the intent of the exclusionary criteria, which is to protect transplant recipients through the safeguarding of cells, tissues, and organs available for transplantation in Canada. We believe that the regulations and exclusionary criteria were based on sound science and broad consultation. They serve to ensure the safety and transparency of the system to the greatest degree possible. Furthermore, the exceptional release procedure ensures that no Canadian is automatically excluded as a donor.

Second, ensure that the regular review mechanism, as outlined in the regulations, is utilized to review current evidence and leading practices so that exclusionary criteria, as worded, are still relevant and viable.

Third, ensure ongoing dialogue with those opinion leaders and organizations expressing concern about the exclusionary criteria.

Fourth, support a comprehensive communications strategy to inform the public and affected groups about the continued need for organ and tissue donation.

In closing, I would like to thank the standing committee for this time and the opportunity to discuss these regulations.

● (1145)

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much, Ms. Young and all the presenters.

Now we're moving to questions from Mr. Thibault.

Hon. Robert Thibault (West Nova, Lib.): *Merci, monsieur le président*.

Thank you to all the presenters for being here today.

There are a couple of points that concern me about this. I think we all agree that we need a safe standard of care, safety in the supply, safety in the chain, and safety in handling. What concerns me a little bit is that when I am on my death bed and I need a transplant, I want to be able to take an informed risk. I'm not going to worry that it's going to make me sick if it's going to keep me alive.

Second, to take that informed risk, there has to be a supply. It appears that with the measures that have been taken, we're reducing the availability of the supply. We're eliminating a whole group of individuals in society who may pose no more risk because of the safety of their organs than I do. But they can't now, based on the criteria given, sign their donor cards. Should they die in an accident, or should they die quickly, their organs are not available for the patient to take an informed risk and consider.

So I think our job is to see if there is a better way to achieve the same thing. It is to see if we can modify what you've come up with in a way that achieves both those things.

The first quick question I would have for Ms. Ballantyne is whether, when these regulations were gazetted, the general standards were included with the regulations. Did the people who were checking the regulations have access to both?

Ms. Meena Ballantyne: No, the general standards weren't included, but there was reference to the standards at the CSA, because that's the current government practice in terms of incorporation by reference. So you don't include the standard in the regulations, but you point to the CSA standard in the regulations.

Hon. Robert Thibault: At that time, Madame Kiraly, could the standards be visited on your website?

Ms. Suzanne Kiraly: The standards were able to be seen before they were published, as well as after they were published.

Hon. Robert Thibault: During the gazetting process, when they were visited, you said, by 1,000 people, or through that whole period, not just during the gazetting period, was annex E included?

Ms. Suzanne Kiraly: Yes.

Hon. Robert Thibault: I have had a hard time doing that follow-up on the Internet, to get through all those areas such that you would see them all. It didn't appear to me to be too user-friendly, that if I checked the regulations, I would automatically be brought to or focused on annex E. If I look at the regulations by the Department of Justice in accordance with the Canada Health Act and then I look at the general standard, in the regulation it points me to section 13.1.3. Then I look at section 13.1.3 and I see nothing offensive there. Then if I go further and look at the annex, I can see where people are concerned, because it raises some questions for me that might not necessarily....

I know, and it has been presented, that you can use disclaimer forms to get around it. So anybody can be a donor with a proper disclaimer, and I understand that it's common practice in the transplant community to get disclaimers signed by, I think, almost every patient. They are asked to sign a disclaimer. But it doesn't take away the problem of the availability, because if I look, the first thing I see is that men who have had sex with another man in the preceding five years cannot be on the donor list. They would not be encouraged to sign a donor card. Certainly we know that community now has reduced. So that one would be altered.

Why don't we include “if that brings risk”? I could maybe understand if somebody has had many partners and was active in the community; there may be an added risk. But for somebody in a monogamous relationship, how would their risk be higher than a heterosexual couple married for 20 years and engaged in anal sex?

● (1150)

Dr. Marc Germain: I guess that question is for me.

There are two points to your question. The first point has to do with the last part of your question, and it's the case not only for organ, cell, and tissue donation, but also for blood donation.

When we assess the risk in a given donor, we work from the principle that we don't assess the risk that is specific to this individual. We assess the risk that exists in a group of individuals to which this person belongs. Of course, a given person is either infected or he or she is not infected. Ideally, you would want to have that information, the exact information, on hand when you determine whether a donor is eligible or not for whatever type of donation.

We don't have that. We have to work with basic information. One is, does this person engage in certain types of behaviour that puts them at risk? One of the types of behaviour we are looking for—and this is a very wide consensus in the community—is men having sex with men. So that is the basic issue.

Hon. Robert Thibault: I think people may disagree with you, Mr. Germain. People may disagree that two men, living together in a monogamous relationship for 40 years and not engaging in intravenous drug use, and not doing body piercing with common equipment that others have done body piercing with, would have no more risk of HIV than the general public.

Dr. Marc Germain: I totally agree with you. In the situation you are describing, it's more than likely to be the case. The problem is that in a real-life situation where you need to assess the risk status of a given donor, you may not have the details of all of what you just explained at hand. First of all, especially for organ, cell, and tissue donation, the donor is often deceased at the time of the donation.

Hon. Robert Thibault: I agree, Mr. Germain, you may not have all those things, but I'm informed by the transplant community that prior to doing the transplant, there is an interview with the donor's family. There are those questions to discover that type of information to establish risk as much as possible.

Dr. Marc Germain: This is why the procedure for exceptional release is in place. Once you have the basic information that this person might be at increased risk of transmitting an infectious disease based on the assessment that's put forth in the standards, if you have that possibility by reviewing the donor's chart, by interviewing the family members, you might fine-tune your evaluation of the risk status and then decide to go forward with the organ donation through the procedure of exceptional release. And that is what's being done on a daily basis, I would say.

Hon. Robert Thibault: I understand that, but I submit that you are removing people from the list of potential donors with which you could have that consideration.

The Vice-Chair (Mr. Lui Temelkovski): Madame Gagnon can probably continue on that line of questioning.

[*Translation*]

Ms. Christiane Gagnon: In all the testimony I have heard this morning, nothing convinces me of the need to exclude some people who have engaged in high-risk behaviours and not other types of people who have also engaged in high-risk behaviours such as heterosexuals who have had various partners.

I understand that we must be certain about the quality of an organ that we are giving to a recipient, who is very vulnerable as well. Why not group all high-risk behaviours together, including those engaged in by heterosexuals? Just because people at risk are mainly in the gay community, why target only that community for exclusion?

● (1155)

Dr. Marc Germain: I am going to refer back to Ms. Ballantyne's explanation. She explained that identifying some groups as being at especially high risk of these diseases is the result of very rigorous scientific studies that are widely accepted in our community. For example, those studies show that men who have had sexual relations with other men are, generally speaking, at the greatest risk of contracting HIV.

Again, this does not mean that a person in that group will necessarily be infected. That is not the issue. This is about identifying a group at risk. Men who have had sexual relations with other men are at risk. So are intravenous drug users. So are heterosexuals who have had sexual relations with people known to be at risk for HIV, whether they be men who have had sexual relations with other men or intravenous drug users.

These groups are deemed to be at higher risk. The other groups you refer to are at no higher risk than the general population. The basis on which the criteria have been established is a scientific, epidemiological one. The criteria apply to organ, cell and tissue donation just as they apply to blood donation.

[*English*]

Ms. Liz Anne Gillham-Eisen: Thank you very much.

On the point as to who should sign to be a donor, I think every Canadian should. You're not automatically excluded as an organ donor based on this high-risk criterion. I think that needs to be clear.

On the high-risk behaviours, I think they're very difficult to interpret. As the ADM said, the newest statistics show that 40% of the new cases of HIV are within the men having sex with men group. I think many people have interpreted that to mean that they're below the half; 60% are in the other group.

That statistic is 40% of the new cases, which represents a population group of approximately 5%. If we estimate that the gay and lesbian community is approximately one in ten—10% of us are gay and lesbian—approximately half of them are gay men, so that would be 40% of the cases, over 5%, versus 60% of the cases, over 95%, the rest of the population. That's what makes it a risk factor.

Again, it's not to say that every gay man is involved in risky sexual activity, unprotected sex, etc. The question is at that level because that's what's reported on. We depend on the science. The science reports on the category of men having sex with men, so that's what we have used.

Also, as the ADM pointed out, when are we actually asking these questions, and who are we asking in the case of organ donation? We're asking the next of kin. We're asking a family member, who has just recently lost perhaps the most important person in their life. The question of whether a loved one, a man, has had sex with a man is something they may not be able to answer, but I think it's the highest level when you're talking to a parent or a sibling.

As the mother of a 21-year-old gay man, I could not tell you in an interview that my son has protected sex. I don't know the last time he had sex. I don't know how many sexual partners he has. I don't know if he has anal intercourse. That is not information I have. But I can very clearly, and without hesitation, tell you my son is a man who has sex with other men.

In the context of where this organ donation occurs in the case of deceased donors, this is the question. It is not meant to be discriminatory; it is based on science. We are still at a point where 40% of the new cases exist in approximately 5% of the population. That is a very important fact.

Thank you.

● (1200)

The Vice-Chair (Mr. Lui Temelkovski): You have one minute.

[*Translation*]

Ms. Christiane Gagnon: Ms. Young, you said that Health Canada had held wide public consultations but you did not have sufficient information to be able to confirm whether the views of populations affected by the exclusionary criteria had been directly sought. That concerns me a little. It is a little disturbing, and it is why I really wish that we could have heard this morning from the community that is targeted by one of the exclusionary criteria.

You say that, as Health Canada, you are not aware. How did you do your consultations?

[*English*]

Ms. Liz Anne Gillham-Eisen: There were two types of consultation for the development of these standards. The first was the consultative process that was undertaken by the CSA That consultation process included publication on websites. There was identification of over 1,000 programs and establishments and patient advocacy groups, which received the standards by e-mail or Canada Post, etc.

As the CSA pointed out, over 1,000 comments came back. The CSA addressed all 1,000 comments, and they had to review them as part of the process for developing the regulations.

On the regulations, as we pointed out at the beginning, these regulations were called upon by the community itself. The actual draft of the standards existed as far back as 1995. There have been consultations on both a formal and informal basis, because many of the people involved in donation and transplantation participated on these committees.

The consultation on the regulations has been unprecedented. Because the community is not accustomed to regulations, we did face-to-face meetings, and we sent out copies of the regulations. We did information kits explaining the regulations and the incorporation of standards. There was an awful lot done. We did cross-country tours, the website, and we did the whole issue around gazetting in the *Canada Gazette* and the 75-day comment period and responding to—

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much.

Madam Wasylycia-Leis.

Ms. Judy Wasylycia-Leis (Winnipeg North, NDP): Thank you, Mr. Chair, and thanks to all of you for your presentations today.

Let me start with Ms. Gillham-Eisen.

You just said there's nothing in all of this to prevent people from donating their organs, yet it seems to me that the way this whole exercise was done has precisely that effect. It discourages people from offering their organs for donation and leaves a bad taste in many people's mouths on top of that, in the sense that they feel they're being discriminated against.

Was it done this way to in effect achieve a ban but avoid a charter challenge?

Ms. Liz Anne Gillham-Eisen: No. The criteria are science-based, and we are looking at what is identified as a risk factor. Exceptional distribution is a clause used for MSM—it's used for others. Organs from men who have had sex with other men are used in this country, but again we recognize that this is a higher risk factor.

We in this country allow patients to make their own decisions based on health and what they are willing to do, follow up on, etc. So it is not meant by any means to be that. We're using language within standards and regulations that has been used and has been practised since the mid-1990s. This was never identified as an issue before.

I think media attention stating that we have banned gay donors has been a factor in this. When we read the regulations, they do not ban homosexual men from donating organs.

● (1205)

Ms. Judy Wasylycia-Leis: I hear what you're saying. That may be true in the way it's written, but the way it's communicated and the way it affects our whole donation policy is another matter.

Regarding what we're all concerned about, surely there was another way to do this. It seems to me one option would have been to leave your section 13.1.3 as the basis upon which decisions would be made. Why did you feel you had to go beyond that and have a list of exclusionary criteria that specifically identified gay men and put them at the very top of the list? Surely there was another way to do it. What was wrong with leaving it as it was in section 13.1.3?

Ms. Liz Anne Gillham-Eisen: These regulations, and particularly the standards, were developed by the community, by transplant experts. To leave something in without giving it more context.... Again, these are based on science. We have to go back to the science and the risk factors.

Ms. Judy Wasylycia-Leis: Let me ask about the science. Maybe I should ask the transplant specialist.

Can you give us specific scientific studies on the 10 criteria listed as exclusionary? Can you table those with us? I don't expect you to give us a detailed answer now. Can you table with us studies that link each one of those conditions to contaminated organs?

Dr. Marc Germain: On the specific issue of men having sex with men, it has been stated before that there are epidemiological studies showing that the risk of HIV infection in this group is higher compared to the general population.

Ms. Judy Wasylycia-Leis: Could you get some of those studies to our committee?

Dr. Marc Germain: Sure. They're actually included in the references that were—

Ms. Judy Wasylycia-Leis: I'm just wondering if the science has kept up with the changes in which sexual activity takes place. Knowing about the transmission of HIV and AIDS today and the many risk factors involved—multiple partners and unprotected sex—has the science kept pace? Are you referring to recent scientific studies that reflect this? Why not simply include multiple partners and unprotected sex as exclusionary criteria in a list? If that's the best way to describe the risk involved, why not just do that?

Dr. Marc Germain: I'm sorry, why not just do what?

Ms. Judy Wasylycia-Leis: Why not put in your exclusionary criteria people who have had multiple partners and unprotected sex in the last five years?

Dr. Marc Germain: To the best of my knowledge, this is not a situation where we know for a fact there is an increased risk. The simple fact of having multiple partners will not necessarily put you at higher risk. It depends on who the partners are.

The other thing is that it has always been very difficult to define exactly what constitutes multiple sex partners. There is no operational definition for that. What's the number? Is it 2, 5, 10, 15? We don't know, and there are no data to support a cutoff that could be used in daily operations of screening cell tissue and organ donors or blood donors that would reliably identify those who are at higher risk. These groups that are listed in annex E correspond to groups of people who have been shown to be at higher risk compared to the general public.

Ms. Judy Wasylycia-Leis: You could have left it at 13.1.3, which specified persons with HIV, HPV, or HCV or persons at high risk of HIV, HPV, or HCV. Why not leave it at that? Why get into a language that is—

● (1210)

Dr. Marc Germain: That cannot be operationalized. People at higher risk of HIV, what does that mean? How do you define who is at higher risk for HIV? You have to look at specific situations where you can say yes, the person belongs to a higher risk group, or no, he or she doesn't belong. That's why annex E is there. It is to specify very clearly what we mean by higher risk. It doesn't say that someone who is in that group will be infected; it just means that this group has been identified as being at higher risk.

Those who received clotting factors in the days when the blood products were not as safe versus HIV are deemed to be at higher risk. They're not all infected; it's just that as a group they are at higher risk. Therefore, we need to take that into consideration when evaluating the risk.

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much, Dr. Germain.

Now we will move on to Mr. Fletcher.

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

As I listen to this discussion, I reflect back to when I had my car accident and I could have been a multiple organ donor myself, but as it turned out, I was the recipient of a blood transfusion instead. Thankfully, that transfusion proved to be a healthy thing to do. However, a lot of people at that time did not receive clean blood, and they contracted hepatitis C. There is a long saga of compensation for those people who shouldn't have got hepatitis C in the first place but did. It wasn't until the time of this current government that $1 billion compensation was awarded to those victims pre-1986, post-1990.

Having reflected on the past of the Canadian blood system, I wonder if any of our witnesses could comment on what would happen—and by the way, a lot of the hepatitis C blood came from high-risk groups, I understand—if we deviated, as has been suggested, from the science that you are basing your decisions on.

Dr. Graham Sher: Mr. Fletcher, I'm prepared to answer that as the current head of the blood system in all of Canada, except for the province of Quebec.

I think your question is an important one, and I do think, as my colleagues said earlier this morning, this does need to be science-based and evidence-based to the extent that it can. But by their very nature, these exclusionary criteria are broad-based and blanket-approached, and I do think, as Dr. Germain has repeatedly said, it does not address every individual at the time of the criterion, but takes the broad approach to groups of individuals who may pose risk.

I think your points are well said. We are where we are in Canada because of some history of poor screening in a major component of the public health system, namely the blood program. We do have very similar deferral criteria today in the blood program. However, at the same time in that program, you have a slight distinction in that you have a much larger supply of raw materials than you do in the organ situation. Hence the deferral criteria currently in place in the blood system are even more rigid than those contemplated in the cells, tissues, and organs regulations, where first of all you have the current five-year policy, and second, you have the exceptional release component, precisely to balance the risk-benefit equation that a clinician and a transplanter will make at the time they are discussing with the recipient the receipt of an organ.

Those sorts of exceptional release criteria do not exist in the blood program, because we have a much larger supply to draw on and can provide alternate product to a patient in need. However, I think the premise of your question is that if we didn't have these sorts of rigorous, science-based, epidemiologically based and evidence-based approaches to deferral criteria, we could potentially be facing the situation of infected organ recipients as much as we faced transfusion recipients in the past.

My last comment, in closing, is that while I support all the questions and comments raised by committee members, if you're going to bring additional witnesses to bear to this committee, I would suggest you bring transfusion and transplantation recipients as well as bringing some other donors, and particularly groups of excluded individuals or potentially excluded individuals.

Mr. Steven Fletcher: That's a very good point.

I have one more question, Mr. Chair, and I'll pass the remaining time to Ms. Davidson, if there is time.

A few months ago, in November 2007, in Chicago, there were four organ recipients who contracted HIV and HCV from high-risk donors. What was Health Canada's reaction? Are these regulations in reaction to that, or are they there based on past Canadian experience?

● (1215)

Ms. Liz Anne Gillham-Eisen: Again, that was a situation that I think emphasizes the need for donor screening.

In this particular case, there was one organ donor who basically was identified with a high-risk behaviour, a risk of transmitting disease. The decision was reached by the transplanting physician to go ahead and use the organs for transplant.

The media has reported that not all the recipients were made aware that their organ was at slightly higher risk. In media reports, one particular recipient went forward to say they were not given the opportunity to discuss the fact that their donor was at slightly higher risk.

As we've pointed out, within these regulations, which are under the Food and Drugs Act, there would be a requirement to discuss that the donor is at a slightly higher risk. But again it underlines and emphasizes that a negative test result does not always mean that the donor does not have an infection, and that those at higher risk must be identified and a discussion ensue between the transplanting physician and the potential recipient.

I think it just emphasizes exactly why we've put into regulations what we have, and the exceptional distribution and the importance of donor screening.

Thank you.

Ms. Meena Ballantyne: Mr. Chair, if I may respond to the question, no, these regulations were not in response to the Chicago incident.

These regulations, as we've stated, started in the mid-nineties in terms of consultations. They basically formalized and made mandatory current practices in the transplantation community. We went through the CGI, or *Canada Gazette*, part I, process, which is a 75-day comment period. We went through the CGII and asked for a six-month coming into force. The CGII went in June 2007, and the regulations did not come into effect until December, to give the community time to adjust and to register with us. By the way, all 10 donor and transplantation organizations across the country have registered and are aware of our regulations.

Mr. Steven Fletcher: Thank you.

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much.

I'm sorry, Mrs. Davidson, you'll get an opportunity with the second panel.

Thank you very much to all the panellists, the witnesses, for your testimony.

If we could have the second round as soon as possible, that would be great. While everyone is getting prepared, I'd just like to make a few comments.

To those who gave us some written material, presentations, beforehand, if it's possible to cut your testimony a little shorter since we have it in writing, that would be great, because then we can get more questions. You'll find that we will get most of the information that you have through the question and answer period, as opposed to through the testimony. That would be appreciated.

We will be starting with Dr. Levy, director, multi-organ transplant program, University Health Network.

● (1220)

Dr. Gary Levy (Director, Multi Organ Transplant Program, University Health Network, University of Toronto): Thank you, Mr. Chairman. I would like to thank the Standing Committee on Health for giving me the opportunity of presenting today.

My name is Gary Levy. I am the medical director of the transplant program at the University of Toronto and its affiliated hospitals. For those of you who don't know our program, we perform over 600 solid organ transplants a year and take care of between 5,000 and 7,000 patients.

Solid organ transplantation is truly one of Canada's greatest success stories, and it sustains the lives of Canadians who would not be alive without this modality. Results today at one year and five years are greater than 90% and 80%, showing that this is really a remarkable treatment.

Most beneficiaries are in their most active years of life, in the 30- to 50-year range, and they have families that depend upon them.

Today over 3,500 patients are awaiting hearts, livers, kidneys, and pancreases across this country. The transplantation community, many of whom are here beside me, have worked very hard with government and the public to try to increase organ donation rates and to help people who could not be alive without this treatment.

I am here to discuss this recent Health Canada regulation, which I've outlined, and because of the time I will not go into it. It's outlined and published in the *Canada Gazette*, part II. It came into effect in December 2007.

It lists the exclusionary criteria. I think everybody understands what the word “exclusion” means. It means you're excluded if you have the following diseases or disease states: HIV, HBV, and HCV; transmuscular or subcutaneous injection of drugs in the preceding five years; the presence of tattoos; and you are a man who has had sex with another man in the preceding five years.

I want to point out—and it has been said by the previous witnesses—that these criteria are identified in other jurisdictions, and that's true. I brought them with me. I would be happy to leave them with the committee. However, in no other jurisdiction are they rules or laws. They are guidelines.

They provide for an effective process where, on a case-by-case basis, information about potential risk is communicated by an organ procurement specialist to a transplant specialist, and at that time a decision is made whether to use those organs, whether it is safe, and the communication is then made to the potential recipient. That guideline has existed in Canada since the nineties, and we do get recipients to sign a consent for all organs, because there is no such thing as a safe organ.

With the passage of this regulation, Canada has taken the unprecedented step of making these guidelines a law. The result is now that the ability to use organs that fall into these criteria can only occur through exceptional release clauses as outlined in annex E, and I won't read them, for brevity today.

Thus, this new regulation goes far beyond that of other jurisdictions in which donor history is a guideline to transplant physicians and surgeons who ultimately, in concert with other specialists, health care professionals, nurses, and ethicists, make a decision for the benefit of a potential recipient.

First, I want to applaud Health Canada for its unstinting work in continuing to improve the health of Canadians. I believe the intent of the regulation was to improve donor safety. Although there was consultation and representation by transplantation practitioners on the committee—incidentally, I was on that committee until 2001—the directors of the transplant program, many of whom are here today, were not directly consulted. We did not know about this regulation or law. I was not informed about it until a member of the media approached me.

This regulation, as written, will not improve organ safety over current practice, for the reasons that I will now outline for you. I will confine my comments to the most troublesome exclusionary criterion, the singling out of men who have had sex with men, which I personally believe is totally discriminatory.

First, our knowledge of HIV has expanded exponentially since its emergence in the early 1980s. I was actually a medical student and saw one of the first cases of HIV. Although the prevalence of HIV is highest amongst men practising homosexual sex, recent data from this committee, from Health Canada, published in 2006, show that the epidemiology has changed. Worldwide, 50% of new cases are heterosexual in origin.

In Canada, women aged 15 to 24 account for 40% of new cases. Most of these are young women who are immigrants from high endemic areas.

● (1225)

Second, today the new testing modalities for HIV, including third-generation serology, which measures antibody responses, RNA and DNA PCR, provide transplant practitioners with enhanced tools to screen potential donors and organs. Properly used, they make the transmission of HIV exceedingly unlikely. Consistent with this is the safety of our present transplantation system in Canada. This is largely because we've adopted most of these modalities. If Health Canada wishes to reduce the window in which individuals with negative serology, meaning antibody, might be infectious, I advise this body to make DNA and RNA PCR testing mandatory. Don't wait until we have another case. My understanding from talking to HIV experts in Toronto, Montreal, and Vancouver is that if this were undertaken, the risk of transmission, even without a donor history, would be one in a million.

Third, the new regulation will be difficult to enforce with confidence, as it will be nearly impossible to get the information that you are asking us for. In my experience, family members and contacts don't know the information you want from them. It's offensive to them. Why would anybody even volunteer such information? Why would anyone presume to offer information about whether a male has had sex during the past five years? Who knows what anyone has done in the last five years?

Fourth, this regulation has the potential to reduce organ donation. In fact, I believe that since this controversy became public, organ donation has decreased coast to coast. Because of this, last week in our centre three young people died because they did not get access to organs.

Fifth, the legislation as currently worded is exclusionary. I know what the word “exclusionary” means. It excludes gay men from being organ donors. They can become donors only if a transplant doctor executes an exceptional release clause. This regulation targets a specific group in society on the basis of its sexual orientation.

Instead of targeting individuals or groups, we should target high-risk behaviours. There are several reasons for this. Targeting groups brings moral and political dimensions into a law that should be based strictly on medical science and the best possible health care results for Canadian society. Instead of singling out a group, possibly erroneously, the regulation should focus on behaviour as the only thing we use to make a medical judgment. The risk in this case is sex with an HIV-positive partner. It doesn't matter whether it's a homosexual or a heterosexual experience.

As a specialist who has committed himself to the field of transplantation for over 30 years, I believe this controversy has had a negative effect on organ donation. Because of the coverage the issue has received and the misunderstandings that have developed, it is more than likely decreasing people's willingness to donate organs. I know the donation rate in Ontario has declined since December 2007, and I spoke about this to our procurement agency experts yesterday.

I strongly encourage the committee to reconsider this regulation and amend it for its stated purpose, namely, to improve organ safety in line with our current scientific understanding of HIV, HPV, and HCV. What do I want you to do?

One, amend the regulation consistent with the scientific facts.

Two, establish a strong national organ transplantation agency. I have been in contact with Dr. Graham Sher and I know that this is his intent.

Three, consult broadly with experts before instituting changes to legislation.

Thank you for the opportunity to present here today.

The Vice-Chair (Mr. Lui Temelkovski): Thank you, Dr. Levy.

We'll continue with the Canadian Society of Transplantation, Dr. James Shapiro, president.

Dr. James Shapiro (President, Canadian Society of Transplantation): Thank you, Mr. Vice-Chairman, ladies and gentlemen.

I am a transplant surgeon from the University of Alberta. I am the immediate past-president of the Canadian Society of Transplantation. I am joined today by Drs. Lori West, Tom Blydt-Hansen, Lee-Ann Tibbles, and Marcelo Cantarovitch, all of whom are executive members of council of the Canadian Society of Transplantation.

What is our society? It represents our membership of 560 key leaders, physicians, surgeons, nurses, and managers in all provinces and all programs across our country. We are the voice of transplantation in Canada.

The gay donor exclusion is a very important issue. It marginalizes Canadians and it's not acceptable. Monogamous relationships are not associated with increased risk. In practice, organs are utilized, and the laws do permit their transplantation under this exceptional release waiver, which must be signed by the recipient before transplantation. The newly introduced CSA standards have become so stringent, at least in Alberta, that the majority of organ transplants must now proceed under the exceptional release in our site. On occasion this may lead to compromise or potential compromise in donor anonymity.

This issue speaks to a much more fundamental issue, the fact that we lack a national infrastructure for transplantation in Canada. The provincial health care delivery has failed to provide adequate national coordination and accountability for the delivery of transplantation. Organ donation has fallen through the provincial cracks, and as a result, Canada is underperforming. We need a national structure that must be accountable to our Canadian public and to government.

Canada is one of the only remaining western countries not to have a national strategy for organ donation and transplantation. The International Transplantation Society and the World Health Organization have called us to task and have emphasized that in order to diminish trends in transplant tourism, every country must ensure an adequate supply of donor organs for its citizens.

There are 4,167 Canadians currently awaiting an organ transplant, a figure that has remained nearly constant since 2000—and this is an underestimate. However, there were only 492 deceased donors in Canada in 2007. That's a donor rate per capita of 14.7 per million population. Canada's deceased donor rate is half that of countries such as Spain, which has a rate of around 32 per million.

The deceased donor rates in certain provinces are not acceptable. For example, in British Columbia it was 5.9 per million, and in Manitoba 5.1 per million, compared to the average of 14.7 per million. That was in 2005. This falls far short of our national average.

Canada does 40% fewer deceased kidney transplants than the U.S. per capita. We were the same 20 years ago. Canada's current rate of deceased donor kidney transplantation is the same as that of Croatia. This costs lives: 146 Canadians died in 2007 while waiting for an organ. The true cost of loss of life cannot easily be measured.

Transplants save lives. Transplants save costs for health care. The cost of dialysis and other organ-supportive care is enormous. Each kidney transplant results in $100,000 in net savings. We should have done over 500 more kidney transplants last year, which would have saved our health care systems $50 million per year.

The Canadian Blood Services—and you heard from Graham Sher this morning—will take on the initial task of developing a national framework. The Canadian Society of Transplantation has engaged with this process with the Canadian Blood Services and strongly embraces this initiative. The CBS has secured federal and provincial support for the next five years. The Canadian Society of Transplantation enthusiastically applauds Canada's federal government's vision in participating in this process. This is an important start, but it may not be sufficient.

So on behalf of the Canadian public, the transplant community, the Canadian Blood Services, and the Canadian Society of Transplantation, we believe this Standing Committee on Health must commission a task force to work with the CBS. This task force should formulate a report defining Canada's deficiencies in donation and transplantation and offer potential solutions.

The task force should turn to the U.K., for example, where the Department of Health has recently completed its report by the Organ Donation Taskforce. It should turn to the U.S., with its United Network for Organ Sharing, UNOS, and the National Organ Transplant Act, NOTA, and to other countries, such as Spain, that are head of the pack.

We owe it to our Canadian public and to our governments to restore our performance rates in transplantations. The solutions lie in ABCDE: we must “advocate” for our patients, “benchmark” with other countries and between provinces, “collect” reliable data, “distribute” organs as necessary, and “engage” with other international agencies.

● (1230)

Thank you for allowing us to be here today.

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much.

Is there anyone else from your group who is speaking? No? Okay.

We'll move on to the Canadian Association of Transplantation with Ms. Raylene Matlock.

Ms. Raylene Matlock (President, Canadian Association of Transplantation): Good afternoon, everyone. Thank you for inviting us to speak. My colleague Jan Emerton, president-elect of the Canadian Association of Transplantation, is here with me.

Thank you for asking us to speak in request to the exclusionary criteria of the Canadian general standards that are appended to the Health Canada regulations on the safety of cells, tissues, and organs. The Canadian Association of Transplantation, or CAT, as we're known, has represented health care professions in the donation and transplant field for 21 years. Over the years CAT members have participated on steering committees and subsequent advisory committees for the development of these standards.

The purpose of these regulations is to minimize the potential health risk to recipients of cells, tissues, and organs. The most important component of the organ donation process is that of the donor assessment. This provides the information required for decisions regarding acceptance or exclusion of organs for the purpose of transplant.

The following presentation will outline two of the main aspects of the assessment, which include organ function and risk assessment, both of which are required in order for a transplant physician to arrive at an acceptance or exclusion decision.

The organ function component involves a review of past and current laboratory investigations to determine organ-specific function as well as additional direct and indirect testing, which may include x-ray studies, electrocardiograms, echocardiograms, bronchoscopies, cardiac catheterizations, and diagnostic imaging procedures.

The potential donor's past medical history is also reviewed to identify if specific diseases exist that may directly or indirectly impair the organ function. Examples of this would include hypertension, high cholesterol, diabetes, chronic pulmonary lung diseases, or cancer.

The risk assessment utilizes two primary tools to identify any potential for disease transmission. First, serological or blood testing is conducted to determine the presence of infectious disease such as hepatitis B, hepatitis C, human T cell lymphotropic virus types I or II, Epstein Barr virus, cytomegalovirus, or human immunodeficiency virus—HIV—the virus that causes AIDS.

In addition to serological testing, a medical-social history interview is also conducted to identify risk factors. A number of questions are asked, ranging from past hospital visits to recent travel and social behaviours. For example, recent travel to warm climates may indicate a higher risk for West Nile virus. Some social activities have been identified to statistically increase the risk potential for hepatitis B and C and HIV, initially identified by the Centres for Disease Control in a 1994 document.

These activities have become standard screening tools for the American Association of Tissue Banks, the Eye Bank Association of America, and most recently, the Canadian Standards Association in 2003. However, we have been using a screening process since 1996.

The medical-social history is conducted only by trained coordinators in a private setting. The history is reviewed with the potential donor's next of kin, significant life partner, or other appropriate individuals, utilizing a standardized history questionnaire. A medical and social history interview is conducted with sensitivity, discretion, and respect. The purpose of the interview is explained with a brief description of the types of questions that will be asked of these folks. This process allows the presumed historian the opportunity to decide if he or she is the best historian for these types of questions or if another person should be included.

The interview may take place in person or over the phone. The interviewer should indicate that due to the personal nature of the questions, only those individuals who are providing information should be present. The family is welcome to request that others remain in the room. However, it is helpful for the interviewer to request extra individuals leave the room to save the historian potential discomfort.

The interviewer is familiar with the medical-social history questionnaire and always asks questions in a sensitive manner. When given an affirmative answer, the interviewer strives to obtain as much information as possible about the answer. This may include direct quotations from the historian. The interviewer is always aware of non-verbal cues such as looking away, coughing, and fidgeting, which may indicate that a historian is being less than forthcoming, or that another person present has additional information that he is uncomfortable sharing with the group at this time.

● (1235)

In some cases, it may be helpful to ask the historian to recommend another individual who might be able to provide more information to the coordinator. A typical example would be a young adult donor; parents would be providing the medical history, and friends or siblings would be providing the social component to the history.

In addition, the final question for any medical and social history asks the interviewee to consider the donor's behavioural risk factors, and if there is any reason why organ and tissue donation should not proceed. No explanation is necessary from the interviewee. The intent of this question is to allow the next of kin, the significant life partner, or others the opportunity to stop the donation process when they are hesitant to disclose sensitive information regarding the donor.

If the answer is yes and the interviewee does not wish to give more specific information, the donor will be deferred. But again, organs may be used and deemed acceptable by the transplanting physician, when the risk of not receiving an organ is greater than that of disease transmission, through the use of exceptional distribution that includes the informed and verified consent of the recipient.

In summary, I would like to say that the Canadian Association of Transplantation has supported the development of the Health Canada regulations over the past decade. Our primary concern is that of maximizing safety and minimizing risk to the transplant recipients. We feel that the regulations do not discriminate against any individual wishing to donate organs, but instead ensure full assessment of potential donors that better enable transplant physicians to make risk-benefit decisions.

Thank you for allowing CAT to participate in this meeting today.

● (1240)

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much.

We'll move right into the questioning.

Dr. Bennett, you have five minutes. Each party will have one question of five minutes.

Hon. Carolyn Bennett (St. Paul's, Lib.): Yes, and I have to say, Mr. Chair, that it's a bit frustrating. We've had so many witnesses and so many questions that this can't possibly be done this morning.

I'm very grateful, Dr. Levy and Dr. Shapiro, for your suggesting very clear recommendations on what you would like to see from this committee's report from this morning in terms of either a task force or certainly the call to have the regulations consistent with science and the practical, on-the-ground reality.

As much as I have sympathy for Ms. Gillham-Eisen's story of her son, I also think that most of the time, to be a clinician and to have to turn down an organ for what you know is a monogamous gay man, it seems ridiculous that we would actually have to go through.... You know, two of my best friends have been together as long as my husband and I have, for 29 years. They know perfectly well the sexual habits of one another. I just don't understand how we could end up, literally, with tough cases making bad law.

I have no idea where the science has come for most of the annex. What happens if the kids had been vaccinated against hepatitis? What if, in terms of people...know the behaviour of somebody in a prison? It just seems to be so wide, and then you are stuck having to go through all of this exception stuff to be able to turn down an organ. So I am a bit lost here.

I have been a minister where, when the department said they had consulted, I would spend my next two weeks finding out that the people who should have been consulted hadn't been consulted.

So I am not happy with this. I think it's almost impossible to do this today.

I would love recommendations, from any of you, on where you think we go from here in terms of putting the evidence back in instead of ideology, and in terms of real risk. The fact is that we are grown-ups. If my son needed an organ, I hope it would be done through consultations by Dr. Levy and Dr. Shapiro, not some list of things designed in some committee somewhere. So I expect that you would let us decide together whether or not we see this as an acceptable risk for the organ that's forthcoming.

Please let me know what you think we should do next.

Dr. Lori West (Past President, Canadian Society of Transplantation): Could I just say that although the consultation process may have been broad, the Canadian Society of Transplantation was not consulted in this process as an organization—

Hon. Carolyn Bennett: I have a list about as long as my arm of people who say they weren't consulted.

Dr. Lori West: Individuals who are members of CST may have been consulted, but the organization was not. And I thank you for listening to our voice.

Hon. Carolyn Bennett: I want to know if I have to put on my organ card when I last had sex. I mean, this is just nuts. This is craziness.

Dr. Lori West: This clearly will discourage organ donation, and we cannot afford it. I take care of children who have 100% risk of dying without a transplant. There is no alternative therapy for these children, and if we diminish our already not wonderful performance in organ donation, we will continue to not—

● (1245)

Hon. Carolyn Bennett: One of my constituents suggested that there should be a tick-off on your income tax that says you'd be prepared to be an organ donor, and we should give a little tiny tax credit for it. What do you think of that?

Dr. Lori West: It sounds like a great idea.

Dr. James Shapiro: Can I make a comment?

Dr. Gary Levy: I would just comment that, first of all, I've had discussions with the Minister of Health, and I believe the intent was to improve safety. I don't believe anyone in this room did this to try to discriminate or to reduce organ donation. I just don't buy that.

My argument is that this will not take us where we want to go. The public has misinterpreted, or interpreted, this in the way they wish to. I don't think anyone in this room wants to be part of an exclusionary group. I just don't believe anyone feels that in order for them to move forward...that they are excluded, but we have the option of moving them into what we call the "good camp".

I agree with you that it has to be based on science. I've consulted widely with the HIV expert community, coast to coast. I think that as a law, as Dr. West pointed out, and even the previous experts, it was drafted in 1994. HIV has changed since 1994. It is not the same disease.

What we don't want, I think, number one, is roadblocks put up that will limit our ability to help the most unfortunate of our society.

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much, Dr. Levy.

Now we'll move on to Ms. Davidson.

Mrs. Patricia Davidson (Sarnia—Lambton, CPC): Thank you, Mr. Chairman. I have just a couple of questions.

I think everybody has been very clear in this panel and in the previous panel that patient safety is, first and foremost, the issue that we're all supporting, and also that we're trying to stop the transmission of disease and that we don't want to see that happen through a transplant process.

I think everybody has also talked about the science of the decision and that the decision needs to be based on good science. I want to come back to that a little bit, because I think, Dr. Levy, you cited some HIV statistics that were quite a bit different from what Ms. Gillham-Eisen talked about.

So I'd like to ask her if she could comment on this, please.

Ms. Liz Anne Gillham-Eisen: The statistics that we have come from our Public Health Agency of Canada. They bring them together and they report on them every six months. The information that we have, based on the Public Health Agency of Canada's surveillance reports, basically is quite different from Dr. Levy's. So I'm not quite sure where his statistics have come from, but again, we depend on our Public Health Agency for their statistics.

Up to June 2007, within the group identified as being MSM, it's actually 42.6% of the cases. The other highest incidence is intravenous drug users, at 22.8% of the cases. Heterosexuals who don't have sex with either sex trade workers or somebody who is known to be infected or is an IV drug user don't quite register on PHAC's particular statistics.

Again, they report to us under a basic criterion of men who have had sex with men, so it's not broken down. That's another reason we have to move forward. It's not broken down into men who have had sex with men but it's been protected sex. That's not information that we have available. The science is where it's at.

Mrs. Patricia Davidson: Okay. I think Dr. Levy had indicated that everybody was in favour of moving forward and trying to make things better, but still maintaining the donor base that we so desperately need in this country. So if we don't go the exclusionary route, which we're hearing this morning has created difficulties and perhaps misunderstandings with the public, what do we do?

Dr. Gary Levy: First of all, before this regulation came into rule, we had a guideline that we used, and the community accepted the guideline. Incidentally, what has been brought into law or regulation, some people have argued, is not that different from what we have.

So what is the difference between a guideline and a regulation? A guideline is a notice to us. That's what the United States has. We are notified about a high-risk behaviour—very much like what we heard about this morning. We get the results of the serological tests, as we pointed out, for HBV, HCV, hepatitis B, hepatitis C, and so forth.

And you should be aware that we're not working in opposition here; we're also here to provide a safe system—and it is a safe system. So what we've done is use words like “exclusion” in a law, a word that was not used before. We've used very harsh language. I would argue, first of all, that we need to talk about high-risk behaviour. After all, when you've talked about MSM, that's a behaviour, perhaps. I would not get into defining a group, or whatever the case may be. I think we can leave people to decide. I don't think people necessarily want to be defined as groups.

The other thing you should know, in regard to the reference made to the case in Chicago—which is in the courts, and which I've been consulted about but am not allowed to give the details of—is that there was a lack of transmission of the data. That's what happened. There was a failure of the system. Nothing that we would have done would have protected.... This law will not prevent that; it was a breakdown in the system.

You asked what we wanted, Ms. Bennett. One, I think we need to amend this to reflect what we're trying to accomplish, and I would encourage you to mandate that we use the best test possible.

In regard to HCV, incidentally, which Mr. Fletcher alluded to, Canada did not embark on the high road. You didn't use the surrogate test. And I'm not talking about this government, so I apologize if you're assuming I'm a political animal; I am not. I'm an apolitical animal. I'm an advocate for patients. But the reality is that the Canadian government at the time did not take the best advice from the doctors. You should have used the surrogate tests. The United States did, and they didn't suffer the same costs.

● (1250)

The Vice-Chair (Mr. Lui Temelkovski): Thanks very much.

We'll move on to Monsieur Ménard.

[*Translation*]

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

This is a clearly discriminatory regulation and it will certainly not withstand a charter challenge. At the same time, no one wants to compromise the supply of organs for donation and cause a scandal such as we had with tainted blood.

I would really have like to have Mr. Germain back at the table so that he could react to Mr. Levy's comments. I would like you to explain how third-generation HIV screening tests would allow us to maintain the safety criteria to which we all subscribe. It is too easy to say, as others, other witnesses have stated before you that it is “the” scientific community, as if it existed with a capital S and C, and everyone had the same opinion.

Between the time when Brian Mulroney's Conservatives tabled their first strategy in the fight against AIDS and the time when minister Pettigrew renewed it, the face of AIDS had changed. The two sets of statistics presented by Ms. Gillham-Eisen and by Mr. Levy are in agreement. People becoming infected in Canada are not, for the most part, men having sex with other men. That has not been the case for at least three years. So the statistics and the data that were presented to us by the witnesses before you cannot be entirely defended.

Tell us how these third-generation tests, particularly the PCR RNA test, would provide us with the quality standards you are upholding, and explain the difference between an organ donation when the person is alive and consents to it and a organ donation when a person is deceased. Explain to us how things would work in those two cases.

Mr. Chair, I would really like to have Mr. Germain's opinion. Can we get him back to the table?

● (1255)

[*English*]

Dr. Gary Levy: Do you want me to start?

Mr. Réal Ménard: You and Dr. Germain.

Dr. Gary Levy: Okay, I'm happy to start. I know you have a time limit and I'm not going to give you a science lecture today.

The reality is that we can measure your immune response to the virus, which is an antibody, and we can do it with what we call an ELISA, and Dr. Germain alluded to that, but there are now new generations of ELISA, called Luminex or luminescence ELISAs, which have a higher degree of sensitivity. In other words, if I look on the floor there may be a tack there. I can't see it. If I have a microscope I'll find it. It's that kind of phenomenon.

The luminescence assays for serology will reduce the window from the time the person is exposed until they mount a response from 21 days back to 14, but that's not good enough. Now we know that when the person becomes infected there is an infectious virus and we can amplify that. We can use a technique whereby we can take blood out of the patient and we can do it in a four-hour period, in a timely period where it could become practical. It costs, so you'd have to talk to Dr. Sher about instituting this. He's your representative. We could do either the DNA, which means the part of the genome of the virus, or we could do the RNA, which is also part of the genome, and using those techniques we would eliminate almost to zero. Dr. Wainberg in Montreal and other people have said you wouldn't need a history anymore; you would just be able to detect the genome.

[*Translation*]

Mr. Réal Ménard: Just to finish, is it possible to have Dr. Germain come to the table to give us his opinion specifically on that? Would he mind reacting very briefly to his colleague Mr. Levy's remarks?

Mr. Germain, would you mind? I do not want to make you uncomfortable.

[*English*]

The Vice-Chair (Mr. Lui Temelkovski): We're going to wrap up anyway.

Dr. Marc Germain: How much time are you giving me, and should I answer in French or in English? I will speak English for the benefit of the discussion between Dr. Levy and me.

Ms. Judy Wasylycia-Leis: On a point of order, Mr. Chairperson, as long as this doesn't take away from my ability to ask some questions. We'll go a bit over time?

The Vice-Chair (Mr. Lui Temelkovski): We'll take that under advisement. Thank you.

Ms. Judy Wasylycia-Leis: Each round is a separate round.

Dr. Marc Germain: Very briefly, the tests that are used to screen donors for the presence of infectious diseases have improved consistently over the years. We started out with tests that unfortunately would miss some infections because they were recent infections, so-called window period infections; the newer tests are better at identifying those types of recent infections. Also, the overall sensitivity of the screening tests that are used to screen blood donors, for instance, and also tissue donors are getting better and better.

We also added recently, in the realm of blood and tissue donation, the nucleic acid test, or PCR, as you referred to it. Those tests will shorten the duration of the window period and therefore decrease the risk.

I strongly disagree with the notion that we can get away from the assessment of high-risk behaviours. We apply those screening tests, which perform extremely well in the area of blood donation, and we still undergo a risk assessment of our blood donors because there are very well documented instances even today...not in Canada, fortunately, but it has been shown in the U.S. that even with the best technology available it can still happen that the blood of a donor will be taken during a period where the test does not perform as expected because it's too early in the infection or what have you.

Tests will never be perfect. They're not perfect now. They never will be. You always need to take into account the risk behaviour.

The Vice-Chair (Mr. Lui Temelkovski): Thank you very much.

I'd like to thank the panel—

Ms. Judy Wasylycia-Leis: Mr. Chairperson, could we go an extra five minutes?

The Vice-Chair (Mr. Lui Temelkovski): That extra five minutes, Madam Wasylycia-Leis, would give the Conservatives a question.

● (1300)

Ms. Judy Wasylycia-Leis: This is a new round.

The Vice-Chair (Mr. Lui Temelkovski): There is no time. There is another meeting coming in at one o'clock.

Ms. Judy Wasylycia-Leis: You've give the Conservatives the next round. We're on a new round of dialogue. It's a new panel.

The Vice-Chair (Mr. Lui Temelkovski): The meeting is adjourned.

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