House of Commons
CANADA

Standing Committee on Health

HESA • NUMBER 035 • 3rd SESSION • 40th PARLIAMENT

EVIDENCE

Tuesday, November 2, 2010

Chair

Mrs. Joy Smith

Standing Committee on Health

Tuesday, November 2, 2010

● (1105)

[*English*]

The Chair (Mrs. Joy Smith (Kildonan—St. Paul, CPC)): Good morning, ladies and gentlemen. Welcome to the Standing Committee on Health. Pursuant to Standing Order 108(2), the topic today is the study of stem cell donation in Canada.

I'm very pleased today that we are going to be listening to our witnesses talk about stem cell donation in Canada.

We have witnesses from the Canadian Stem Cell Foundation. I want to welcome you. I'm Joy Smith, the chair of this standing committee, and I welcome you to our committee. I think I've met a couple of you recently.

We have Dr. Drew Lyall, chair, board of directors of the Canadian Stem Cell Foundation. Welcome, Dr. Lyall. I'm glad you're here.

From the Hospital for Sick Children, we have Dr. Janet Rossant, chief of research. Welcome.

From the Stem Cell Network, we have Dr. Michael Rudnicki, scientific director. Welcome, too.

Joining us by video conference, from Winnipeg, Manitoba, we have some guests. I'm very happy they've been able to take the time to join us today. First of all, I'd like you to meet Dr. Dhaliwal, president and chief executive officer and the provincial clinical director of oncology.

Welcome, Dr. Dhaliwal. It's nice to see you this morning.

Dr. Dhali Dhaliwal (President and Chief Executive Officer, Provincial Clinical Director of Oncology, CancerCare Manitoba): Good morning.

The Chair: Can you hear me well?

Dr. Dhali Dhaliwal: Yes, thank you.

The Chair: Secondly, we have Dr. Geoff Hicks, director of regenerative medicine, University of Manitoba, senior scientist, Manitoba Institute of Cell Biology.

Welcome, Dr. Hicks.

Dr. Geoff Hicks (Director of Regenerative Medicine, University of Manitoba, Senior Scientist, Manitoba Institute of Cell Biology, CancerCare Manitoba): Thank you. Good morning.

The Chair: We have Dr. Donna Wall, physician, pediatric hematology and oncology. Welcome, Dr. Wall. It's nice to see you.

We also have Dr. Spencer Gibson, provincial director of research. We're very happy you're going to be here as well.

Today we have presentations, 10 minutes each, from each of our organizations.

Dr. Dhaliwal, when we go to the video conferencing, will you be the lead with the group of people there?

Dr. Dhali Dhaliwal: Yes.

The Chair: That's fine, then.

How it proceeds is that we will begin with 10-minute presentations from each of our guests. Following that, we go into two rounds of questioning.

As you know, the health committee is made up of all parties across our great nation, and each one of those parties has questions they want to ask.

Are you set to go?

We'll start first with Dr. Michael Rudnicki, from the Stem Cell Network.

Dr. Rudnicki.

Dr. Michael Rudnicki (Scientific Director, Stem Cell Network): Good morning. Thank you very much for your invitation to testify today.

I'm speaking to you as a Canada research chair, a senior scientist and director of the regenerative medicine program at the Ottawa Hospital, and also as scientific director of the Canadian Stem Cell Network. The Stem Cell Network is funded through the national centres of excellence.

First of all, why is stem cell research important? Stem cell research, first, is an area of true strategic strength scientifically in Canada; and secondly, stem cell research is paving the road for regenerative medicine to enter the clinic. Regenerative medicine is going to transform medical practice by alleviating, or possibly curing, many of the devastating diseases that plague mankind, including cancer, type 1 diabetes, Parkinson's, Alzheimer's, heart disease, strokes, spinal cord injury, and so on. Regenerative medicine will not only transform clinical practice, but it will change the paradigm of health care and the pharmaceutical industry in a very profound way.

These are truly exciting times in stem cell research. It's been over seven years since I last presented to this committee, and in that time a lot has happened.

In the next few minutes I'm going to touch on three different areas where advances have occurred: a new source of stem cells, new ways in which stem cells are being applied in the lab, and some recent examples of clinical trials.

You'll remember that the last time stem cells were debated in the House—not just here but around the world—much attention was paid to the relative merits of adult versus embryonic stem cells. Embryonic stem cells are derived from four-day-old to five-day-old embryos. These embryos have been created for the purpose of in vitro fertilization and they would otherwise be discarded.

The Chair: Dr. Rudnicki, may I interrupt you for a minute? You're speaking a little too fast for our interpreters. All conversation is being translated in both languages, so perhaps you could slow down a little bit. Thank you so much.

Dr. Michael Rudnicki: I'll slow it down. I'm sorry. It's too much coffee this morning.

Embryonic stem cells are derived from four-day-old to five-day-old embryos. These embryos were created for the purposes of in vitro fertilization and would otherwise have been discarded. These embryonic stem cells have the capacity to generate all possible cell types in the body. Adult stem cells, on the other hand, are more specialized. They reside within tissues and they give rise to a limited spectrum of cell types that are present in that tissue. For example, hematopoietic stem cells only give rise to different types of blood cells. Adult stem cells are found in all of us, in all of our tissues. They are also present in cord blood, amniotic fluid, and possibly the placenta.

The debate around embryonic stem cells has been overtaken by scientific progress. The most significant advance in the stem cell field in the past decade has been the seminal discovery by Shinya Yamanaka, of Kyoto, Japan in 2006, of induced pluripotent stem cells, so-called iPSC. What Yamanaka showed was that you could take any cell in your body—a skin cell from the tip of my nose, for example—and by applying a very simple procedure, introducing four genes into it, reprogram that cell to make it closely resemble in a way that the cell is essentially indistinguishable from an embryonic stem cell. So you can derive an embryonic stem-cell-like cell from any adult cell type. This is a paradigm-shifting discovery, a very, very important advance.

While this has not completely obviated the need to work with embryonic stem cells—we still need to compare and contrast iPSC cells with embryonic stem cells, and research needs to be conducted with human embryonic stem cells—this discovery has really transformed the field.

Seven years ago most of us were thinking about stem cells being used to regenerate replacement cells for transplant purposes for diseased organs, to treat degenerative diseases, and so on. That work still goes on. For example, here at the Ottawa Hospital my colleague Duncan Stewart is undertaking a trial to treat patients with pulmonary hypertension—this is a fatal disease that affects primarily women in their thirties, and it's a lethal disease—where stem cells are derived from the blood, are temporarily modified to contain a gene that stimulates blood vessel growth, and those cells are reintroduced into the circulation.

Another colleague, Harry Atkins, at the Ottawa Hospital has been using bone marrow transplant protocol for the treatment of severe cases of multiple sclerosis. Essentially, what he's doing is curing the autoimmune disease in those patients. It's really quite a phenomenal advance.

In a recent clinical trials workshop held by the Stem Cell Network, we identified over 50 Canadian-based trials involving stem cell therapies, and these will be entering the clinic in the next three to four years. So the field is advancing tremendously fast, much faster than all of us had anticipated.

Advances are being made at a similar pace outside of Canada. As committee members, I'm sure you've read about Geron, a U.S. company that has just initiated a clinical trial whereby spinal cord patients are receiving cells that have been differentiated from human embryonic stem cells, so-called oligodendrocytes, that will be used to treat spinal cord injury. That's just been started and is the first clinical trial using embryonic stem cell-derived material anywhere in the world.

Returning to iPSC cells, Yamanaka's discovery has opened the doors to the rapid and efficient creation of disease-specific stem cells and patient-specific stem cells. This has opened up whole new lines of inquiry and has allowed researchers, for example, to screen these cells against drug libraries. A library of drugs can be thousands and thousands—perhaps even up to one million or so—of compounds that represent all possible classes of chemicals. They can also be a library of drugs that's already in the clinic so they can rapidly move into clinical trials.

I'll give you a couple of examples. My colleague Bill Stanford at the University of Toronto has derived induced pluripotent stem cells from patients with progeria. Progeria is a genetic disease where kids rapidly age. They die at around age 13, resembling 96-year-olds. They die of atherosclerosis; they die of heart attacks and strokes.

He has derived iPSC from those patients and isolated vascular smooth muscle cells—blood vessel cells—from those patients. The remade blood vessel cells start off healthy, but they rapidly age in petri dishes, recapitulating the disease. So he's going to use those cells to screen for drugs that will prevent that aging process. These drugs could be used for the progeria patients, but they could also be used more widely in patients suffering from atherosclerosis.

● (1110)

Another colleague, Lee Rubin at Harvard Medical School, has done a similar procedure with SMA patients. This is a disease where spinal motor neurons die, and kids at a very young age are affected. It's a horrible disease. He screened for drugs that would promote neuron survival. These neurons were differentiated from the iPS cells. He identified drugs, and at least in mice he can treat SMA at this point. So it's a very exciting way to personalize drug screening approaches to identify new drugs that can be used rapidly in the clinic.

Other cell types can also be screened in the same way. Another Stem Cell Network member, David Kaplan at SickKids Research Institute in Toronto, has isolated cancer stem cells from neuroblastoma tumours in kids and screened for drugs. He identified some drugs that killed the tumour-initiating cells, the cancer stem cells. Within two years this has found its way into a compassionate clinical trial at SickKids, and is now in a multi-site trial across Canada and the U.S. It's phenomenal progress. Using the same approach, they're now attacking three other tumour types that cause cancer. It is really quite phenomenal.

Using stem cells to generate replacement cells and identify drug targets are just a couple of ways in which stem cells are transforming medical research. Some groups are using stem cells to better understand the diseases of early development. Other groups are using them to generate large quantities of human cardiac and neural cells to use to test drugs for toxicity before they are ever given to a patient, making clinical trials safer. Many groups are working to derive liver cells for the same purpose.

In short, the field remains exciting and is progressing very rapidly. It's not without challenges. This work is very important. What we're talking about is making changes to clinical practice that are going to help people. It will save lives and alleviate suffering.

At this point I will ask my colleague Drew Lyall to continue.

● (1115)

The Chair: Thank you, Dr. Rudnicki.

Now we will go to Dr. Lyall. He's the chair of the Canadian Stem Cell Foundation.

Mr. Drew Lyall (Chair, Board of Directors, Canadian Stem Cell Foundation): Thank you.

For full disclosure, I should also let you know that I'm executive director of the Stem Cell Network. We all wear many hats but hopefully speak with one voice.

I'd like to thank the chair and the committee for inviting the Stem Cell Foundation to present this morning. We're a relatively young organization, and we're delighted to have the opportunity to contribute to these proceedings.

As you heard this morning, stem cell research is beginning to reach the clinic. Even if you exclude bone marrow transplants, which have been around for 40 years and still account, together with umbilical cord work, for more than 95% of all the clinical trials going on around the world, over 350,000 patients have now been treated with approved stem cell products across the globe, for diseases ranging from chronic wound healing to cartilage repair. While treatments for such diseases as Alzheimer's may still be ten, twenty, or thirty years away, treatments for stroke, multiple sclerosis, pulmonary hypertension, heart disease, Crohn's, neuroblastoma, and others are already entering the clinic.

The impact of this really will be profound, in several ways. First and foremost will be the improvement in the quality of life for both patients in Canada and around the world and the families and communities around them.

Second, delivering cures for these chronic degenerative diseases can have a really significant impact on the health care burden in Canada, not just through alleviating the direct costs of treatment but also through returning the patients and the families, to whom their care often falls, to productive lives.

Finally, the development of these new drugs and therapies will actually present a really great opportunity to create new high-level jobs in Canada in the growing regenerative medicine industry.

This is an opportunity that Canada should be capitalizing on, but it's also one that we should be taking great pride in. Stem cells are actually Canada's gift, if you like, to the world. Stem cells were discovered here in Canada. Next year marks the 50th anniversary of when Jim Till and Ernest McCulloch made the discovery at the Princess Margaret Hospital in Toronto.

Over the last 50 years, Canadian scientists have continued to make landmark discoveries in this field. In fact, Canada scientifically is probably as strong as any country in the world. But that leadership and the long-term opportunities that flow from it are somewhat at risk.

Other jurisdictions around the world are recognizing the same opportunity and are investing heavily in the field. The clear benchmark for this is California. What California did three or four years ago was to invest $3 billion to create the California Institute for Regenerative Medicine. That's an investment of $300 million a year over ten years. It represents about ten times the current federal investment in stem cell research, and close to one-third of the entire annual budget of CIHR. Those funds are being used to support the full spectrum of activities needed to move therapies from fundamental research to research and manufacturing facilities, to funding for phase I and II trials, and even to providing non-dilutive capital to start-up companies through loans. In a sense, it's simply not realistic to expect Canada, or indeed anybody else, to keep up and to remain globally competitive in the long term without some further dedicated investment in the field.

Even within the current context of our funding, there are still some challenges. Let me give you a couple of examples.

The utility of cord blood as a treatment for many types of cancers has been well established. In many centres in the United States, cord blood is now used more often than bone marrow transplants in these types of procedures. Here in Canada, the business case for a public cord blood bank has been well made. Not every umbilical cord needs to be banked. Cords from a small but statistically significant subset of the population would provide sufficient genetic variation to cover almost all of the needs.

We understand that discussions have been taking place between the provinces and territories to see if Canadian Blood Services and Héma-Québec could establish a public cord blood bank. In fact, there was a consensus statement around the need to do so in June 2007. But here we are at the end of 2010, there is still no visible progress, and patient needs remain unmet.

Let me give you another example. Just over $80 million of federal, provincial, and philanthropic funding is being invested right now in building three GMP-compliant cell-manufacturing facilities in Toronto, Montreal, and Edmonton. Collectively, these world-class facilities should have enough capacity to accommodate Canada's cell manufacturing needs for the next decade. The clinicians behind those facilities are already working with each other to determine how best to manage these effectively as a virtual national organization. How can we triage requests to the right city? How can we set up standard operating procedures? How can we develop common education programs?

The challenge is that as funding priorities have shifted across federal and provincial governments, it has become less and less clear where the operating costs for these facilities, or the funds to support the associated clinical trials, will come from.

● (1120)

To give an example, it might be necessary to do half a dozen trial runs of creating some cells in the facility before you actually put them into the patient. But that isn't the kind of research the granting councils typically fund; and because it's a clinical trial rather than an approved health care procedure, it's not eligible for provincial health care funding either. So we run the risk of these clinical trials falling into a black hole where no real opportunity for funding exists. The 50 trials mentioned by Dr. Rudnicki earlier in his presentation may never happen in the absence of that funding.

Finally, there are opportunities to improve both the regulation of the research environment and the regulation of therapies, if they move from the lab to the clinic. My colleague Dr. Rossant is going to talk to some of those challenges.

I'd like to wrap up with a plea. Stem cell research is an area in which Canada has pioneered and led the world. We have the talent, the will, and the expertise to continue to do so. I know this committee understands the significant benefits that stem cell research can bring to our health care system. Let's not squander the legacy of Till and McCulloch but make sure that Canadians patients are the first to benefit from their discovery.

The Chair: Thank you, Dr. Lyle.

We'll now go on to Dr. Janet Rossant.

Dr. Janet Rossant (Chief of Research, Hospital for Sick Children): Good morning, and thank you for the opportunity to speak.

I'm an active stem cell scientist and I'm also chief of research at the Hospital for Sick Children, which is one the largest child health research institutes in the world. I am also deputy scientific director of the Stem Cell Network.

My colleagues have spoken about recent progress in stem cell research and its application to the clinic in Canada and worldwide. These really are exciting times for stem cell research. In particular, these new approaches to reprogramming cells from adult tissues into stem cells that regain the potential to make all the cell types of our body—so-called induced pluripotent stem cells, or iPS cells—really have transformed the way we think about studying human disease in a petri dish.

Already the Ontario iPS facility located at SickKids, for example, is taking samples of tissues from patients with developmental disorders such as congenital heart disease, neuro-developmental problems such as Rett syndrome and autism, and lung disorders like cystic fibrosis, and developing banks of patient-specific stem cells, these iPS cells. Then we can take these cells, distribute them to scientists, coax those cells to form the appropriate cell types in the petri dish—heart muscle cells, nerve cells, and lung cells, for those particular diseases—and then study those cells to determine what goes wrong in the disease and then how to fix it with new therapies.

In the future, however, this whole concept of being able to take adult cells and make stem cells, pluripotent cells that make every cell type, gives us the opportunity to think about population-based banks of normal iPS cells that could serve as sources of cells for cell therapy for many different diseases. We're not there yet. The technologies for generating iPS cells and for differentiating them into the right cell types for therapy, such as bone marrow stem cells, nerve cells, etc., are just not efficient enough yet to make such banking worthwhile. But the rapid progress of science here tells us that this will come in the future. And we need to stay on top of the science to be ahead of the opportunities to translate new advances into broadly available stem cell therapies for Canadians.

Science is moving extremely fast in this area, and this, of course, has ongoing implications for the regulatory environment for stem cell research. In Canada, human stem cell research, embryonic stem cell research, and iPS cell research are all governed by three separate regulatory instruments. There's the Assisted Human Reproduction Act, AHRA , the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, the TCPS—we all like these acronyms—and the Canadian Institutes of Health Research's *Updated Guidelines for Human Pluripotent Stem Cell Research*. So we have the act, the tri-council statement, and CIHR's guidelines.

Of these, only CIHR's guidelines were really established specifically to address the ethical issues of all human pluripotent stem cell research, including the newly developed technologies we've been talking about that do not involve derivation of stem cells directly from human embryos. The CIHR has a stem cell oversight committee that is mandated to provide ethics review across the country of all human pluripotent stem cell research funding applications in CIHR-funded institutions in Canada. The guidelines cover essentially all of the major pluripotent stem cell initiatives that are taking place in Canada in academic institutions. And although they don't have regulatory application, they would have strong moral suasion on any commercial entities that are dealing in this area, most of which have arisen as offshoots of academic programs.

However, at present, the Canadian policy framework is in a bit of a state of flux. The tri-council policy statement is currently being revised by the Interagency Advisory Panel. As well, the constitutionality of several of the provisions of AHRA, the Assisted Human Reproduction Act, have been challenged before the Supreme Court of Canada, and the decision still outstanding. Furthermore, the AHRA is overdue for its mandated parliamentary review, which has the potential to have real impact on the field because of all these recent advances in stem cell research, which were certainly not contemplated by the crafters of the act. Moreover, given that only one regulation, regarding consent, has actually been adopted pursuant to the AHRA since it came into force in 2004, various aspects of the existing legislation do not have the necessary regulations in place.

So we have a lack of clarity regarding the application of present policy frameworks to new and emerging stem cell technologies, and that creates uncertainty for scientists, regulators, funders, and members of the public alike. It also has the potential to have an unintended impact on the advancement of research, for example, by restricting the parameters of permissible research in Canada.

● (1125)

Responding to these challenges in an informed, balanced, and evidence-based manner is crucial to both the continued success of the field of stem cell research—you've heard how strong that field is in Canada—and of course, on the other side, to the maintenance of public support for and trust in this work.

As an example of some of the issues that are unclear in the regulatory environment, definitional ambiguity—a terrible thing—occurs throughout. It creates a significant area of confusion for the application of these different provisions, particularly in the Assisted Human Reproduction Act.

For example, the legislation provides that human reproductive material, which is the basis of the legislation in the act, means a sperm, an egg, or other human cell, or a human gene, and includes any part of them. That's almost everything. If you actually interpret that norm literally, it could be construed in such a broad manner as to include almost any human cell or tissue, including iPS cells, as human reproductive material. Clearly that doesn't make any sense. A cell that you grow in a petri dish is not human reproductive material and cannot be used in human reproduction.

Given that iPS cells don't require the use of the material that we would normally consider as human reproductive material—that is, early embryos, eggs, or sperm—it seems that iPS cell research, unless it itself is being used to create reproductive material, should not be covered by the AHRA. Bringing iPS cell research under the ambit of that act would introduce more policy and regulatory hurdles, further uncertainty, and then potentially impact the growth and direction of the field in Canada.

The CIHR stem cell oversight committee has already considered these issues and has determined that the generation of iPS cells from tissue samples does not require the approval of SCOC, or stem cell oversight committee, because it does not involve the derivation of material from human embryos. It has to go through normal informed consent, but the use of any pluripotent cells that are derived that way would need SCOC oversight.

Interestingly, as the use of stem cells, pluripotent and otherwise, moves towards the clinic, I think the regulatory environment is actually clearer about their use in the clinic than it is about their research uses. Any cell-based therapy that requires extensive growth of cells outside of the body would fall under Health Canada regulation or the Food and Drug Administration in the United States. The extensive safety and efficacy data that is required before any new therapy can be introduced in clinical trials and eventually to market would be no different for stem cells than any other therapy. No special regulation is required, but the regulatory barrier for the application of stem cell trials, as was seen for the Geron embryonic stem cell trial for spinal cord injury, is appropriately high and should remain high.

The policy development committee of the Canadian Stem Cell Network, of which I am co-chair with Dr. Bartha Knoppers, who has probably appeared before this committee many times, is developing a policy statement on these issues around the advances in stem cell research and the regulatory environment. We propose the following overriding principles for regulation in the area of stem cell research and its application.

First of all, recognize the continued importance for ongoing scientific input into law and policy making in order to foster informed decision-making; encourage respect for scientific freedom while ensuring that any limitations that are placed on the research are justified in a free and democratic society; and promote the use of clear and transparent principles in regulatory frameworks, which should be harmonized across all regulatory instruments, against which new developments in research can be evaluated.

So these are exciting times, there are challenges, and I think the scientists, the regulators, the ethicists, and the clinicians need to work together.

Thank you.

● (1130)

The Chair: Thank you, Dr. Rossant.

We'll now go to our video conference from Winnipeg, Manitoba, from CancerCare Manitoba.

Welcome, Dr. Dhaliwal. Can you begin your presentation, please?

Dr. Dhali Dhaliwal: Thank you.

I want to thank the chair for the invitation to present before this committee.

My group represents CancerCare Manitoba, a provincial cancer agency, and the regenerative medicine program at the University of Manitoba.

As the fourth presenter, forgive me if I repeat some of the comments that have been made, but it will re-emphasize the unity of feeling, and I hope it gives you some idea of the need for across-the-country infrastructure and expertise development.

We are using the definition of stem cells the same way other researchers have used it here, and are not focusing on hematopoietic stem cells.

The University of Manitoba and CancerCare Manitoba, together with local, provincial, and federal partners, have identified stem cells as a strategic research priority. As a result, the university has established a dedicated regenerative medicine program, appointing Dr. Geoff Hicks as the director. Major sources have been mobilized regionally for this effort, but I realize that in the context we're talking about, such as the California investment, this must seem a very small amount. For us it's a substantial effort that includes newly designed laboratory space of nearly 25,000 square feet, six tenure-track faculty positions, two of which are Canada research chairs, and major equipment infrastructure, including flow cytometry and stem cell culture facilities, as well as access to the Faculty of Medicine's transgenic, genomic, proteomic, and bioinformatics platforms.

The vision, as we've heard, is to pursue discoveries in stem cell biology and to facilitate their translation into the clinic. The program is well aligned with major research strengths at our institution in cardiovascular disease, cancer, neurodegenerative disease, and so on.

This infrastructure support occurred, I may emphasize, at a time marked by limited new resources, which reflects the strategic priority our organizations have placed on this. As we have heard, we are at a stage that could radically change the way we treat a wide variety of diseases, including cancer, which we believe, for many of the malignancies we treat, is driven by cancer stem cells. However, all parts of the body depend on some form of self-renewal, and stem cells are at the heart of that process.

As we've heard, we're at the doorstep of rethinking how we manage a wide variety of chronic and major diseases: developmental defects, congenital heart disease, spinal cord injury, and all the other diseases we have heard about.

I'm delighted that we are part of that network, in which Canada is at the forefront, for stem cell research. But as we heard, we need to maintain that impetus by developing capacity across the country. There is a need to support the private sector to move these discoveries into the market and provide the high-tech jobs we've heard about.

● (1135)

But times are changing, and Canadians' expectations of the health care system are changing very rapidly. We've seen elements of that, because families, as they cope with the devastating effects of brain injury from birth insult, and degenerative loss of function from Alzheimer's, multiple sclerosis, and so on, are seeing that all of these are potentially treatable with stem cell therapy, and patients are desperate for new treatments. As a result, more and more Canadians are seeking treatment at foreign medical tourism destinations, or will seek such treatment in the future if we do not step up to the plate and develop that capacity to offer therapies across the country.

We need the infrastructure that we heard about, including regulatory bodies, so that we are in a position to rapidly translate these technologies into the clinical use.

We believe these therapies will create personal, financial, medical, and government crises if we do not proceed with a transparent and comprehensive program and framework to bring these studies into clinical use. That will require the support of basic and translational research across the Canadian health spectrum.

We must be prepared to rapidly bring these technologies through well-designed clinical trials that cover all phases of treatment and development, including not only the early phase trials that test safety and demonstrate efficacy, but also large multi-centre trials that are well designed to address the need for the new treatments and how they improve outcomes and replace standard treatment.

We must be prepared to monitor, in a new way, for unexpected side effects that could occur years later. All along the way there will be observations that need to be taken back to the laboratory for further investigation, and it is critical to have, across Canada, a robust pool of clinical scientists.

There needs to be flexibility in funding to support laboratory studies driven by clinical observations, in a timely manner. In tandem with basic and clinical research, new research initiatives into ethics, cost effectiveness, and the utility of these treatments will be necessary.

We know that clinical trials are expensive and difficult to mount at the level that we are discussing here. So we will have to bolster existing networks, such as the National Cancer Institute clinical trials network, and develop this capacity right across the country so that we can apply what we have heard will be paradigm-changing.

Dr. Rossant talked about the regulatory issues, so I will not address them.

National health care policy planners and provincial health care programs must work with researchers to ensure that financial and infrastructure supports are in place to take these discoveries into routine care. Special laboratories and facilities will be necessary.

Our greatest challenge is really to meet the expectations of Canadians to provide treatments, and even cures, for currently untreatable diseases. I believe building capacity right across the country will be absolutely essential to prevent inequalities in access to these new and exciting and innovative treatments.

● (1140)

Thank you.

The Chair: Thank you, Dr. Dhaliwal.

Do you have a written presentation you could submit to the clerk?

Dr. Dhali Dhaliwal: Yes, absolutely.

The Chair: Thank you. We'll get the clerk to translate it into French and distribute it to our committee members.

Now we'll go into our first seven-minute round of questions and answers. Starting with the Liberal member, there's going to be a sharing of time with Mr. Dosanjh and Dr. Duncan. They will ask questions and within the seven minutes, you will have time to answer them.

Who wants to begin here?

Mr. Dosanjh.

Hon. Ujjal Dosanjh (Vancouver South, Lib.): Thank you.

Thank you to all for speaking to us.

I have a very brief question. I understand the issue is largely a question of resources and a question of money. I'm not a scientist, so I'll focus on the money and the law.

Dr. Lyall, you raised the issue of the cord blood bank. You said there's been a proposal floating around for some time. What stands in the way of that being established, other than money? Money I recognize. Is there anything else that stands in the way?

● (1145)

The Chair: Dr. Lyall.

Mr. Drew Lyall: I don't know if I'm the best-placed person to answer the question—

Hon. Ujjal Dosanjh: Point it to someone else on the panel, then.

Mr. Drew Lyall: By that I mean that maybe Canadian Blood Services, who've been kind of managing that process, would be a better group to talk to.

The Chair: I think Dr. Wall has raised her hand.

Dr. Wall, would you like to comment on that?

Dr. Donna Wall (Physician, Pediatric Hematology and Oncology, CancerCare Manitoba): Sure.

I've had the pleasure of working with Canadian Blood Services on this project, and have been involved with several cord blood banks in the U.S. over the last several years. The proposal has been approved across the provinces and territories, but there was no funding in the past year allocated to it. At issue, I believe, is that the Canadian Blood Services charter works through the provinces, and making any commitment to a Canadian Blood Services project needs 100% buy-in from the provinces and territories. That was received last year, but there were no funding dollars attached to that.

Hon. Ujjal Dosanjh: Thank you.

Dr. Duncan.

Ms. Kirsty Duncan (Etobicoke North, Lib.): Thank you.

Thanks to all of you for being here to discuss regenerative medicine and the future of medicine. Thank you for your world-leading research.

I think you've raised a really good point: if Canada doesn't step up to the plate, people will go overseas. They are going now. They are going for help with multiple sclerosis, for adult mesenchymal stem cells.

Could you please compare and contrast the utility of cord blood stem cells, iPS cells, adult mesenchymal stem cells, and others from the research stage through to therapeutics? Do we need all types of stem cells? Will iPSCs replace the other types?

Dr. Michael Rudnicki: I can speak to that.

Without question, researchers are working with all of these cell types. We need to compare and contrast them. And they're being used for different types of therapies. So iPSC will not replace everything else, and neither will embryonic stem cells be used for all possible trials. We're talking about hundreds of different diseases with multiple solutions. The best solution for each disease may well come from using different types of cells.

These drug screens that I talked about are making using iPSC cells. The Geron trial is making use of human embryonic stem cells. Cancer stem cells are being derived from tumours to develop cancer treatments. Mesenchymal cells are being used to modulate the immune system.

So there's no one solution, and one particular cell type doesn't fit all sizes.

Ms. Kirsty Duncan: Thank you.

What specific recommendations would you make to this committee—Dr. Rossant talked to some of the legal challenges—to address all of the legal, ethical, and scientific issues, so that we can move forward to getting more treatments here in Canada?

Dr. Michael Rudnicki: Perhaps I can address that.

Certainly the system is very bureaucratic, and we have overlapping jurisdictions and we have contradictory aspects for the different instruments.

The Chair: Dr. Rossant.

Dr. Janet Rossant: I think we are in a situation in which the regulatory environment is a little confused. The CIHR has jurisdiction over all aspects of research, and I think the stem cell oversight committee of CIHR does a very good job. That is the number one thing we should focus on, making sure that we have one system for the research.

But it is more complicated than that, because there are legal aspects as well. Our overriding goal is that whatever regulatory frameworks are set up, they should be harmonized. So if we have to have—and we probably will have—multiple regulations on different aspects of stem cell research and of course their application, there needs to be harmonization across all of those. That's the one thing I think I would really make a plea for.

● (1150)

Ms. Kirsty Duncan: Okay.

What do cord blood stem cells offer? At this time, we may be able to treat small-sized adults. Over time, will we be able to treat full-sized adults, or will iPS cells replace that? The question I'm asking is what need there is for cord blood stem cell banks.

Dr. Janet Rossant: Can I try that one?

Actually, let Dr. Wall take it.

The Chair: Excuse me, could you pay attention to the chair so that we don't get chaos in here?

Dr. Janet Rossant: Sorry.

The Chair: Dr. Young, could you address that...?

I'm sorry, I meant to say Dr. Wall.

Dr. Donna Wall: I'll take Dr. “Young”.

Voices: Oh, oh!

The Chair: Okay, Dr. “Young”: I won't be coming to see you again.

Voices: Oh, oh!

Dr. Donna Wall: We have to be a little bit careful here, because we're using stem cells in a very wide application. When we're talking about a Canadian public cord blood bank, at this point the application is specifically for what we used to call bone marrow transplantation, or blood and marrow transplantation.

Looking at that very small focus, cord blood offers a tremendous opportunity to offer transplantation to people who have rare immune types and thus are on wait lists for transplant and may not be able to have a transplant to treat their blood disorder, immune disorder, or cancer.

The issue with cord blood that you alluded to was that when you collect cord blood at the time of delivery, you collect roughly a cup of blood, and that amount of blood is used to “transplant” a baby or an adult. The cell dose is low. There is active research in the area to expand cord blood. We have now found out that we can use two cord blood units at once, and this has largely overcome our size issue. We in Manitoba and other Canadian transplant centres are using cord blood as a transplant option for adults now.

The Chair: Thank you, Dr. Wall.

We'll now go to Monsieur Malo, please.

[*Translation*]

Mr. Luc Malo (Verchères—Les Patriotes, BQ): Thank you, Madam Chair. Thank you as well to our witnesses for their presence here with us this morning.

Dr. Rossant, allow me to put my first question to you. In your presentation, you stated that research is directed via three professional bodies or in accordance with the recommendations of three instruments, namely the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, CIHR and the Assisted Human Reproduction Act.

I would simply like to come back to the Assisted Human Reproduction Act, because, as you know, it is presently being challenged before the Supreme Court. I was wondering what impacts, if any, this legal challenge is having on your work.

[*English*]

Dr. Janet Rossant: I'll answer in English, if you don't mind.

The fact that the act is not able to move forward because of the judicial challenge means that the regulations that the act requires to be set in place are not in place. Currently, the act that should apply to the derivation of human embryonic stem cells or any use of human reproductive material would require a licence through the regulations of the act. The regulations are not in place, so there in fact is no means, for the act, of actually looking over stem cell research and the use of human reproductive material.

It's a big issue, not just for stem cell research but for human reproductive technologies. IVF programs are supposed to be regulated under the act, and they are currently not because the act is in limbo and the regulations are not in place.

So it has actually a broad impact on the use of human reproductive materials.

[*Translation*]

Mr. Luc Malo: But if, for example, the regulatory framework is not there, does this prevent you from pursuing your research work?

● (1155)

[*English*]

Dr. Janet Rossant: No, it's not affecting our ability to do research, but it's affecting the confidence scientists have that we have a clear regulatory environment. I think it affects the public's confidence in the same thing: that research in Canada is moving forward in a clear environment.

We are in a very competitive international environment. We need to be sure that in Canada we can be clear with scientists coming in about what they can do and what they can't do. So it's really about clarity and openness and transparency at all levels: to the public, to the scientists, to the regulators, and indeed to Parliament.

[*Translation*]

Mr. Luc Malo: I would like to know what proportion of the stem cells being used today are imported, and what controls these stem cells are subject to. Are they the same procedures as those used for stem cells retrieved from Canadian citizens, for example?

[*English*]

Dr. Janet Rossant: I'm not sure; maybe Dr. Wall is going to try to answer.

The Chair: Dr. Wall, go ahead.

Dr. Donna Wall: I can answer that from the field of blood and marrow transplantation. There is a robust sharing across countries of the best-matched cell products. This includes cord blood. When importing cells, we follow Health Canada regulations that would apply to Canadian products.

To date, a vast majority of the cord blood units that have been used for transplantation in Canada have been sourced internationally.

The Chair: Dr. Rossant.

Dr. Janet Rossant: I would address this on the embryonic stem cell side.

Embryonic stem cell lines have been generated around the world, and some of them are imported into Canada. They have to be approved by the CIHR stem cell oversight committee, which reviews their derivation and the informed consent. They have to be approved under the same regulations as occur in Canada, and then they can be used.

It's very important, again, to be able to share expertise internationally and to share and cross-compare research across different jurisdictions.

Mr. Drew Lyall: Just to give some sense of numbers, in Canada, four human embryonic stem cell lines have been derived by scientists who were grandfathered under the provisions of the bill when it came in in 2004, but around the world there are probably a couple of hundred stem cell lines now.

The Chair: Mr. Malo, you have one more minute, if you'd like another question.

[*Translation*]

Mr. Luc Malo: Thank you very much.

I would like to come back to a statement made by Dr. Dhaliwal with regard to medical tourism for stem cell transplantation. I would simply like to have an idea of the scope of this phenomenon.

[*English*]

The Chair: Dr. Dhaliwal.

Dr. Dhali Dhaliwal: It varies from province to province, but at this moment we know that every province has had applications to the provincial health ministries for support of the funding necessary to access. But I must point out that at the moment, there are not well-established studies that have gone through the test of rigorous clinical testing. So it is in that early phase at which the patients hear of advances or processes or procedures that are available outside Canada and then undertake to go there.

I think this is going to increase dramatically if we do not support the research and the clinical application infrastructure across the country. I believe we will need before that a rigorous process of testing the utility of these therapies and their cost-effectiveness and the long-term impacts.

The Chair: Thank you, Dr. Dhaliwal.

We'll now go to Ms. Hughes.

Mrs. Carol Hughes (Algoma—Manitoulin—Kapuskasing, NDP): Thank you.

I want to touch base on the issue of cord blood. I'm just trying to get some sense of it, because obviously there's a demand out there for that. Basically, from what I can gather from the information you've provided, there's not really a bank out there that could easily provide that information and how to collect it all.

I'm just wondering what could be put in place with respect to ensuring that there's access to cord blood. How do we go about collecting all of that?

● (1200)

The Chair: Dr. Wall, would you like to comment on that?

Dr. Donna Wall: Yes. It's a good question, but it's hard to answer that in a sound bite.

The issue is that we in the blood and marrow transplant community are networked worldwide with donors for cord blood, and for adult volunteer donors, good Samaritans, who are willing to donate bone marrow for patients in need. That is an established network.

The focus of a Canadian cord blood bank would be, in my opinion, to enrich the number of units that represent our ethnic minorities, our mixed-heritage families, which is an increasing number of families, because your immune type goes along with your ethnic background. The patients we have a hard time finding donors for are first nations families, new immigrants, patients of mixed heritage, so the needs we have in the transplant community are to get cord blood units banked specifically in this area.

The Chair: Dr. Rossant.

Dr. Janet Rossant: I want to make it clear, in case people haven't twigged, that there are cord blood banks in Canada, but they are largely private. There's a very different rationale in a private cord blood bank, where a cord from a baby is stored for the use of that baby. Those are commercial undertakings with a fee.

What Dr. Wall is talking about is a very different undertaking, a much more open and publicly available bank, where, again, people would be asked to donate their baby's cord blood, but it's like putting it in a bank and you can pull out not necessarily that blood again but any blood that you need later on.

So I think it's a very different concept and it's really one that we need to embrace in Canada.

Mrs. Carol Hughes: I'd like to follow up on a comment that Dr. Wall has actually indicated with respect to first nations as well.

I come from a mostly rural riding, and the difficulties there...so I'm trying to figure this out. I'm assuming that one of the suggestions would probably be that we educate people so that when someone becomes pregnant, there's an opportunity to educate—i.e., if you want, you can actually make a donation.

I'm simply trying to get some sense as to what we need to do here federally in that respect.

The Chair: Dr. Wall.

Dr. Donna Wall: I've done this for many years now—so I'm not Dr. “Young” in this—and the issue—

The Chair: Dr. Wall, there is a rule here at my committee, you know.

Do you want to hear it?

Voices: Oh, oh!

The Chair: Continue on.

Dr. Donna Wall: The issue here is not, in my past experience, the willingness of parents and obstetricians and hospitals in participating in cord collections. It's very easy to get the word out, and Canadians have big hearts. I don't anticipate problems in that early phase of donation. The difficulty is that in order to bank cord blood units for use in clinical transplantation, we need to meet manufacturing standards, and we need to have the infrastructure support for high-quality banking. That would include rigours on the collection, the transportation, the processing, the storage, the characterization.

So it's a big effort, all of which is doable, but it needs to be well funded.

● (1205)

Mrs. Carol Hughes: Just on that note, I'm trying to get some sense as well....

This is something that Dr. Dhaliwal has mentioned on a number of occasions, and we've from some other speakers here, with respect to financial and infrastructure support and capacity building.

I don't know if anybody wants to add to that. I know that as you're making your presentations and you're hearing others, you may have other things to say, and sometimes you don't have time to say it.

So if you had to get your message out to us, what would it be?

The Chair: Who would like to comment?

I noticed that Dr. Hicks and Dr. Gibson....

Do you have any comments on this particular subject? We haven't given you a chance to really make comment. Is there anything you'd like to say in this regard?

Yes, Dr. Hicks.

Dr. Geoff Hicks: Sure.

I think the capacity building is really one of the most essential things to move this vision forward. We're very good provincially, and I would imagine nationally, in programs that have successfully recruited great scientists and great clinicians such as the Canada research chairs program.

Funding agencies and foundations are very good at providing infrastructure, building things, and buying tools. Where the capacity really needs a lot of support is in maintaining the research operating funding opportunities, allowing flexibility to move forward with some of these developments, both in engineering and GMP manufacturing.

Most importantly—if I'm going to have my say at today's meeting—I think we've heard a lot about how Canadians are the ones who have discovered stem cells. Canadians have led and continue to lead internationally, not just nationally, in the science, the biology, and the research of stem cells. Canadians, as a people, believe in stem cells. Of course, we all believe in the hope of translating this into clinical and health care. What would really bridge the gap is the ability to make that realization.

One of the strongest ways that can move this forward, and it hasn't been mentioned yet, is the ability to take the researchers and put them together with clinical fellows and clinical scientists, so that the two sides are working closer and this translation can happen at a much more efficient process.

There are two examples of ways in which support could directly enable and enhance this program.

The Chair: Thank you, Dr. Hicks.

We'll now go to Mr. Brown.

Mr. Patrick Brown (Barrie, CPC): Thank you, Madam Chair.

Thank you for all the interesting testimony today. It's very apropos. We just had a neurological disorders subcommittee from 9 a.m. to 11 a.m. and we were talking about some of the challenges we face with ALS.

Could you comment a little bit about the promising current developments in regenerative medicine? I know there was reference to potential treatments. Do you believe we are on the cusp of any breakthroughs—if there was a framework set up that would allow greater research, greater investments?

What are we hoping for? Can you paint a picture for us of what some of the realistic possibilities are?

The Chair: Dr. Rudnicki.

Dr. Michael Rudnicki: Scientists don't like to talk about breakthroughs, first of all. It's an incremental process and it's a research continuum that starts at the bench and ends up at the bedside. We need support at every step of the way to move findings through that pipeline and to implement them to change clinical practice.

I think it is clear, and the evidence supports without question, that regenerative medicine will transform the practice of medicine. It's coming. It will find its way into the clinic through many different avenues for many different diseases. But we will move from the current practices to practices where we'll be harnessing the power of stem cells using drugs, using cells, using all the tools at our disposal to repair tissues through regenerative mechanisms.

I think we gave five or six examples today already, and I'm sure we can answer more questions with more specific examples. The Geron trial has just been started. It's the first example of human embryonic stem cells being used in a clinical context. It's the first trial using those anywhere in the world. That started a few weeks ago.

We know of 50 trials in Canada happening in the next three to four years using cell-based approaches, ranging from Duncan Stewart's trial, where early-phase endothelial progenitors are being genetically modified in a transient way, to promote blood vessel growth for the treatment of pulmonary hypertension where blood vessels fall off the lung, alveoli—I'm being overly technical, I apologize—through to treating heart attack patients.

Trials are being planned to chemically expand cord blood stem cells so that one can use one graft per patient or have earlier engraftment. The science is advancing and those trials should be under way very soon, and on and on. Cancer stem cells are also an area where we lead. A Canadian, again, was the one who discovered cancer stem cells, tumour initiating cells, and we're the first in the clinic with drugs that attack them. It's really quite remarkable.

● (1210)

The Chair: Dr. Dhaliwal.

Dr. Dhali Dhaliwal: I totally agree with what is being stated, but we must be visionary and look to the future to building that capacity right across the country. Otherwise, it will inevitably result in inequalities that the public will not be happy about.

Mr. Patrick Brown: Earlier we referenced neurological disorders, I think MS or ALS.

Dr. Michael Rudnicki: It was multiple sclerosis.

Mr. Patrick Brown: What did you believe was a potential treatment there?

Dr. Michael Rudnicki: A rather mature clinical trial has been under way for many years; over 30 patients with severe MS have been transplanted. They receive an autologous bone marrow transplant of purified hematopoietic blood stem cells. Essentially, this reboots the immune system. You have to receive all your vaccinations, otherwise you'll get all your childhood infections all over again, and then the rebooted immune system forgets it's attacking the nervous system. So essentially you no longer have MS. Those patients do very well.

The younger you are, the better the outcome, but we know of particular patients.... Jennifer Molson is one who was in a bed. She had to be fed. She had to be taken care of by personal caregivers. She was in a rehab facility. She's now skiing. She's working. She's living with her husband. She got her driver's licence. It's phenomenal.

That work is being performed by Harry Atkins and colleagues at the Ottawa Hospital. It's not published yet, but I'm sure it should be coming out in a high-profile journal. It changes the practice of care.

Mr. Patrick Brown: This is certainly a fascinating and exciting area.

I read that there are approximately 200,000 potential donors with the Canadian Blood Services OneMatch program. An international network has 11 million, according to the notes I had from the library.

What is the sufficient number we need to meet the demands of Canadian patients? If you envision how many potential donors we need, what is the target?

The Chair: Who would like to answer?

Dr. Wall.

Dr. Donna Wall: It's a hard question to answer, because what we need is not so much the raw number of donors, we need to have donors who are available to donate. We prefer to use male donors. We prefer to use young male donors. And we need to have donors who are of a mixed ethnic heritage, or of our ethnic minorities, to increase the odds that a given donor is going to be a good immune match.

So it's not the absolute number that we need; it's a subset to target those for whom we have trouble finding donors. There is no absolute number on that.

Mr. Patrick Brown: What could government do to assist in having that larger, more diversified donor group?

The Chair: Dr. Wall.

Dr. Donna Wall: I think efforts, such as that led by Joy Smith, in bringing out the donor campaigns really help a lot. Helping establish a cord blood bank will help, as will basically continued funding of the national registry, the OneMatch program.

● (1215)

The Chair: Your time is up now, Mr. Brown, I'm sorry. It was getting so interesting there.

This is an extremely informative, interesting panel we have here today.

We'll now go into our second round. We'll go into a five-minute question and answer round.

We will begin with Dr. Dhalla.

Ms. Ruby Dhalla (Brampton—Springdale, Lib.): Thank you very much to everyone for coming, especially to the folks from Manitoba. Being a former Winnipeger, it's great for me to see some of the work that's being done out there.

I have a couple of questions building upon what one of our other colleagues, Mr. Brown, just asked in terms of the awareness campaign and reaching out to get donors from young men and people from ethnic communities, and from the first nations communities. As the MP from Brampton—Springdale, I can tell you that we have one of the larger multicultural and multilingual demographics across the country.

There are some awareness campaigns already under way, but what other initiatives is the Stem Cell Foundation undertaking to reach out to ethnic communities in various languages and through the mediums, perhaps, that they're accessing?

The Chair: Who would like to answer that?

Dr. Lyall, and then Dr. Wall.

Mr. Drew Lyall: We're a very young organization and only beginning to tackle some of these initiatives, but the kinds of things you're suggesting are exactly the kinds of things we're hoping to fund as we move forward.

The Chair: Dr. Wall.

Dr. Donna Wall: This is a major campaign for the OneMatch program at Canadian Blood Services. Their recent donor accruals to their registries have shown a marked increase in younger donors in ethnic minorities. Basically, this needs to be an ongoing process.

Ms. Ruby Dhalla: The Canadian Stem Cell Foundation has a stem cell charter. Perhaps you could share with our colleagues what some of the objectives of that charter are, how it's going to be promoting responsible science, and ultimately how it's going to allow accessibility for Canadians.

Mr. Drew Lyall: Sure.

The concept behind the stem cell charter really arose from a lot of the debate around stem cell research over the years and to bring some focus to the key principles that the scientific community, as a starting point, thought should be observed. It talks about the integrity of the science. We heard from one of the other questioners about stem cell tourism. If therapies are going to be offered, they really ought to be therapies that have been proven in the clinic. There should be rigorous testing before we get there.

The charter also talks about transparency and openness, so that when all these tests are being undertaken and research is moving forward, it should be in full visibility of the public to ensure that the public and policy makers have confidence in the scientists, that we're moving forward in a responsible manner and people can take comfort from that.

Really, it's about the responsible advancement of the science and making sure that as it moves forward to the clinic, the public can have confidence in the therapies offered to Canadians.

Ms. Ruby Dhalla: Perhaps I could request, through Madam Chair, that perhaps Dr. Lyall or Dr. Wall could forward to the committee some information on the stem cell charter and some of the initiatives under way for increasing awareness of being donors for the program.

If you could have that forwarded to the committee, I think it would be of great interest to all of our colleagues. We send out newsletters to our constituents that talk about some of the work that's being done, and I think this would be of interest to many people.

The Chair: That's a very good point.

I would ask anyone here on the panel today who has any of that information to send it to the clerk. She will translate it and give it to the committee members.

Thank you.

Ms. Ruby Dhalla: I have one more question before I turn it over to my colleague.

The Chair: You have a minute.

Ms. Ruby Dhalla: Okay.

Dr. Dhaliwal, you spoke about the increase in medical tourism and about ensuring that we provide...or Dr. Rossant spoke about harmonizing our regulatory frameworks.

If you could give one recommendation on that—Dr. Dhaliwal, and perhaps Dr. Rossant as well—it would be much appreciated, to ensure that Canadians receive the treatment here in our country versus having to travel abroad.

● (1220)

Dr. Dhali Dhaliwal: Dr. Rossant?

Dr. Janet Rossant: I was going to say, “Dr. Dhaliwal?”

Voices: Oh, oh!

Dr. Janet Rossant: One recommendation is really that any treatment that uses stem cells or is related to stem cell therapy has to go through full and careful clinical evaluation for safety and efficacy by all the means, through Health Canada regulation and through clinical trials.

We also need to educate people that stem cell tourism, in some cases, is very dangerous. When you look at treatments being offered in China or India, they are often not done under the same kind of clinical evaluation we have here.

The Chair: Dr. Dhaliwal, did you want to comment on it as well?

Dr. Dhali Dhaliwal: Yes.

There are examples of patients who have gone abroad and come back with infections, because their immune systems were compromised and the treatments being administered were not clear.

I would say that it is imperative that we develop a broad structure that allows rapid assessment of these therapies that the public can have good confidence in. Then we will not have the tourism that could occur.

I think that will be impacting the health care system in a big way, and all of the provinces are going to be mired in having to evaluate untested therapies. We have seen the problems that arise, such as the procedure for multiple sclerosis that's causing a lot of heartache and difficulties for the regulatory bodies.

The Chair: Thank you, Dr. Dhaliwal.

We'll now go to Ms. McLeod.

Mrs. Cathy McLeod (Kamloops—Thompson—Cariboo, CPC): Thank you, Madam Chair.

It's certainly been a fascinating discussion, and I've learned a lot. I'm also very pleased; I didn't realize that Canada had played such a role in terms of the development of stem cell research, so that's been added to my learning today.

This may be a bit elementary, but it would just help me understand things a bit better. Essentially, right now, we have four sources of stem cells: bone marrow, embryonic, umbilical, and iPSC. Is that right?

Dr. Michael Rudnicki: There exist in every tissue resident stem cells. There are probably over 300 different cell types in our bodies. I think the exact number of stem cells is unclear. There's a large number of different types of stem cells.

Mrs. Cathy McLeod: I meant in terms of sources we're using for either clinical trials or for therapeutic uses.

Dr. Michael Rudnicki: Well, there are also brain stem cells that have been isolated for transplantation. Skin stem cells are being used for burn victims. Islets transfers perhaps can be thought of as stem cell. The Edmonton Protocol might be another type of stem cell transplantation.

So that exact list, I don't know what it would be, but....

The Chair: Go ahead, Dr. Lyall.

Mr. Drew Lyall: In broad terms, though, in terms of where you're going there, the types of cells Dr. Rudnicki is describing are adult stem cells. Then there are embryonic stem cells, sourced from embryos, and then these new iPS cells. You have kind of these three broad categories.

Mrs. Cathy McLeod: So adult stem cells are mostly through the OneMatch process? Those are either from individuals' families or through the OneMatch process?

The Chair: Dr. Wall and then Dr. Rossant.

Dr. Donna Wall: We're talking about two things at the same time, and that's where it gets a little bit confusing.

There are adult donors and cord blood donors for hematopoietic stem cells for use in blood and marrow transplantation. So that's the OneMatch part, only for blood and marrow transplantation indication at this point.

The discussion for most of this discussion today has been a much broader discussion about the use of stem cells that actually may be taken from yourself and enriched and expanded to treat yourself or modified to treat yourself, and this is actually the more exciting and the bigger part of the discussion.

● (1225)

The Chair: Dr. Rossant.

Dr. Janet Rossant: That's fine.

The Chair: Okay.

Ms. McLeod.

Mrs. Cathy McLeod: So then currently, if you're looking for umbilical cells, we don't have a Canadian-wide system. We've asked to look at a Canadian-wide system. Where are the sources right now in terms of...?

We talked about some private banks, but those are really for people saving for “self”. Are there different centres throughout Canada that perhaps have a collection of umbilical stem cells for...?

The Chair: Dr. Wall and then Dr. Rossant.

Dr. Donna Wall: The standards that are applied to banking cord blood for use in transplantation from one person to another person, which is the field of blood and marrow transplantation, are very different from the private banking. At this point, we have the young but really well-developed Héma-Québec bank, which is just now at the point of being ready to release cord blood units for transplantation. We, as a transplant program, will routinely search their inventory. But their inventory of 2,000 to 3,000 cord blood units is dwarfed by an international inventory of probably close to 600,000 cord blood units that we can now search. When we're looking for a cord blood unit, we're looking for the best immune match and we're looking for the most number of young blood-making cells.

The Chair: Dr. Rossant also wants to make a comment.

Dr. Janet Rossant: I would just point out that what this means is that most of the cord blood transplants that take place in Canada are using material that's imported from outside of Canada, because we are not really paying our way into the banking system.

Mrs. Cathy McLeod: That was what I was going to ask about, that we're not really paying our fair share. For the proposal that is in, what's the cost? Would there be centres across Canada? What are some of the details around what it would actually take in terms of setting up a pan-Canadian system?

The Chair: Dr. Wall.

Dr. Donna Wall: There is a formal OneMatch proposal that has a full business plan that's been developed in.... I think probably the best way is to get that directly from Canadian Blood Services.

There are many ways of going about establishing a Canadian cord blood banking system. That is one approach. There are other ways that can be attacked. You have a really nice solid base with the Héma-Québec bank operations at this point.

The Chair: Thank you.

Now we'll go on to Monsieur Dufour from Quebec,since we talked about the Quebec bank.

[*Translation*]

Mr. Nicolas Dufour (Repentigny, BQ): Thank you very much, Madam Chair.

I am happy to see the advances being made vis-à-vis Héma-Québec.

First of all, allow me to thank the witnesses. It is a privilege to participate in a debate as interesting as the one on stem cells. We are all aware of the importance they will have in the future.

Mr. Lyall, you stated earlier that, in the future, this is an area where there will be a lot of job creation, many of these jobs high-paying ones. At the present time, what does the economic picture look like with regard to stem cells? Do we know how many employees will be required? What is the investment worth? Do we have a global idea of the economic picture?

[*English*]

Mr. Drew Lyall: It's very difficult to quantify those kinds of opportunities. I should maybe caveat the comments as well, by saying that for some of the therapies that are going to be developed —so we think of bone marrow transplantation as one paradigm— there isn't really a business built around that. It's a procedure that is done in a hospital, and we need to understand exactly how to isolate those cells, how to transplant them, how to give them to a patient. So in those kinds of cases, it's not so much that you're going to generate large numbers of jobs there as that you're going to get cures to patients and return them to economic productivity, and there'll be a benefit to the system from that.

But separately, as new drugs are identified using stem cells as screens to identify those drugs, just as biotech companies start now —discovering jobs through other mechanisms—so biotech companies will spin out in that way. Similarly with cell therapy companies; Geron is a good example. To give some scale there, Geron has brought the first embryonic stem cell therapy to clinic. It has something like 200 employees, I believe, and they've raised over $100 million in venture capital financing just for the development of that single therapy. When you start applying that kind of metric across many different kinds of therapy, you can see that there are going to be a lot more opportunities there.

There are also economic opportunities in other aspects too. There's a fabulous company in Vancouver called STEMCELL Technologies, and they have built their business around, if you like, the picks and shovels of the regenerative medicine business. They provide tools and reagents to companies, and they've grown from a company of 50 to 100 employees 10 years ago to over 400 employees now. They're supplying the regenerative medicine research market.

So there'll be opportunities there. Then you can start thinking about the wider opportunities of different kinds of tissue repair. There are all kinds of different companies that are likely to spin off it and the expertise that you then build as a country in that space.

● (1230)

The Chair: Thank you, Dr. Lyall.

I think Dr. Dhaliwal, before our time runs out, would like to make a comment as well.

Dr. Dhali Dhaliwal: I have just a quick comment.

It's not only that new jobs are created but also that there is the potential of loss of jobs, because this will be a very competitive field in which researchers, clinicians with expertise in this area, would be heavily headhunted internationally. We are in a global market arena, and therefore there is loss of expertise elsewhere, which will translate into loss of capacity and our ability to lead in a field that we have led. I believe there is an opportunity cost if we do not act.

[*Translation*]

Mr. Nicolas Dufour: Madam Chair...

[*English*]

The Chair: You have one minute, Monsieur Dufour.

[*Translation*]

Mr. Nicolas Dufour: I agree with you. I simply wanted to have an idea of the investments in this area on the part of the government of Canada. As Dr. Dhaliwal was saying, if we do nothing in this area, the scientists will leave the country, as has been the case in other fields of research since 2006. Researchers have left for foreign countries because of the consistent lack of funding in various fields of research. We saw some of them go to Florida, to California. We see that this is not necessarily a priority for this government. I find this sad because the more we invest, the greater chances we will have of retaining quality researchers.

What does the government's investment in this area look like?

[*English*]

The Chair: Who would like to make comment on that?

Dr. Rudnicki.

Dr. Michael Rudnicki: Without question, federal funding of research, through the Canadian Institutes of Health Research, has not kept pace with the capacity that's been added or with inflation. The proportion of grants that have been funded is in free fall. The times are very tight right now.

So Canadian researchers look to places like California. It's very tempting. I'm headhunted several times a year. A few times, I've had to really think about it. But I'm a Canadian, and I'm pretty nationalistic, and...but anyhow.

The Chair: Well, thank you for staying, Dr. Rudnicki.

Dr. Michael Rudnicki: The funding is very tight right now. New investigators are having a hard time getting funding. Established investigators are losing their funding. On the proportion of grants, I think the last CIHR competition...that was funded was 18%, and it's expected to become even smaller.

You know, this is an incredibly important area for Canada, and there's a very essential role for the federal government to support research that's basic, that's translational and clinical. Without the CIHR we cannot do this work.

The Chair: Thank you, Dr. Rudnicki.

We'll now go to Ms. McLeod.

Mrs. Cathy McLeod: Thank you, Madam Chair.

I also want to thank my colleagues as I continue developing my rudimentary understanding of this issue. I apologize if these questions seem basic, but they are helping me kind of frame the issues.

On the umbilical cord issue, if you were looking at, say, a Canadian bank, first of all, are there challenges around collections? Could mothers who deliver in small hospitals in rural communities be donating? Is there a percentage of newborn infants that would be optimal?

Perhaps you can talk a little about what it would mean and what the process would be.

● (1235)

The Chair: Dr. Wall, I can just see you smiling, ready to answer there. Go ahead.

Dr. Donna Wall: I'm speaking for myself now, and not necessarily for other cord blood banking operations in Canada.

Absolutely any cord blood bank that's developed in Canada needs to be established such that no matter what size of hospital or where it is, you can collect that cord blood unit. That translates into putting the resources into developing the tools to train the collectors, and it's not rocket science. It's not a complicated procedure to collect the cord blood unit, but you need to have transportation.

We have special transportation challenges in Canada, but nothing insurmountable. We're good at this.

Then we need creative ways of meeting good manufacturing practices with a distributor network.

All of this is surmountable and would really improve the quality of the Canadian cord blood bank in being able to represent the true flavour of who makes up Canada.

The Chair: Do you want some further clarification on that, Ms. McLeod?

Mrs. Cathy McLeod: I guess I would ask this. To have an optimal kind of collection, what percentage of the population...? I know you would be looking at diversity, but is there a certain target—like, one baby in ten—to represent the diversity of Canada?

Dr. Donna Wall: It's one baby in ten but with a representative, a proportion; you don't need a high number of cords. There are a lot of babies born in Canada, and you don't need all their cord blood units in the bank. That would be a prohibitive expense. You need high-quality cord blood units, and that translates into units that pass a multitude of potency tests. You need large units that come from a diverse population.

On the absolute number of cord blood units we ought to get into the bank to represent our population, if we got to 20,000 to 50,000 high-quality cord blood units in the bank, we would start to be able to contribute to the international inventory of cord blood units and meet the needs of Canadians.

Mrs. Cathy McLeod: On the OneMatch system, I expect there's a profile of donors. Our chair, Ms. Smith, did a great job. I think a number of folks showed up here in Ottawa.

Is there a plan to be strategic about getting some of the under-represented population to add to that bank? Is that happening?

The Chair: Dr. Wall.

Dr. Donna Wall: Yes, that's an ongoing initiative as part of Canadian Blood Services. I'll circle around to them to submit something to the Clerk of the House to address that.

But that is recognized and implemented as an initiative.

The Chair: Okay.

Mrs. Cathy McLeod: Mr. Rudnicki, you talked about challenges at the very start. The challenges we've heard about involve the regulatory framework and optimal funding. We talked a little about the research. Are there any other challenges that you see?

Dr. Michael Rudnicki: A big challenge is jurisdictional, between the federal government and the provinces. The CBS program is well worked out. They have a mature business plan. They have the resources, and they can implement this. They can have quality cords available that represent the diversity of Canada.

The provinces don't have the funds right now, given the times we're in, to fund this. It's in an area of provincial jurisdiction, the funding of CBS, so how could the federal government provoke provincial funding? Maybe they could match that, I don't know; it's a jurisdictional issue. Regulations also have jurisdictional issues with the provinces.

That's a problem inherent to Canada, I think. It's something we struggle with, and I'm sure you do on a regular basis.

So I view that as a big area.

● (1240)

The Chair: Thank you, Dr. Rudnicki.

We'll now go to Mr. Dosanjh. I think you're going to share your time with Dr. Duncan.

Hon. Ujjal Dosanjh: I'm always sharing my time.

The Chair: That's a good thing.

Hon. Ujjal Dosanjh: I believe in sharing. I know Deepak doesn't, but....

Dr. Rossant, you mentioned that the Assisted Human Reproductive Agency and the act, particularly the act, is challenged before the courts. You then said that the regulations haven't been done because of the challenge.

As a lawyer, I believe unless there is an injunction from the court that is in place to say nobody can do anything with respect to this act, the government has the right to proceed with the regulations and proceed with dealing with the issues if it sees fit, and let the challenges come whenever they may.

I want you to address that. I don't want to be partisan, but there is an elephant in the room here that nobody is talking about. This government has been fairly resistant to this kind of research, and that's why, perhaps, they have not proceeded with the regulations pursuant to the legislation.

Dr. Janet Rossant: I'm going to actually shift that to my colleagues who did meet with the regulatory group.

Would you like to address that, Michael?

Dr. Michael Rudnicki: Well, what they told us was exactly that. It's on hold because of this court challenge.

Hon. Ujjal Dosanjh: But there's no injunction in place, is there?

Dr. Michael Rudnicki: Not that I know of.

Hon. Ujjal Dosanjh: Because if that were the case, I could bring perhaps the whole government to a standstill simply by issuing a writ.

Dr. Michael Rudnicki: I really don't have any idea what—

Hon. Ujjal Dosanjh: Well, if the government believed that, then they couldn't do anything with respect to anything. A writ would simply stop the government from proceeding. And that's what has happened in this case.

Thank you.

Go on, Madam Chair.

The Chair: Thank you, Mr. Dosanjh.

Ms. Kirsty Duncan: I was going to pick up on the MS issue. You were talking about Mark Freedman's work.

I think it's important for the committee to understand that chemo is used to wipe out the immune system, and that it's only undertaken in people who are at the very end stages. Chemo is used to destroy the immune system and then do the stem cell transplant. Elsewhere in the world, that is not being done.

Dr. Michael Rudnicki: The bone marrow transplant procedure that's being used by Harry Atkins, the hematologist, as part of that trial, does involve a mild blade of therapy, which is chemo. The hope is that by using drugs that modulate the immune system they can move forward and not do that in the future. They are only treating the most severe patients at this point in time. It's not a general cure for MS. You're quite right; I stand corrected.

Ms. Kirsty Duncan: People need to know that there were adverse effects associated with that.

The question I have is really around private banks, individual collection for individual families. The national cord blood bank would look at 10% of the population. In an individual family you can look at the individual plus, potentially, a number of family members who might be able to be treated.

We talked about bone marrow transplants, also the promise of about 70 diseases that might be treatable. If we go to the 10%, what will the coverage be? Would you meet the same coverage if you did it individually?

The Chair: Who would like to comment on that?

Dr. Wall.

Dr. Donna Wall: This is going to be confusing. When we do a bone marrow transplant for a child or an adult with leukemia, we don't want to use their own cells again. On purpose, we want to use cells from somebody else, because part of the treatment is to get immune therapy. That's the reason why we think we cure leukemias with transplant.

When we do a bone marrow transplant for somebody who has a broken blood-making system—somebody who makes bad red blood cells, someone with sickle cell anemia, thalasemia, someone who has a broken immune system—we can't use that person's own cells. If there's private banking for that patient, we can't use that cord blood for that patient, so we're talking about something very different.

When you take a look at reasons for banking privately, you find that the indications are very small at this point in time. The indications for my field are next to zero for treatment of cancers and blood disorders. The purported indications for treatment of cardiac disease, diabetes, or neurodegenerative diseases at this point have no foundation on clinical trial experience and no foundation on clinical experience. Given the speed of development in the field of stem cell sources such as mesenchymal progenitors—cells isolated from other tissues in the body, induced pluripotent stem cells—I am not at all clear whether cord blood will be useful as a tool for these other indications, as opposed to drawing a tube of blood or sampling some fat.

● (1245)

The Chair: Go ahead, Ms. McLeod, please.

Mrs. Cathy McLeod: We've talked a lot about potential applications and we've talked somewhat about the current clinical applications in terms of what's being used. Can we talk a little more about current clinical applications and things that aren't researched but are helping patients every day? Can we talk a little more about some of the different applications? We just talked about leukemia....

The Chair: Go ahead, Dr. Rudnicki.

Dr. Michael Rudnicki: Blood transplantation is the major clinical application of stem cells today. I think that's without question. It's huge. In North America there must be hundreds of thousands of bone marrow transplantations done on an annual basis, if not more.

The Chair: Go ahead, Mr. Lyall.

Mr. Drew Lyall: Aside from the major products that are out there right now, there's one really for dealing with severe burns and diabetic ulcers. Essentially, skin stem cells are transplanted over the wound. I think about a quarter of a million patients have been treated with that product. The numbers are growing by 50,000 to 100,000 a year.

Part of the challenge, and it's going to be a challenge as we get into the delivery of therapies later on, is that it's not just about developing a therapy that works: there's a whole challenge in having that adopted as the standard of care in the hospitals and in clinicians being ready to use it and accept it, because that's the way to move forward. Our challenges don't end once we get something into the clinic. It's going to be an ongoing process. Burn victims are one, and the others are cartilage repairs and tendon repairs, and drugs as well.

The Chair: Dr. Dhaliwal, would you like to comment?

Dr. Dhali Dhaliwal: I would add that I believe we are not training enough of those kinds of clinicians in the technologies that they need to use. Therefore, we need action now, because experts don't just develop overnight. It takes 10 years or more to develop clinicians who are well versed and able to advise patients as well as take part in systems planning for appropriate utilization of these kinds of technologies. We need to train a lot more, and there aren't enough funds to train clinician scientists.

The Chair: You have one and a half more minutes, Ms. McLeod.

Mrs. Cathy McLeod: Thank you.

I think you were going to talk a little bit about pharmaceuticals.

Dr. Michael Rudnicki: Yes. There are examples of drugs that target stem cells or progenitor cells. For example, erythropoietin, EPO, is a drug that expands the progenitors in the blood system to make more red blood cells. It's a widely used drug. There are other examples of drugs like that in the clinic as well. Various cytokines are used for specific applications, mostly in the blood system.

As an example of drugs that target stem cells, I think they illustrate how this will become more widespread as findings around mechanisms of stem cell functions are exploited to develop new drugs in the clinic. Therapies can involve cells, but they can also involve drugs. That's very important to remember.

● (1250)

Mrs. Cathy McLeod: Thank you.

The Chair: I want to thank everybody for joining us today on the health committee.

We're going to suspend the committee in just a moment because we have some committee business that has to be attended to before we go back to the House of Commons.

This has been an extremely useful and very valuable day. I can say that your expertise is of paramount importance to this committee, so I want to thank you all for joining us.

[*Proceedings continue in camera*]

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

SPEAKER'S PERMISSION

Additional copies may be obtained from: Publishing and Depository Services
Public Works and Government Services Canada
Ottawa, Ontario K1A 0S5
Telephone: 613-941-5995 or 1-800-635-7943
Fax: 613-954-5779 or 1-800-565-7757
publications@tpsgc-pwgsc.gc.ca
http://publications.gc.ca

Also available on the Parliament of Canada Web Site at the following address: http://www.parl.gc.ca

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

PERMISSION DU PRÉSIDENT

On peut obtenir des copies supplémentaires en écrivant à : Les Éditions et Services de dépôt
Travaux publics et Services gouvernementaux Canada
Ottawa (Ontario) K1A 0S5
Téléphone : 613-941-5995 ou 1-800-635-7943
Télécopieur : 613-954-5779 ou 1-800-565-7757
publications@tpsgc-pwgsc.gc.ca
http://publications.gc.ca

Aussi disponible sur le site Web du Parlement du Canada à l'adresse suivante : http://www.parl.gc.ca