

GE³LS

Embryonic Stem Cell Research

Researchers around the world are investigating the potential of stem cells to treat neurodegenerative diseases such as multiple sclerosis, Alzheimer's, Parkinson's, muscular dystrophy and cystic fibrosis, and spinal-cord regeneration.

Stem cells are found in embryos and adults. Embryonic stem cells have the ability to make all somatic cell types as well as the cells that make up the membranes of the placenta. They can make primordial germ cells that are in sperm or that constitute the subset of cells making up a finite number of oocytes in the female. They are more versatile and aggressive than adult stem cells, since they can proliferate, renew themselves and differentiate into different kinds of specialized tissue. Adult stem cells are highly specialized, and have been

used in bone marrow transplants. Recent research suggests that adult stem cells may have broader potency than first thought, but more work needs to be done in this area.

La controverse soulevée par la recherche sur les cellules souches, au Canada et dans d'autres pays, s'explique à la fois par la source des cellules souches et par l'utilisation qu'on en fait. À travers le monde, les cellules souches font l'objet d'un débat qui se concentre essentiellement sur les cellules souches embryonnaires. Les principales questions posées lors de ce débat se concentrent sur : les lignées de cellules souches embryonnaires (capables de maintenir une production cellulaire tout au long de leur vie); l'utilisation des cellules souches embryonnaires qui ont été prélevées d'embryons

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Génome Québec
Chercheur principal :
Bartha Maria Knoppers
Université de Montréal

La génomique dans la société : responsabilités et droits

« C'est passionnant d'être à la fine pointe de la réflexion en ce qui a trait aux technologies émergentes », dit le professeur Bartha Maria Knoppers, professeur de droit, spécialiste du génome humain à l'Université de Montréal et présidente du comité d'éthique de l'Organisation du Génome Humain. « Chaque fois qu'une nouvelle technologie apparaît à l'horizon, les réactions sont ou bien enthousiastes ou bien craintives face à d'éventuels effets imprévus. Dans une large mesure, nous essayons de faire des projections dans le futur, d'extrapoler à partir de ce que nous savons déjà. »

Le professeur Knoppers est chercheur principal de *La génomique dans la société : responsabi-*

lités et droits, projet de recherche multidisciplinaire qui implique six universités au Québec, dans le cadre du programme des Enjeux éthiques, économiques, environnementaux, de droit et de société liés à la génomique chez Génome Québec. Ce projet reçoit l'appui de Génome Québec (Ministère de la Recherche, Science et Technologie, Gouvernement du Québec) ainsi que de Génome Canada, dont le financement fédéral de 300 millions de dollars lui permet d'élaborer et mettre en œuvre une stratégie nationale de recherche en génomique. La mission de Génome Québec vise à tailler une place au Québec parmi les dix principaux centres de génomique et de protéomique au monde.

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Interview with • a • v • e • c

Dr. Martin Godbout, President
and CEO of Genome Canada
PDG de Génome Canada



Vision and
Mission of
Genome
Canada

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Introducing Canada's GE³LS projects...

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Embryonic stem cell research is a timely and controversial issue. In March 2002, the Canadian Institutes of Health Research announced new guidelines for stem cell research in Canada. In May 2002, the Government of Canada tabled draft legislation – the proposed *Act Respecting Assisted Human Reproduction* – that will ultimately establish the parameters of stem cell research in Canada.

It is important that the Canadian public be involved in an issue of this magnitude. That is why we are featuring an article about stem cell research in this issue of GE³LS, a Newsletter to be published three times a year by Genome Canada. This issue of GE³LS also gives an overview of five Genome Canada projects on ethical, economic, environmental, legal and social issues related to genomics.

Genome Canada is supporting these projects as part of its national strategy on genomics. With \$300 million in federal funding, Genome Canada is the primary funding and information source relating to genomics and proteomics in Canada.

La recherche sur les cellules souches embryonnaires soulève bien des questions. En mars 2002, les Instituts de recherche en santé du Canada ont rendu publiques les lignes directrices pour le financement de la recherche sur les cellules souches. En mai 2002, le Gouvernement du Canada a présenté un projet de *Loi concernant la procréation assistée* qui établira les paramètres de la recherche sur les cellules souches au pays.

Lorsque les enjeux sont fondamentaux, il est très important que le public canadien participe à la prise de décisions. Voilà pourquoi ce premier numéro de GE³LS, un bulletin qui sera publié trois fois par an par Génome Canada, comprend un article de fond sur les cellules souches. Ce numéro de GE³LS vous offre également une vue d'ensemble des cinq projets financés par Génome Canada qui traitent des enjeux de la génomique liés à l'éthique, l'environnement, l'économie, le droit et la société. ▶



This is the first issue of GE³LS, and we hope you like it. We would also like to hear from you. Do you find the Newsletter interesting? Do you have ideas about new content or improvements to existing content? Are there features you would like to see in future issues? What is your perspective on ethical, environmental, economic, legal and social impacts of genomics and proteomics? Drop us a line c/o Genome Canada. ▶

Voici le premier numéro de GE³LS et nous espérons qu'il vous plaira. Trouvez-vous ce bulletin intéressant? Aimeriez-vous qu'il traite de sujets spécifiques? Avez-vous des suggestions pour l'améliorer? Quel est votre point de vue au sujet des problèmes éthiques, environnementaux, économiques, de droit et de société liés à la génomique? Faites-nous parvenir vos commentaires à Génome Canada. ▶



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Interview

with • a • v • e • c

Dr. Martin Godbout

President and CEO
of Genome Canada

PDG de Génome Canada



Could you state the vision and mission of Genome Canada?

Genome Canada was created a little more than two years ago. The main objective is to work in the field of genomics and proteomics where the need for financing is so huge. Large-scale projects, such as those supported by Genome Canada, could not be supported by already-existing programs. We have sought to position our large-scale projects among the leaders in the world, in their specific niches – because of their outstanding science and because they could lead the way to the development of international consortia. We will invest over \$14 million over the next three years, in the five projects related to GE³LS. Moreover, there are major GE³LS components in many of the other 51 platforms and projects supported by Genome Canada.

Why are these resources being committed?

You cannot invest \$600 million up to 2005 (a figure that includes co-funding), without addressing ethics and society. Genomics and proteomics will have a huge impact on society. We cannot ignore the consequences of genomics and proteomics. That's why we wanted peer-reviewed research in an area of such vital importance to Canadians. It's one thing to say "you have to address issues," and it is another to say "here is the money, here is the competition to look at ethical, economic, environmental, social and legal impacts of genomics."

L'approche de Génome Canada tient compte de la pluralité des perspectives dans notre société...

Par définition, les chercheurs dans le secteur des sciences sociales doivent bien définir la problématique. Une fois que les hypothèses sont sur la table, il faut être ouvert aux réactions. Notre approche à l'éthique est une approche pluraliste, qui

ne cherche pas la « réponse unique ». Ce sera à chacune des communautés et aux politiciens d'élaborer leurs réponses. Au Canada, nous serons définitivement, d'ici trois ans, dans une position de leadership mondial en matière de recherche sur les enjeux éthiques, environnementaux, économiques, de droit et de société liés à la génomique. Il faut préciser que Génome Canada est la principale source de financement et d'information liés à la génomique et la protéomique au Canada. Génome Canada est une société sans but lucratif qui se consacre à l'élaboration et à la mise en œuvre d'une stratégie nationale de recherche en génomique et protéomique au profit des Canadiens. Nous avons donc la responsabilité de nous assurer que l'éthique se trouve au cœur même de nos recherches.

Qu'avez-vous appris des chercheurs dans le domaine des enjeux éthiques, environnementaux, économiques, de droit et de société liés à la génomique?

J'ai travaillé en biologie moléculaire il y a quelques années, j'ai déjà travaillé en génomique. En tant que chercheur scientifique, vous devez toujours communiquer avec le public. La diffusion des résultats doit se faire de façon simple, claire et précise. Ce que j'ai appris des chercheurs dans ce domaine, c'est la façon de communiquer avec le public pour lui faire connaître les grands enjeux. Si le public ne comprend pas ce que vous faites, alors vous avez perdu votre temps. En dernière analyse, c'est le public qui décidera. ▀



Invitation

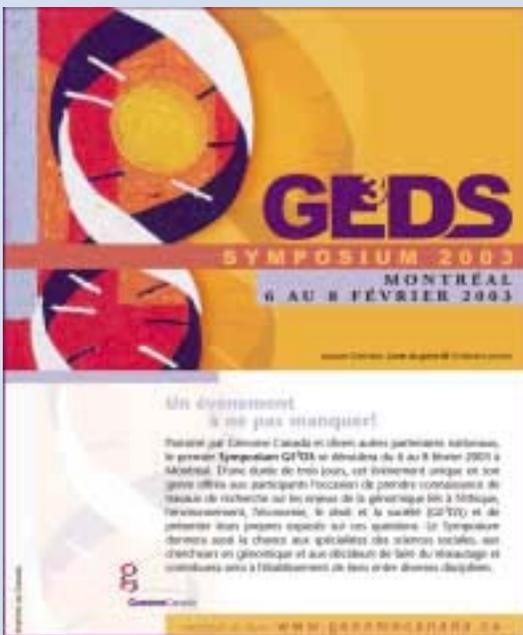


Table: Reproductive/Therapeutic Cloning, Embryo Research, Stem Cell Research (Legislation)

Prepared by: Marie-Hélène Pégivier and Bartha Maria Knoppers
 Funded by: Stem Cell Network and Genome Canada

Country	Reproductive Cloning	Therapeutic Cloning	Embryo Research	Stem Cell Research	Source
Austria	N	N	N	N	Reproductive Medicine Law 1992; (Creation of embryos for reproductive purposes only)
Australia (Federal)	N	N	Y	Y	Research Involving Embryos and Prohibition of Human Cloning Bill 2002 (Embryos created before April 5, 2002 for stem cell and embryo research. Subject to licence)
Canada	N	N	Y	Y	CHR Guidelines; Bill C-56, An Act Respecting Assisted Human Reproduction (Surplus embryos only. Subject to licence)
France	N	N	Y	Y	Projet de loi relatif à la bioéthique, tel qu'adopté par l'Assemblée nationale le 22 jan. 2002 (Subject to licence)
Germany	N	N	N	Y	Embryo Protection Law 1990; Law on Stem Cell Importation 2002 (Imported stem cell lines created before January 1, 2002. Subject to licence)
Ireland	N	N	N	N	Constitution of Ireland art. 40 para. 3 (3°)
Israel	N	Y	Y	Y	Prohibition of Genetic Intervention Law (1999); (Five-year moratorium; ad 2004); Bioethics Advisory Committee of the Israel Academy of Sciences and Humanities (Section B – surplus embryos only)
Japan	N	Y	Y	Y	The Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques (Art.3) (Surplus and created embryos. Subject to licence)
United Kingdom	N	Y	Y	Y	Human Reproductive Cloning Act 2001 (extends to Northern Ireland); Human Embryology & Fertilisation Act 1990 (Subject to licence)
United States	N	N	Y	Y	No federal funds for embryo research nor for creation of stem cell lines after August 9, 2001

As this selective table of international positions illustrates, there is an emerging consensus on the use of human embryos for research. Only human reproductive cloning attracts a common prohibition. Therapeutic cloning, involving as it does the deliberate creation of embryos for research, is also subject to general prohibition except in Japan and the United Kingdom. Moreover, the use of surplus embryos for therapeutic cloning is permitted in Israel. It should be noted that in the absence of a specific legal prohibition of the creation of embryos for research, countries having only general embryonic research guidelines that do not explicitly exclude such therapeutic cloning, could also technically permit it. Furthermore, those countries which permit embryo research generally would not preclude stem cell research on surplus embryos (Austria, Canada, France, Israel, Japan, UK, USA). Finally, total prohibition of any embryo research (Germany) or the complete prohibition of federal funding (USA) does not prevent these countries from importing (Germany USA) or using (USA) stem lines developed prior to a certain date. Generally, most countries require that such research be performed in licensed centres and approved on a project-by-project basis.

High School Students Debate Stem Cells

“The word ‘urgency’ is often associated with medical science,” says Erin McFadden, “because scientists sometimes promise breakthrough technologies and medical treatments. But we need to stop and reflect on what we are doing because it will change the shape of the world in the future.”

In the summer of 2002, Erin McFadden and Erin Court, two high school students funded through the Ontario Genomics Institute summer student program, worked with Shauna Nast, a research assistant at the University of Toronto Joint Centre for Bioethics, on a stem cell teaching module for high schools.

A module is a self-contained teaching unit that can be inserted into the curriculum. The stem cell module takes four days to complete and contains relevant supporting documentation. “In the development of the module,” says Ms. Nast, “we consulted with three high school teachers – at Upper Canada College, a private boys’ school, Branksome Hall, a private girls’ school, and Harbord Collegiate, an inner-city public school – and they were very enthusiastic.”

The stem cell module contains basic information on the science of stem cells, the regulatory environment in different countries and the ethics of stem cells. For example, it introduces students to the science, ethics and legislation of stem cells; defines stem cells; explains the difference between embryonic and adult stem cells; looks at why there is such controversy on the issue; examines the sources of embryonic stem cells; examines cloning; and then opens an ethical debate on the issues.



From left to right: Erin Court, Anisa Mnyusiwalla and Erin McFadden

“We show different sides and do not try to reach a consensus,” says Ms. Nast. “We explain what is being said and we do not try to resolve issues. The role-playing mimics the process the Canadian government used to develop stem cell draft legislation. We start with a student committee of five to seven members, and this committee will draft the legislation. The rest of the class is divided into four stakeholder groups. These groups inform the committee about their perspectives: patient organizations, scientists, industry and an interfaith group representing four religious perspectives – Catholic, Protestant, Jewish and Muslim.”

Four potential stem cell activities are debated, and high school students are then asked to decide whether these four activities should be permitted, prohibited or controlled (i.e., allowed but restricted) – and in what circumstances.

Then the committee redrafts legislation, deciding what should be done, engages in consensus building and ultimately votes on the legislation as a committee. Finally, the teacher wraps up the four-day module by comparing what the students have decided with Canada’s draft legislation.

“My main hope,” says Ms. Court, “is that the module is interesting and enjoyable for high school students. It is a great feeling to be able to design a module coming right out of high school. I think the whole role-playing is a key aspect of the projects, since textbooks are very bland. The interaction makes learning much more interesting.”

... continued on page 9

Democracy, Ethics and Genomics: Consultation, Deliberation and Modeling

Project Leader:
Michael Burgess
University of British Columbia
Vancouver, BC

Genomic research and its potential commercialization raise public hopes for its future application and concerns over its appropriateness and regulation. Consequently, if Canada is to determine policy and support research that is in the public interest, those mandated with the oversight of genomic research and its products must find ways of involving the public in discussions about ethical, environmental, economic, legal and social issues. These methods of involvement must meet the democratic values of representation, transparency and accountability.

The objective of *Democracy, Ethics and Genomics: Consultation, Deliberation and Modeling* is to develop a defensible methodological framework within which government, industry and other parties can conduct defensible consultation processes. Led by Dr. Michael Burgess, Chair of Bioethics at the University of British Columbia's Centre for Applied Ethics, the project is designed to take advantage of the Centre faculty's diverse expertise by bringing together three research streams – consultation, deliberation and computer-based modeling. The process, which will involve groups with no experience with genomics research, those with limited experience and those with direct personal, political, professional or financial interests, including biotechnology companies, genome researchers and activists, is being done in collaboration with Canadian and international researchers and GE³LS components of Genome Prairie, the Ontario Genomics Institute and Génome Québec, as well as a private sector consultation company.

The co-investigators within the three research streams are :

Consultation: Michael Burgess, Ph.D., Chair in Biomedical Ethics and Professor in Medical Genetics; Michael McDonald, Ph.D., former Director of the Centre for Applied Ethics and Maurice Young Chair of Applied Ethics; Susan M. Cox, Ph.D. (Sociology), Research Associate, Centre for Applied Ethics; Conrad Brunk, Ph.D.

(Philosophy), Professor and Director of the Centre for Studies in Religion and Society, University of Victoria; Ben Koop, Ph.D., Professor and Head of Biology at the University of Victoria, Acting Director of the Centre for Environmental Health, and Co-director with W. Davidson of the Genome BC Research Project on Atlantic Salmon.

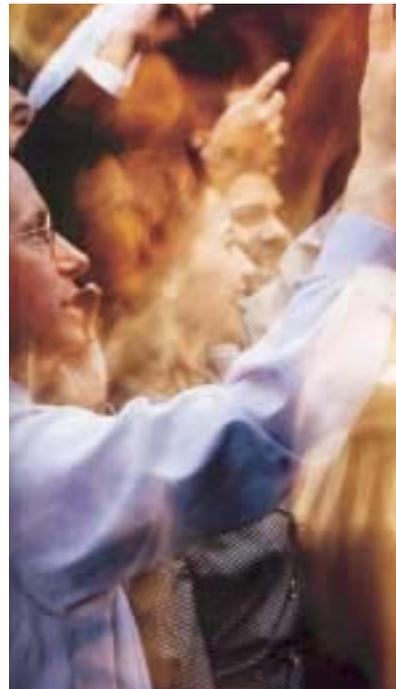
Deliberation: Wayne Norman, Ph.D., Chair in Business Ethics, and Associate Professor in the Faculty of Commerce.

Modeling: Peter Danielson, Ph.D., Director and Mary & Maurice Young Professor of Applied Ethics.

The extended research team includes collaborators from across Canada, the United States, the United Kingdom, Australia and New Zealand. In British Columbia, collaborators will ensure identification of interests and concerns relevant to Genome BC and identify appropriate participants, experts and representative advisors. They will collaborate with visiting faculty and in workshops, and some will participate in research team meetings.

The research team also includes a public consultation company – Praxis Inc. – and Brewster Kneen, an experienced activist and author, as collaborators.

While the primary objectives of this project are to develop a defensible consultation methodology and to recommend appropriate processes and criteria for the democratic governance of genomics in relation to ethical, environmental, economic, legal and social issues, the project does have significant secondary objectives. These include providing other GE³LS components in Genome Canada, and science projects at Genome BC, Genome Prairie, the Ontario Genomics Institute and Génome Québec with a list of concerns raised by participating groups. The project team will also make recommendations for enhanced communications between public groups, researchers and funding agencies and enhancing public education.▶



The project is designed to take advantage of the Centre faculty's diverse expertise by bringing together three research streams – consultation, deliberation and computer-based modeling.



Canadian Program on Genomics and Global Health

Project Leader:
Dr. Peter Singer
University of Toronto
Toronto, Ontario

W“We want to be a spark, a crystal. We want to distil knowledge that can make a difference,” says Dr. Peter Singer, of the University of Toronto.

Genomics – the study of genes and their functions – has grown into a technological wave in recent years. It has opened up understanding of the molecular mechanisms of disease, revealing thousands of new biological targets for drug development, which may in turn bring about a revolution in health care.

“The challenge,” in the words of Dr. Singer, “is to harness this genomics technological wave, to improve health in developing countries, to sustain development there, and to do it in an ethical way.”

Dr. Singer and colleagues Dr. Abdallah Daar and Dr. Trudo Lemmens from the University of Toronto, and Dr. David Castle from the University of Guelph, are co-project leaders of the *Canadian Program on Genomics and Global Health*, a large-scale research project which is part of Genome Canada’s Genomics, Ethical, Environmental, Economic, Legal and Social Issues (GE³LS) program. The project is funded through the Ontario Genomics Institute and by Genome Canada, which is leading a national strategy on genomics, with \$300 million in federal funding. Co-funders of this project include the Ontario Research and Development Challenge Fund, the University of Toronto, Sun Life Assurance, GlaxoSmithKline and Merck & Co.

The *Canadian Program on Genomics and Global Health* (CPGGH) analyzes the social implications of advances in genomics/biotechnology in order to identify problems associated with these advances at an early stage of their development. “Identifying problems early on gives stakeholders the opportunity to address them,” says Dr. Singer. “Advances in genomics/biotechnology can then be applied in a manner that maximizes their global benefits and minimizes their risks.”

CPGGH has created an innovative process for conducting interdisciplinary research on ethical, environmental, economic, legal and social issues, in order to focus on global health, engage industry and promote dialogue and consensus building before the introduction of new technologies. The program focuses on several areas. One area is the genomics policies of governments in developing countries. According to Dr. Singer, “Cuba is a country that is doing well in genomics, with limited resources. Brazil, China, India, Egypt and South Africa are others. We want to learn what these countries have done right to stimulate biotech

industries, and also to understand how products of local biotech industries can be harnessed to local health problems.”

Dr. Castle and Dr. Daar’s research teams will also explore the use of plant vaccines, nutrients and drugs. For example, it may be possible to develop a banana, which would contain a vaccine for cholera. The vaccine could be extracted once the banana ripened and then be administered to infants at risk of infectious disease. This would be of practical benefit in many developing countries where transport, storage and, if necessary, refrigeration of medical supplies can be problematic. In addition, the team will investigate the ethical impacts of the introduction of genetically modified animals to the food system.

Dr. Lemmens and his team will conduct an analysis of international and comparative perspectives on the regulation of genomics research. The project will address issues of intellectual property as well.

According to the co-project leaders, health in developing countries has not been well served by the “let the market decide” approach. Several market failures involving pharmaceutical companies have had serious consequences on health equity. The motivation behind the project is to set the agenda, get people to think about genomics and help develop ideas that people can then implement.

“The potential of genomics is not only in Toronto and New York, but also in New Delhi, Johannesburg and Santiago,” says Dr. Singer. “If you are interested not in abstract theorizing but real change, then you need all the parties at the table.”

“We sense a real leadership role for Canada in genomics globally. As the world’s leading genomics diplomat, Canada can harness genomics for development, assist developing countries build up genomics, and help biotechnology improve health.”



“We sense a real leadership role for Canada in genomics globally. As the world’s leading genome diplomat, Canada can harness genomics for development, assist developing countries build up genomics and help biotech companies improve health.”

Dr. Peter Singer



Bridging the Emerging Genomics Divide

“There are stunning inequities in health in developing countries,” says Dr. Peter Singer of the University of Toronto. “We are opposed to the genomics divide because it is something we can still prevent. We are at the very beginnings of the genomics revolution in health. If genomics is only used to make designer medicines in developed countries, and not address HIV/AIDS, malaria and the burden of disease in developing countries, then it will perpetuate and even worsen global health inequities. This is among the most important ethical challenges in the world today.”

Dr. Singer and his colleagues, Dr. Abdallah Daar and Dr. David Castle, are co-project leaders of *Bridging the Emerging Genomics Divide*, a large-scale research project funded through the Ontario Genomics Institute, by Genome Canada. Co-funders on this project include: the International Development Research Centre, the Indian Council for Medical Research, the Food Systems Biotechnology Centre and Communications Network, NIH, Merck & Co, the University of Toronto and the University of Guelph.

“Our project has a very broad focus,” says Dr. Castle. “It seeks a convergence in genomics, ethical, economic, environmental, legal and social research across health, nutrition, agricultural and environmental applications of genomics and biotechnology.”

“Until now, medicine has dealt with symptoms,” says Dr. Daar. “Genomics is drilling down to the roots of disease, leading the way to drugs which are safer and more reliable. Genomics will make it possible to deliver and administer more powerful and effective treatments and vaccines at a lower cost.”

But, according to the World Health Organization’s *Genomics and World Health* report, “the capacity for genomics research and downstream biotechnology varies enormously between countries and, if uncorrected, this situation will undoubtedly exacerbate existing inequalities in health.”

Drs. Singer, Daar and Castle share WHO’s view that a genomics divide is beginning to deepen between developed and developing countries – much the way the digital divide, in the realm of computers, created huge information technology disparities, beginning in the 1970s, between the First and Third Worlds. “We will be conducting research to ensure that the benefits of the unfolding revolution in health and nutrition genomics and biotechnology, which encompasses health and agri-

culture, are available to all,” says Dr. Castle. The Joint Centre for Bioethics was recently named the world’s first WHO Collaborating Centre for Bioethics in over a decade.

Bridging the Emerging Genomics Divide will study the ethical strategies of multinational pharmaceutical and biotech companies and make recommendations for good practices. According to Dr. Singer, “Industry is a key player in genomics, in developed and developing countries. There are good examples of good practices of some companies. We want to study these practices, to see what a code might look like.” The researchers will also be involved in developing ethical frameworks for genomics as applied to nutrition or nutrigenomics. “This is an emerging science that blurs the traditional distinctions among agriculture, medicine and nutritional science,” says Dr. Castle. “Nutrigenomics offers the potential to enhance health and nutrition. But there are several ethical concerns that arise in anticipation of nutrigenomics,” he adds. Exploring and addressing these concerns is part of the project.

In addition, the team will study *enviropigs* which produce manure that contains less phosphorus, making the pigs more environmentally friendly. They will also look at ethics, consumer concerns, public reaction and other related issues.

A key component of this project is capacity building in developing countries, where the base of genomics expertise will be broadened. “We will conduct five executive courses on genomics and public health policy where opinion leaders from academia, industry, NGOs, government and the media can meet and exchange views,” says Dr. Singer. The first executive development course was held in March 2002 in Nairobi, with attendees from science and technology ministries, the health sector and the media in nine different African countries. A second executive development course was offered at the Rotman School of Management in Toronto, in May 2002.

Finally, the project will lay the ground for creation of a Commission on Genomics and Global Health. This important Canadian initiative, led by Elizabeth Dowdeswell, who is the former director of the UN Environment Program and Undersecretary General of the United Nations, could provide the international community with an institution for developing collective approaches to complex genomics issues. Such an initiative is highly strategic, given the growing importance of genomics for many developing countries.



“This is an emerging science that blurs the traditional distinctions among agriculture, medicine and nutritional science. Nutrigenomics offers the potential to enhance health and nutrition. But there are several ethical concerns that arise in anticipation of nutrigenomics.”

Dr. David Castle

“Innovation is good domestic policy as the innovation agenda shows. It is also good for Canada’s foreign policy,” says Dr. Singer.

“The applications of genomics to global health is not a panacea,” says Dr. Daar. “But before Genome Canada came along, no organized group in the world has pushed this theme forward as an action item.”

« excédentaires » dans les cliniques de fécondation *in vitro* (si, afin de procréer, un couple a recours à la fécondation *in vitro*, et si plus d'embryons sont créés que le couple n'en désire, est-il acceptable d'utiliser les cellules souches prélevées des embryons excédentaires?); l'utilisation d'embryons créés délibérément par la fécondation *in vitro* dans le but de récolter des cellules souches embryonnaires; et le clonage thérapeutique (le transfert cellulaire somatique, qui sert à transformer une cellule somatique en état embryonnaire).

D'après le *U.S. Committee on the Biological and Biomedical Applications of Stem Cell Research*, « la recherche sur les cellules souches affectera possiblement la vie de millions de personnes aux États-Unis et à travers le monde. Elle fait régulièrement les manchettes à cause de la controverse entourant le prélèvement des cellules souches d'embryons humains. Si nous voulons que les cellules souches ouvrent la voie à de nouvelles thérapies médicales, nous allons devoir nous interroger sur

bien plus que des incertitudes scientifiques. En effet, le débat entourant les cellules souches a obligé scientifiques et non-scientifiques à s'interroger sur des enjeux profonds, tels : qui sommes-nous et en quoi réside notre humanité? »

In Canada, research into stem cells is being undertaken by organizations such as the federally funded Stem Cell Network, which includes more than 50 leading scientists, clinicians, engineers, and ethicists. The network has the mandate "to investigate the immense therapeutic potential of stem cells for the treatment of diseases currently incurable by conventional approaches. The Network brings together experts from all sectors and backgrounds, to share and build on their experiences and ideas, and to work together to achieve the following Network goals: to be a catalyst for development of new therapies for a wide variety of chronic degenerative diseases; to create a critical mass of knowledge and people in Canada by contributing to the training and education of specialists in stem cells; to facilitate the transfer of technologies to the marketplace; and to promote informed debate on the source and use of stem cells."

Genome Canada is also supporting work on the ethical and legal implications of stem cell research. For example, Dr. Bartha Maria Knoppers, project leader of *Genomics in Society: Responsibilities and Rights*, and Marie-Hélène Régnier are undertaking research on legislation in

ten countries with respect to reproductive cloning, therapeutic cloning, embryo research and stem cell research (see table on page 4). As part of Dr. Peter Singer's project, *Canadian Program on Genomics and Global Health*, Dr. Rosario Isasi at the University of Toronto Joint Centre for Bioethics is making an international comparative study of stem cell research. Dr. Isasi, a post-doctoral fellow, previously worked on the United Nations' reproductive cloning ban.

Moreover, the *Stem Cell Genomics Project* at the Ottawa Health Research Institute (project leader: Dr. Michael Rudnicki) will investigate the genes in mice and humans that determine the identity of stem cells and their ability to replace other tissues. The team will look for similarities and differences in mouse and human embryonic and in adult stem cells. "We know that stem cells exist," Dr. Rudnicki says, "but we don't know what makes them tick. We want to look at the genes that are expressed, and that are restricted to particular lineages. By performing a genomic comparison of the various types of stem cells, we can subtract the housekeeping functions of these cells and look for genes and pathways that are unique to stem cells."

Until early 2002, Canada lacked detailed research guidelines and legislation dealing adequately with the issues. And the issues are complex, since they involve: the potential of medical science to treat and cure disease and improve quality of life for millions of people; the research community's determination to undertake original work of benefit to Canadians that is also competitive internationally; the interests of industry; the standards of Canada's communities, as well as cherished values about the nature of life; the possibilities and limits of scientific interventions, and what ought to be done with embryonic cells and tissues.

En mars 2002, les Instituts de recherche en santé du Canada ont rendu publiques des lignes directrices. À cette époque, Tim Caulfield, professeur de droit de la santé à l'université d'Alberta – et qui a fait partie du Groupe de travail spécial des IRSC sur la recherche sur les cellules souches – a dit que « ces lignes directrices autoriseront plus de recherche qu'on en fait aux États-Unis, mais moins qu'au Royaume-Uni. Les lignes directrices établissent quatre règles : les chercheurs doivent utiliser des lignées de cellules souches embryonnaires pré-existantes; ils doivent utiliser des embryons qui ont été créés à l'origine à des fins de reproduction et dont on ne veut plus; les personnes pour lesquelles les embryons *in vitro* ont été créés doivent donner au départ leur consentement libre et éclairé pour que ces embryons soient utilisés à des fins de recherche; les embryons eux-mêmes ne doivent pas être obtenus à la suite de transactions commerciales ».



The Canadian Institutes of Health Research guidelines prohibit growing embryos solely for research, as well as the insertion of a person's DNA into a stem cell (by means of therapeutic cloning or somatic cell transfer). But these guidelines raised concerns among a number of MPs, who considered that CIHR had pre-empted the parliamentary process, since government had not yet introduced its legislation. Draft legislation tabled in May 2002 allows embryonic stem cell research, but certain conditions must be met, such as: no human clone can be created or transplanted, the embryo must be created for the purposes of human reproduction, written consent from the donor must be obtained – in accordance with regulations, and no payment or consideration may be made to the person donating the embryo. This bill would ensure that only stem cells from surplus embryos are used. Until Canadian legislation is adopted, Genome Canada's research projects have to follow the CIHR guidelines where research on stem cells is concerned.

In an op-ed article on stem cell research that appeared in *The Globe and Mail* in early May 2002, Professor Caulfield, Dr. Singer, Dr. Daar and Dr. Knoppers stated, "The politicization of stem-cell research in Canada is unfortunate, not only for Canada but also for the world. Canada is well placed to stand as an international leader in both the science and regulation of stem-cell research. We have leading-edge stem-cell researchers poised to make scientific breakthroughs that could save lives and improve the quality of life for thousands of Canadians and people around the world. In world-class science, delaying a year is like delaying a lifetime. As one of the last Western countries to legislate in the area, Canada can learn from the mistakes of others and produce a regulatory system that could be a model for the world."

Moreover, they wrote, "One gets the impression that, to some degree, the politicians attacking the CIHR guidelines and the timing of their release are removed from the true public mood. There's no doubt that a minority of Canadians have very strong views about stem-cell research involving human embryos, and these views must be respected. However, surveys have consistently shown strong public support for stem-cell research. In March 2002, a poll done by Environics found that 76 percent of Canadians approve of embryonic stem-cell research."

Prof. Caulfield's current work focuses on how best to regulate this complex area. For example, he says, "given that there is little or no consensus within the public or even among the academic community, what role should 'social consensus' play in the development of regulatory policy? Moreover, many policy entities, such as the Canadian Bar Association and the US Hastings Center, have

recommended a flexible regulatory approach to the area. But how can we ensure that such a regime is democratically accountable?" Regulatory issues associated with Bill C-56 were addressed at a September 21st 2002 workshop involving several Genome Canada researchers. Results of the workshop will be published in a special issue of the *Health Law Review* and distributed to key policy makers, including the Standing Committee on Health.

The issues at stake are very difficult. According to Dr. Rudnicki, "there is a consensus that the practice of medicine in the next century will become regenerative medicine. By understanding the genes that control regenerative cells, we may be able to harness the power of these cells to help humans regenerate."

That is why Canadians need access to objective information about the science and ethics of stem cell research. They should also be invited to think about the possible benefits of stem cell research, as well as the costs. Public consultations will require careful articulation of various stakeholder positions, as well as community and religious values, so that judicious decisions can be made about the future of embryonic stem cell research in Canada. Genome Canada's GE³LS projects are contributing to public consultation by examining ways to engage the public, articulate positions, and make decisions in a way that is democratic, transparent, evidence-based and grounded in respect for values.

Voilà pourquoi les Canadiens ont besoin d'accès à de l'information objective au sujet des enjeux scientifiques et éthiques soulevés par la recherche sur les cellules souches. Il faudrait encourager les Canadiens à réfléchir aux retombées potentielles et aux coûts éventuels de la recherche sur les cellules souches. Les projets GE³DS de Génome Canada contribuent à cette consultation publique en explorant les moyens d'engager le public, d'articuler des positions et de prendre des décisions, de façon à respecter à la fois les données scientifiques et les valeurs, dans un contexte de démocratie et de transparence. ▀



High School Students Debate Stem Cells

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According to Ms. McFadden, doing the module was a learning experience in itself. "I guess it is a lot harder being a teacher than you think. I also learned there are many perspectives and there is much more to each perspective, and you can't classify perspectives easily. There are so many issues out there, and they involve people's values and choices."

The stem cell module will be piloted in Toronto-area schools in the fall of 2002. According to Dr. Peter Singer at the University of Toronto Joint Centre for Bioethics, modules on other technologies could follow in years to come, if everything works out well. ▀

Genomics in Society: Responsibilities and Rights



Standing, left to right:
Thérèse Leroux, Susan Phillips-
Nootens, Hubert Doucet, Kathleen C.
Glass, Bruno Leclerc, Lyne Létourneau.
Front row, left to right:
Marcel Mélançon, Béatrice Godard,
Bartha Maria Knoppers, Liane
Bélanger.
Not in this photo:
Marie-Hélène Parizeau and Marc-André
Sirard

“What I like about Génome Québec is that it crosses the whole genome – not only the human genome, but also other genomes as well, such as plants and animals – and finally situates them in the environment.”

Bartha Maria Knoppers

“I find it very interesting to be at the leading edge of thinking about emerging technologies,” says Dr. Bartha Maria Knoppers, a law professor specializing in the human genome at the Université de Montréal, and who chairs the ethics committee of the Human Genome Organization worldwide. “Every time a new technology is on the horizon, there is either a great fascination or there is fear that the technology may have unforeseen effects. A lot of what we do is to project into the future, by extrapolating from what is known.”

Dr. Knoppers is principal investigator of *Genomics in Society: Responsibilities and Rights*, a multidisciplinary research project involving six universities in Québec, on behalf of Génome Québec’s program on ethical, economic, environmental, legal and social issues related to genomics (GE³LS) program. The project is supported by Génome Québec (Ministère de la Recherche, Science et Technologie) and Genome Canada, which is leading a national strategy on genomics, with \$300 million in federal funding. Génome Québec’s mission is to make Québec one of the ten most important centres for genomics and proteomics research in the world.

The project led by Dr. Knoppers will analyze the rights and responsibilities of researchers and address the issues of population research and professional accountability in the collection, use, transfer and protection of genetic information. It will explore a series of vital questions concerning genetic information about regional populations, communities and families.

Questions such as: How can the sampling and banking of DNA be standardized and harmonized? How can the confidentiality both of individuals and communities be safeguarded? How can professional responsibility issues be resolved, with respect to reproductive counselling, confidentiality and communication with the public? Is it possible to develop mechanisms to oversee genomic research?

Genomics in Society will take into consideration the power of genomic techniques to transform already existing relationships in Nature. It will address the differences between the utilitarian approach to genomics and approaches grounded in diverse cultural and religious values. And it will explore social attitudes on what is “natural,” how species are defined and how the diversity of plants and animals can be protected.

The project will have conceptual as well as infrastructure outcomes. At the conceptual level, the GE³LS team will analyze professional standards, including standards for basic scientists, as well as issues of cultural and religious diversity and ethical and legal issues arising from the creation of biobanks.

At the infrastructure level, the GE³LS team will create platforms of well-documented and easily accessible information drawn from a wide range of sources.

The infrastructure platforms will include development of HumGen, an international resource on ethical statements around the world; TransGen, a resource on questions related to the genetic manipulation of plants and animals; the third will be a proactive rapid action think tank mandated to respond to the concerns of policy makers; and the last will involve public consultation.

Génome Québec is unique among funding agencies around the world, in integrating ethical issues and social impacts into the work even of basic scientists.

“What I like about Génome Québec,” says Dr. Knoppers, “is that it crosses the whole genome – not only the human genome, but also other genomes as well, such as plants and animals – and finally situates them in the environment.”

Ethical issues are very much a part of genomic research, she says: “Many people think ethics and social impacts have to do with problems. Actually, the collective human genome and individual human genome, as part of our human patrimony, are reviving the importance of fundamental philosophical issues.”



La génomique dans la société : responsabilités et droits

... suite de la page 1

Le projet dirigé par le professeur Knoppers analysera les droits et responsabilités des chercheurs et abordera les enjeux de la recherche sur la population ainsi que sur la transparence professionnelle entourant la collecte, l'utilisation, le transfert et la protection de l'information génétique. Il soulèvera par ailleurs toute une série de questions importantes au sujet de l'information génétique concernant les populations régionales, les communautés et les familles.

Des questions telles que : comment normaliser et harmoniser l'échantillonnage et les banques de données de l'ADN? Comment sauvegarder la confidentialité des individus et des communautés? Comment régler les enjeux de la responsabilité professionnelle dans les domaines de l'orientation concernant la reproduction, la confidentialité, la communication avec le public? Est-il possible de développer des mécanismes de surveillance de toute la recherche en génomique?

La génomique dans la société prendra en considération la grande capacité des techniques génomiques de transformer les rapports existant dans la nature. Il abordera différentes approches à la génomique, allant de l'approche utilitaire aux approches fondées sur diverses valeurs culturelles et religieuses. Il s'étendra ensuite sur les perceptions de ce qui est « naturel », sur la façon de définir les espèces et sur la meilleure manière de protéger la diversité des plantes et des animaux.

Le projet visera deux sortes d'objectifs, au niveau des concepts et des infrastructures. Au niveau conceptuel, l'équipe de recherche analysera les normes socio-éthiques, légales et professionnelles, y compris les normes pour la recherche fondamentale,

de même que les enjeux déontologiques et juridiques entourant la création des banques de données.

Au niveau des infrastructures, l'équipe de recherche créera quatre plateformes.

La plateforme HumGen comprendra le développement d'une ressource internationale réunissant des politiques et énoncés à travers le monde sur ces questions; la deuxième sera TransGen, une ressource traitant des questions qui entourent la manipulation génétique des plantes et des animaux; la troisième sera un groupe de réflexion proactif incluant une équipe d'intervention ayant le mandat de répondre aux préoccupations des gouvernements; et la dernière prévoit la consultation publique.

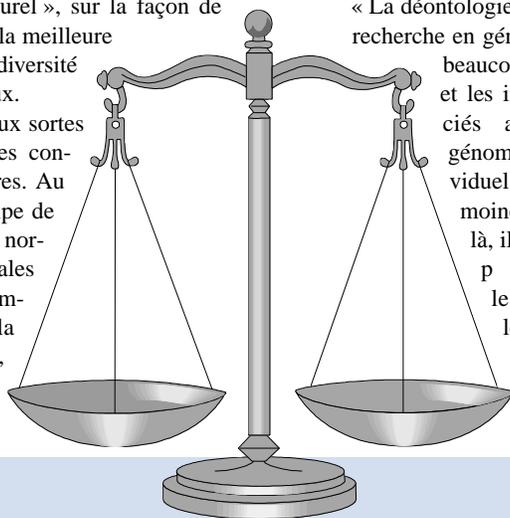
Génome Québec est une société unique de financement qui intègre les enjeux déontologiques et les impacts sociaux dans le travail même de la recherche fondamentale.

« Ce que j'aime chez Génome Québec », dit le professeur Knoppers, « c'est le fait que l'agence s'intéresse au génome entier – non seulement au génome humain, mais aussi bien aux génomes des plantes et des animaux. »

« La déontologie fait partie intégrante de la recherche en génomique », dit-elle. « Pour

beaucoup de gens, la déontologie et les impacts sociaux sont associés aux problèmes. Or, le génome humain collectif et individuel fait partie de notre patrimoine humain et dans ce sens-là, il suscite un regain d'intérêt pour les enjeux philosophiques les plus fondamentaux. »

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Bartha Maria Knoppers

Commercialization and Society: its Policy and Strategic Implications

Project Leaders:
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Front row, left to right:
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Back row, left to right:
Tim Caulfield, Health Law Institute, University of Alberta;
Peter Phillips, Agriculture Economics, University of Saskatchewan.

The science of genomics is essentially aimed at deciphering and understanding the entire genetic information content of an organism and finding applications for this information.

The overall theme for this project is commercialization and society and its policy and strategic implications. The project will map the development of controversial biotechnology applications from initial research to commercialization and will examine the factors that contribute to public controversy.

The researchers will analyze the nature and source of socio-political concerns associated with the commercialization of genomics technologies and attempt to improve the understanding of how the transmission of information affects consumer behaviour relative to genomics technology.

The science of genomics is essentially aimed at deciphering and understanding the entire genetic information content of an organism and finding applications for this information. This research offers revolutionary scientific advances that are already radically altering the structure and output of the agricultural, food, forestry, fishing, environmental and health care sectors in Canada and elsewhere. At the same time, this research raises a number of ethical, environmental, economic, social and legal challenges, some of which have aroused considerable public concern and continue to pose major policy challenges. The nature of these social concerns, the institutional responses, and the structures and processes for managing the innovation process are the focus of the Genomics, Ethical, Environmental, Economic, Legal and Social Studies (GE³LS) research program.

With the completion of the human genome project, prenatal, neonatal, and presymptomatic testing will be extended to completely new orders of magnitude. The challenges of privacy, confidentiality and discrimination can be enormous. When genes are identified for a specific disease, how should patenting issues be addressed? What information should be in the public domain? When animals are genetically engineered to produce vaccines, tissues or organs for human use, what socio-ethical issues are implicated and addressed? What accounts for the international concerns over genetically engineered food and how have policy bodies responded? Will private intellectual property rights exclude public R&D projects and new market entrants in the crop sector? These are some of the myriad social, organizational and policy questions raised by genomics.

Despite these issues, it is clear that genomics can be the basis for improved quality of life, for a more sustainable environment, and for wealth cre-

ation. In Canada, the state has staked a claim to genomics as part of a national program of innovation. It has encouraged collaborations between universities, industry, and the public sector, and provided research and development financing and incentives. At the same time that the state promotes, the state also protects. Its regulatory standards are designed to ensure products are safe, but also to accommodate the need for an economically viable as well as environmentally sustainable set of products or processes. Sometimes, this balance is a precarious one. Here, there are important social, political, economic and managerial questions as well. How are risks assessed? What standards are used and how are these applied? Is information for citizens available, accessible, and adequate? What mechanisms are available for publics to be consulted or to participate in major decisions? What processes or mechanisms are used for the accommodation of social values?

It is questions such as these that the GE³LS research program is designed to address. In addition, for the Genome Prairie (GP) GE³LS program in particular, the Centre's focus on both agricultural and biomedical sectors offers unique challenges and opportunities. Already, there are examples where these two sectors are converging (growing plants for vaccine production, using livestock such as pigs for transplant organ production). The public policy and social questions posed across both agricultural and medical sectors will be the focus of GP GE³LS.

The program goals of the project are: to advance the development and application of the bodies of theories and methodologies associated with genomics commercialization; to develop a pool of research personnel trained in interdisciplinary Genomics-and-Society issues and approaches; to develop social research relevant to policy needs and interests; and to address social issues arising from the specific Genome Prairie science initiatives.

Specific research objectives are: to investigate public and institutional responses to genomics issues; and to investigate the organizational and public policy structures and processes that influence genomics innovation.▶

