HumGen GenInfo
A Newsletter on the Socio-Ethical and Legal Issues in Human Genetics
May-June 2004

Close

Yann Joly
Editor

In this summer edition of GenInfo there are many references to the notion of "genetic discrimination", whether it be related to insurance, employment or used in its broader context. Although there is a lack of statistical data demonstrating the presence of such discrimination in Canada, there exists real public concern regarding genetic progress which may hinder genetic research. Taking this into consideration, the *Canadian Genetics and Life Insurance Task Force* has written an important document entitled, "*Genetics and life insurance in Canada: points to consider*", which addresses Canadian policy makers and insurers. I invite you to consult this document along with the other articles pertaining to this topic in this edition of GenInfo. I hope your readings will give you a better understanding of the issues relating to discrimination and genetics.

To be available in the near future, two new modules of HumGen :
GenConsult: GenConsult is both a source of information and documentation as well as a virtual forum to discuss the social, ethical and legal issues concerning applied genomics. This site addresses in particular graduate students and researchers interested in the social, ethical and legal issues raised by genomics and its applications.
IPGen: The IPGen module addresses questions concerning intellectual property and human genetics. In addition to presenting the latest work produced by members of McGill University's *Centre for Intellectual Property Policy* (CIPP), this module will also consist of a bibliography of guidelines and literature pertaining to different domains in intellectual property (ex. property, commercialization, benefit sharing, patents, copyright, etc.)

NEWS

The News section of GenInfo provides a brief listing of events that will be held in the coming year which are organized by our team or linked organizations. We are also pleased to include a publications section with a summary of all books, articles and editorials published by members of our team.

EVENTS

MAY 2004

La génomique et l'industrie des biotechnologies (as part of the **Genomics and Public Health** conference series)
Date : May 5, 2004 at 12pm
Location : University of Montreal, Faculty of Law
Host : *Canada Research Chair in Law and Medicine*
Description : Guest speaker: Claude Laberge, M.D., Ph.D., Professor of Medicine and Paediatrics from the Faculty of Medicine, University of Laval, and Director of the Quebec Network of Applied Genetic Medicine (RMGA). This conference is open to the public.
For additional information visit : http://www.crcdm.umontreal.ca

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Les multiples visages de la bioéthique
Date : May 6 & 7, 2004
Location : University of Montreal, Faculty of Law
Host : *Groupe de recherche en bioéthique (GREB)*
Description : Three different aspects of ethics will be put into perspective: clinical ethics, research ethics, and health policy ethics.
For additional information visit : http://www.fes.umontreal.ca/bioethique

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Séminaire d'actualité du DIU de droit médical. Le respect du corps humain pendant la vie et après la mort.
Date : May 6 & 7, 2004 from 9:00am to 4:45pm
Location : Université Paul Sabatier de Toulouse, France
Host : *L'Institut International de Recherche en Éthique Biomédicale (IIREB)* et *Le Réseau Européen de Recherche en Droit Médical de L'ARFDM*
Description : Topics that will be discussed include: history of anatomy and the body, respect of the human body in the practice of bioethics in the context of cultural diversity, healing after death, access to tissue samples of deceased patients for human genetic research.
To register and for additional information contact: duquet.am@chu-toulouse.fr

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Le concept de responsabilité : vers une perspective de chercheurs en génomique. Conference : Le post humain en évolution naturelle ou programmée (organized as part of the **72ème congrès de l'ACFAS)**
Date : May 12, 2004 at 2:15pm
Location : Université du Québec à Montréal (UQÀM)
Host : *Association francophone pour le savoir (ACFAS)*
Description : The objective of this conference is to encourage a public debat concerning genomics, and in particular the responsibilities within this field.
For additional information visit : http://www.acfas.ca/congres/

Analyse de l'éthique de la génomique. Conference : La relève scientifique et les enjeux de la génomique. (organized as part of the **72ème congrès de l'ACFAS)**
Date : May 13, 2004 at 9:30am
Location : Université du Québec à Montréal (UQÀM)
Host : *Association francophone pour le savoir (ACFAS)*
For additional information visit : http://www.acfas.ca/congres/

Éthique et recherche qualitative dans le secteur de la santé : échanges sur les défis (organized as part of the **72ème congrès de l'ACFAS)**
Date : May 14, 2004 from 8:30am to 4:30pm
Location : Université du Québec à Montréal (UQÀM)
Host : *Axis 1 of the International Institute of Research in Ethics and Biomedicine (IIREB)*
Description : The objective of this conference is to discuss the problems which researchers and ethics committees face concerning current legislation in Canada (in particular the Tri-Council Policy Statement). International legislation will also be explored. The conference will encourage all participants to discuss their work along with their visions of the future of ethics.
For additional information visit : http://www.acfas.ca/

Premier rendez-vous de l'Association des chercheurs(es) professionnels(les) du Québec : " Naissance d'une profession : Forum sur l'identité et le rôle du chercheur professionnel " (organized as part of the **72ème congrès de l'ACFAS)**
Date : May 14, 2004 at 9:00am
Location : Université du Québec à Montréal (UQÀM)
Host : *Association des chercheurs(es) professionnels(les) du Québec (ACPQ)*
Description : Besides being the inaugral meeting for the ACPQ, this forum will serve to introduce the profession and to allow practitionners of all disciplines to familiarize, be informed, and to engage in debat concerning the position of professional researchers within Québec.
To register and for additional information contact: comite.fondateur@globetrotter.net

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Journées Génétiques : Who does What?
Date : May 17 & 18, 2004
Location : Omni Hotel, Montreal
Host : *Network of Applied Genetic Medicine (RMGA)*
Description : In order to further basic genetic research, the RMGA organizes bi-annual scientific meetings. These "Journées" are an occasion for Quebec researchers to present the latest developments in their research in human genetics.
For additional information visit : http://www.rmga.qc.ca/en/

One-day International Conference: Bioethics and Pharmacovigilance
Date : May 19, 2004
Location : Best-Western Hotel, Dorval, Quebec
Host : *Atlantic Life Sciences Inc. (ALS)*
Description : This forum is for everyone involved or interested in clinical studies, medical information, pharmacovigilance, pharmacoepidemiology and bioethics.
For additional information visit : http://www.alsclinic.com/english/event.html

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Genomics, Health and the Environment (as part of the **Genomics and Public Health** conference series)
Date : May 20, 2004 at 12pm
Location : University of Montreal, Faculty of Law
Host : *Canada Research Chair in Law and Medicine*
Description : Guest speaker: Laura Palazzani, Professor, Faculty of Law, LUMSA University, Rome. This conference is open to the public.
For additional information visit : http://www.crcdm.umontreal.ca

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SEPTEMBER 2004

La génomique et l'industrie des biotechnologies (as part of the **Genomics and Public Health** conference series)
Date : September 13, 2004 at 12pm
Location : University of Montreal, Faculty of Law
Host : *Canada Research Chair in Law and Medicine*
Description : Guest speaker: Grégory Bénichou, Professor in Ethics and Biotechnologies, ESSEC, France. This conference is open to the public.
For additional information visit : http://www.crcdm.umontreal.ca

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OCTOBER 2004

Dix-Septièmes Entretiens du Centre Jacques Cartier "Symposium on Oncogenetics : Achievements and Challenges"
Date : October 7 & 8, 2004
Location : Crowne Plaza, Montreal
Hosts :

- *Centre Jacques Cartier, Dix-septièmes entretiens*
- *The National Centre for Scientific Research(France)*
- *CIHR INHERIT BRCAs (Canadian Institutes of Health Research, Interdisciplinary Health Research International Team on Breast Cancer Susceptibility)*
- *Université de Montréal, Centre for Research in Public Law, Canada Research Chair in Law and Medecine*
- *Université Laval, Canada Research Chair in Oncogenetics*

Description : World experts will discuss the latest developments as well as achievements and challenges in cancer genetics. The topics will include genetic susceptibility to breast, ovarian, paediatric, gastro-intestinal cancers, as well as multiple endocrine neoplasia.
For additional information visit: http://www.humgen.umontreal.ca/CJC/

PUBLICATIONS

BOOKS

Rothstein M. A., *Genetics and Life Insurance : Medical Underwriting and Social Policy*, Cumberland, MIT Press, 2004.

ARTICLES

Knoppers B.M., et al. *Genetics and life insurance in Canada : points to consider*, CMAJ, Apr.27, 2004. Vol. 170 (9)
Abstract : Over the past year, insurers, patient advocates, researchers and/or clinicians involved in the Genetics and Society Project of the University of Montreal, Genome Canada projects (Quebec and Ontario) and in the INHERIT BRCAs Project (Interdisciplinary Health Research International Team on Breast Cancer Susceptibility, Canadian Institutes of Health Research) met as the Canadian Genetics and Life Insurance Task Force to further debate on genetics and life insurance in Canada.

Knoppers B.M., Joly Y., *Physicians, genetics and life insurance*, CMAJ, Apr. 27, 2004, Vol. 170(9)
Abstract : In contrast to the large number of European countries that have clarified their positions regarding the future of genetics and life insurance, Canada has yet to take a position. Any initiative in this regard should be based on an understanding of how life inusurance works, the nature of genetic information, the history of the debate on genetics and life insurance in Canada and the reasons why a Canadian task force decided to take up the challenge.

GENEDIT

The primay focus of the editorial GenEdit, which is exclusively written for HumGen, is to enhance our current understanding of policy statements related to human genetics through comparative legal, social and ethical analysis.

PAST ISSUES

Volume II No.1
Protecting Genetic Information: A Comparison of Normative Approaches
Patricia Kosseim, Martin Letendre and Bartha Maria Knoppers

Volume I No.1
Stem Cells in a Pluralistic Society: Consequences of Proposed Canadian Legislation
Dorothy C. Wertz, Marie-Hélène Régnier and Bartha Maria Knoppers

CURRENT ISSUE

Volume II No.2
Genetic and Life Insurance : A Comparative Analysis
Trudo Lemmens, Yann Joly, Bartha M. Knoppers

The debate surrounding the role of life insurance, the necessity of risk rating, and the notion of "acceptable discrimination" has raised questions about the larger social role of insurance. This debate has been exacerbated by the availability of an increasing number of genetic tests, allowing insurers to make use of genetic results as a new underwriting tool.
The article presents a comparative study of approaches adopted by different countries or organizations when faced with issues in genetics and life insurance. We analyze the position of 44 countries with regards to their potential for ensuring equitable access to life insurance.

NEW LAWS & POLICIES

The following section contains new policy (legal, ethical) statements on human genetics from international, regional and national sources.

We are constantly searching for documents to enrich our data bank. If your organisation has published policy statements relating to genetics, or if you are aware of such new publications, please be kind enough to send us the relevant information and we will consider including them in the data bank.

Australian Law Reform Commission (ALRC), *ALRC Discussion Paper, Gene Patenting and Human Health (DP 68),* Sydney, March 2004, http://www.austlii.edu.au/au/other/alrc/publications/dp/68/ (date accessed: April 8, 2004)

On December 4, 2002 the Australian Government announced that it would ask the Australian Law Reform Commission (ALRC) to conduct an Inquiry into intellectual property issues raised by genetic information. Soon afterwards, the Government released the Terms of Reference for the Inquiry, signalling the formal start of the Inquiry. The Government's media releases indicated that an examination of these issues was important because of the rapid advances in human genome research and genetic and related technologies.

This Discussion Paper considers ways to:
- establish an express defence of 'experimental use' in the Patents Act, to make clear that researchers are entitled to study and experiment upon a patented invention;
- provide rules for the patentability of inventions involving stem cells and stem cell technologies;
- develop policy on the circumstances in which it may be appropriate for the Australian Government to acquire a patent for the purposes of promoting human health under the 'Crown use' provisions of the Patents Act;
- develop policy on the circumstances in which the public interest would require the compulsory licensing of a patented genetic invention;
- deal with intellectual property rights in genetic research databases;
increase the capacity of patent examiners and the courts to scrutinise applications for gene patents;
- ensure patent applications are not overly broad—which can restrict other geneticists from pursuing particular lines of research;
- ensure that publicly funded research, where commercialised, results in appropriate benefits to the community;
- encourage universities and other publicly funded research institutions to raise the awareness of researchers about patenting issues and the commercialisation of research; -and apply competition law more fully and effectively to business practices involving patented genetic inventions, including through prices surveillance by the ACCC.

China/Government (Ministry of Science and Technology & Ministry of Health), *Ethical Guidelines for Research on Human Embryonic Stem Cells,* Beijing, January 2004, http://philosophyol.com/academy/ArticleShow.asp?ArticleID=23&ArticlePage=4 (date accessed: April 28, 2004)

The Ministry of Science and Technology and Ministry of Health issued the Ethical Guidelines for Research on Human Embryonic Stem Cells, the first time China has put out written policy on human cloning. The Chinese government has officially banned research on human cloning for procreation purposes, but allows therapeutic cloning.

Human Genetics Society of Australasia (HGSA), *Issue Paper 27: Intellectual Rights over Genetic Materials and Genetic and Related Technologies (Response from the Ethics and Social Issues Committee of the Human Genetics Society of Australasia to the Australian Law Reform Commission's Issue Paper),* Alexandra, 2004, http://www.hgsa.com.au/Pdf/HGSA%20response%20Sep03.pdf (date accessed: April 8, 2004).

In response to the ALRC Issue Paper "Gene Patenting and Human Health", the HGSA states that it believes the initial premise that DNA sequences may be patented is flawed.

There is a risk that past common law practice and precedent will be insufficient to address the challenges that medicine and (the new) genetics is now presenting. For this reason, the HGSA recommends the principle of patentability of the "normal" (consensus) human genetics sequences needs to be revisited. The preferred outcome is an acceptance of the principle of non-patentability of the consensus human genetic sequence and its naturally occurring variants and polymorphisms. However, if there is to be a reluctant acceptance that past patents granted on naturally occurring human genetic sequences cannot be annulled, then an acceptable outcome might be to address the significant specific negative health outcomes that might arise. The HGSA has prepared this response to the ALRC to highlight some of these potential health outcomes, present its concerns and to suggest possible solutions.

European Group on Ethics in Science and New Technologies to the European Commission (EGE), *Ethical Aspects of Umbilical Cord Blood Banking (Opinion No. 19),* Belgium, March 16, 2004, http://europa.eu.int/comm/european_group_ethics/docs/avis19_en.pdf (date accessed: April 8, 2004).

The European Group on Ethics in Science and New Technologies (EGE), has adopted on March 16th 2004 its Opinion no. 19 on the ethical aspects of umbilical cord blood banking. The EGE is an independent, multidisciplinary and pluralist instance, composed of twelve members. Its role is to advise the Commission on how the ethical values of the European society can be taken into consideration in the scientific and technological development promoted by Community policies.

Since 1988 umbilical cord blood cells are used for transplantation to treat patients with blood and immune disorders requiring a source of haematopoietic stem cells.Usually, cord blood is stored by public or non-profit banks which collect it from voluntary donors. Cord blood is therefore available for any patient in need, provided the HLA types of the donor and the recipient are compatible. The EGE is of the opinion that “support for public cord blood banks for allogeneic transplantations should be increased and long term functioning should be assured”.

The ethical implications of such cord blood banks are the same as for any tissue bank. In its previous opinion n° 11 on the ethical aspects of tissue banking, the Group underlined the values at stake: body integrity, respect of privacy and confidentiality of data, promotion of solidarity, fairness of access to healthcare and information and consent of the donors.

The is why the EGE is of the opinion that “the legitimacy of commercial cord blood banks for autologous use should be questioned as they sell a service which has presently no real use regarding therapeutic options”. This raises therefore serious ethical concerns.

Hastings Center and the American Association for the Advancement of Science, *Genetic Differences and Human Identities - On Why Talking about Behavioral Genetics Is Important and Difficult,* New York, January-February 2004, http://www.thehastingscenter.org/pdf/genetic_differences_and_human_identities.pdf (date accessed: April 16, 2004)

"Genetic Differences and Human Identities" is a special supplement in the January-February 2004 issue of the Hastings Center Report. It reviews the findings of the AAAS-The Hastings Center project that examined the science of behavioral genetics and the ethical issues raised by such research and its possible applications.

Canada/Government, *An Act Respecting Assisted Human Reproduction and Related Research (Bill C-6),* Ottawa, March 29, 2004, http://www.hc-sc.gc.ca/english/pdf/protection/ahr/C-6_4_RA.pdf (date accessed: April 16, 2004)

The Act Respecting Assisted Human Reproduction and Related Research prohibits human cloning and other unacceptable activities, while protecting the health and safety of Canadians who use AHR. The Act provides controls for AHR-related research and will lead to the establishment of the Assisted Human Reproduction Agency of Canada, responsible for licensing, inspecting and enforcing activities controlled under the Act.

The Act will have a staged implementation, with prohibitions and penalties for activities such as human cloning and payment to egg and sperm donors coming into force within the next month. Control of other activities will be phased in over a period of time.

European Parliament and the Council of the European Union, *Directive 2004/23/EC of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells,* Strasbourg, March 31, 2004, http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_102/l_10220040407en00480058.pdf (date accessed: April 21, 2004)

The Directive applies to the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells intended for human applications and of manufactured products derived from human tissues and cells intended for human applications.

The transplantation of human organs requires a different policy approach due to their specific nature and the severe shortages that result in many patients going untreated. This Directive does not intend to cover research using human tissues and cells, such as when used for purposes other than application to the human body, ie. in vitro research or in animal models. Only those cells and tissues that in clinical trials are applied to the human body should comply with the quality and safety standards laid down in this Directive.

European Commission/Data Protection Working Party, *Working Document on Genetic Data - adopted March 17, 2004,* Brussells, March 17, 2004, http://europa.eu.int/comm/internal_market/privacy/docs/wpdocs/2004/wp91_en.pdf (date accessed: April 21, 2004)

The Working Party was set up under Article 29 of the Directive 95/46/EC. The group, which has an only advisory character, examines above all questions of uniform application e.g. European Union guideline, the data security level in the community and in third countries, data security-legal measures of the community and the behavior rules according to the article 27 of the guideline, compiled on community level. The results of the meetings as well as the annual reports on the activities are published in papers.

The Working Party has adopted the present working document on the protection of individuals with regards to the processing of personal data.

European Commission, *The 25 recommendations on the ethical, legal, and social implications of genetic testing,* Brussels, 2004, http://europa.eu.int/comm/research/conferences/2004/genetic/pdf/recommendations_en.pdf (date accessed: April 21, 2004)

In order to help decision-makers at all levels to introduce necessary requirements rapidly, the European Commission's Research Directorate-General has invited a group of experts from various backgrounds to discuss the ethical, legal and social implications of genetic testing and to draw up relevant and urgently needed recommendations.

The recommendations include a call for screening for rare diseases, as well as a regulatory framework outlining when such tests should be carried out, and for what purpose the results should be used.

The recommendations will form the basis for a conference, to be held on 6 and 7 May in Brussels. The event will provide an opportunity to assess whether or not the recommendations, which are described as both a 'code of conduct' and an 'action plan', have been fully understood by the stakeholders, and whether all fields have been adequately addressed.

The recommendations are listed under three headings: 'general framework'; 'implementation of genetic testing in healthcare systems'; and 'genetic testing as a research tool'.

Commission Européene, *25 recommendations sur les implications éthiques, juridiques et sociales des tests génétiques, Bruxelles, 2004,* http://europa.eu.int/comm/research/conferences/2004/genetic/pdf/recommendations_fr.pdf (date consultée le: 21 avril 2004)

Afin d'aider les décideurs, à tous les niveaux de responsabilité, à mettre rapidement sur pied les dispositions nécessaires, la Direction générale de la recherche de la Commission européene (CE) a invité un groupe d'experts, issus de differents horizons, à débattre des implications éthiques, juridiques et sociales des tests génétiques et à formuler les recommendations pertinentes, devenues désormais impératives.

Les recommandantions suggèrent un dépisatage des maladies rares ainsi que l'encadrement des conditions d'accès à ces tests et de l'utilisation des résultats.

Les recommandations, qui doivent fonctionnées comme un "code de conduite" mais aussi comme un "plan d'action pour les tests génétiques" serviront de bases à la conférence organisée par la Commission européenne les 6 et 7 mai à Bruxelles. Cet événement permettra de poursuivre la discussion sur ces recommandations, d'évaluer leur degré de compréhensibilité et d'identifier les domaines qui n'ont pas encore été suffisamment traités.

Les 25 recommendations, qui suivent, ont été organisées en 3 chapitres traitants: du cadre général; de la mise en oeuvre des tests génétiques dans les systèmes de soins de santé; et des tests génétiques en tant qu'outils de recherche.

The President's Council on Bioethics, *Reproduction and Responsibility - The Regulation of New Biotechnologies, Washington, March 2004,* http://www.bioethics.gov/reports/reproductionandresponsibility/_pcbe_prepub_reproduction_and_responsibility.pdf(date accessed: April 21, 2004)

The President's Council on Bioethics has released a consensus report on reproductive technology that calls for federally funded research, more self-regulation and a ban on "outlying experimental practices."

In its report "Reproduction and Responsibility: The Regulation of New Biotechnologies," the President's Council on Bioethics unanimously recommended the following:

- Federally funded studies and increased long-range health data collection on women using reproductive technology and the children it produces.
- More effective dissemination of information for patients considering assisted reproduction.
- More robust and effective and professional self-regulation.
- Targeted legislation to prohibit "outlying experimental practices," including human reproductive cloning defined as "attempts to conceive a child by any means other than the union of egg and sperm."

European Commission, *Ethical, legal and social aspects of genetic testing: research, development and clinical applications,* Brussels, 2004, (Report)http://europa.eu.int/comm/research/conferences/2004/genetic/pdf/report_en.pdf (date accessed: April 29, 2004)

The Commission's aim was to create a European stakeholder dialogue on the sensitive issue of genetic testing, in which representatives of civil society, including those from patients' groups, the healthcare industry and academic experts in the fields of genetics, ethics, law and social sciences, could meet and discuss the ethical, legal and social implications of genetic testing.

By creating a new dialogue between different stakeholders, the Group discussed points of consensus aiming always to reach a common position between members, who did not, a priori, share the same opinions, on how best to move forward in genetic testing.

This report is the working document that reflects the long and interesting discussions of the Group.

The Canadian Genetics and Life Insurance Task Force, *Genetics and life insurance in Canada: Points to consider,* Montreal, April 2004, http://www.cmaj.ca/cgi/data/170/9/1421/DC2/1 (date accessed: April 29, 2004)

The 2003 "Public Opinion Research into Genetic Privacy Issues" found that the wide majority of Canadians reject the right of insurance companies to ask for genetic information and this even if applicants have knowledge of a genetic condition.

Over the past year, insurers, patient advocates, researchers and/or clinicians involved in the Genetics and Society Project of the Université de Montréal, Genome Canada projects (Quebec and Ontario) and in the INHERIT BRCAs Project (Interdisciplinary Health Research International Team on Breast Cancer Susceptibility, Canadian Institutes of the Health Research) met as the Canadian Genetics and Life Insurance Task Force to further the debate on genetics and life insurance in Canada.

Le Groupe de travail canadien sur la génétique et l'assurance vie, *Réflexions sur la génétique et l'assurance vie au Canada,* Montréal, avril 2004, http://www.cmaj.ca/cgi/data/170/9/1421/DC2/2 (date consulté: le 29 avril 2004)

En 2003, la *Recherche sur l'opinion publique concernant les renseignements génétiques et leur protection* a démontré que la vaste majorité des Canadiens s'oppose à ce que les compagnies d'assurance puissent demander des informations sur son statut génétique à un candidat à l'assurance, et ce, même si ce dernier dispose au préalable de cette information.

Au cours de 2003, des assureurs, des représentants de groupes de patients, des chercheurs et (ou) cliniciens impliqués dans le projet Génétique et société de l'Université de Montréal, ainsi que dans les projets Génome Canada (Québec et Ontario) et le projet du Groupe de recherche international et interdisciplinaire sur la susceptibilité au cancer du sein des Instituts de recherche en santé du Canada (INHERIT BRCAs - Interdisciplinary Health Research International Team on Breast Cancer Susceptibility) se sont réunis pour constituer le Groupe de travail canadien sur la génétique et l'assurance vie dans le but de faire progresser le débat portant sur la génétique et l'assurance vie au Canada.

Federation of American Societies for Experiemental Biology (FASEB), *FASEB Statement on human Somatic Cell Nuclear Transplantation (SCNT) and Embryonic Stem Cells,* Bethesda, February 12, 2004, http://www.faseb.org/opa/ppp/nr_2x12x4_stem.pdf (date accessed: April 29, 2004)

The Federation of American Societies for Experimental Biology (FASEB) firmly believes that embryonic stem cells have the potential to contribute both to regenerative medicine and to our understanding of basic principles underlying cell and developmental biology.

FASEB reaffirms their opposition to human cloning for the purposes of reproduction, and believes legislation to ban this practice should proceed without delay. However, FASEB believes SCNT to produce embryonic stem cells should be allowed to continue under strict ethical oversight.

Conseil de la santé et du bien-être, *L'information génétique et l'accès à l'information des chercheurs: Il est urgent de protéger la population,* Québec, Septembre 2003, http://www.csbe.gouv.qc.ca/fr/publications/memoires/20031022_memo_cfr.pdf (date consulté: le 29 avril 2004)

Cette mémoire a été présenté à la Commission de la culture de l'Assemblée nationale du Québec chargée de la consultation générale à l'égard du rapport quinquennal de la Commission d'accès à l'information intitulé: Une réforme de l'accès à l'information: le choix de la tranparence.

Ce mémoire présente également les commentaires du Conseil sur les recommendations formulées par la Commission afin de mieux encadrer l'accès à l'information par les chercheurs et la constitution d'entrepôts ou de banques de données personnelles.

Centers for Disease Control and Prevention, Genomics and Population Health: United States 2003, Atlanta, March 1, 2004, http://www.cdc.gov/genomics/activities/ogdp/2003/2003_foreword.htm (date accessed : June 20, 2004).

With the completion of the Human Genome Project in 2003, the stage has been set for an accelerated pace of discovery of thousands of genetic variants. Many variants will be studied for association with diseases of major public health importance, including adult chronic diseases, childhood conditions, infectious, environmental and occupational diseases. Applications of genetic information in diagnosis and prevention of various diseases must be driven by evidence on gene functions in normal and disease states as well as by the value of such information to improve health outcomes. In spite of the potential promise and excitement about human gene discoveries, there are still immense gaps in the knowledge needed for a successful translation of new research results into population health benefits. This “translation gap” calls for an important public health leadership role in applied research, policy development and integration of genomics into the practice of 21st century medicine.

In this first report, the CDC present some examples to show how public health is beginning to address three major gaps along the genomics “translation highway”:

- conducting genomics and population health research,

- developing evidence on the value of genomic information, and
- integrating genomic information in practice and programs.

DRAFTS

France/Gouvernement, *Projet de loi no.1364 sur la politique de santé publique- modifié par le sénat,* Paris, 20 janvier 2004, http://www.assemblee-nationale.fr/12/projets/pl1364.asp (date consultée: le 16avril 2004)

Le présent projet de loi s'inscrit dans le cadre de la réforme de l'ensemble de notre système de santé. Les problèmes de santé publique mettent en relief la nécessité de développer une politique de prévention ambitieuse. L'Etat, garant de la protection de la santé, doit déterminer des objectifs de santé publique puis agir en partenariat avec les principaux acteurs de la santé.

Il s'agit d'abord d'élargir la formation et le rôle des professionnels et ce par trois moyens : donner toute sa place à la formation dans le domaine de la santé publique, en remédiant à la méconnaissance de cette discipline par la création d'une structure d'enseignement ; rénover la formation médicale continue ; enfin, adapter les compétences des professionnels de santé en modernisant la profession des sages-femmes, en expérimentant des transferts de compétences et en encadrant les conditions requises pour exercer la psychothérapie, disposition introduite par l'Assemblée nationale.

Le projet de loi tend aussi à l'amélioration de la législation relative aux recherches biomédicales. Le bilan de la loi de 1988 relative à la protection des personnes qui se prêtent à la recherche biomédicale est satisfaisant. Néanmoins, certaines de ses dispositions sont précisées dans le présent projet.

Medical Research Council (MRC), *Code of Practice for the UK Stem Cell Bank,* London, April 2004, http://www.mrc.ac.uk/pdf-stem_cell_bank_code_interim.pdf (date accessed: April 16, 2004) (For consultation)

This Code specifies the good practice standards that the UK Stem Cell Bank must adopt in terms of validating, screening, processing, storing, providing and delivering stem cell lines to users. It also specifies the criteria against which the UK Stem Cell Bank will be audited by the Steering Committee and the funding agencies. The Code covers banking of all forms of stem cell lines derived from human tissues.

The Steering Committee has now produced an Interim Version of this Code of Practice is provided for information only. It may need to be revised further in light of the responses to the consultation on the draft Code of Practice for the Use of Human Stem Cell Lines.

Medical Research Council (MRC), *Code of Practice for Use of Human Stem Cell Lines,* London, March 2004, http://www.mrc.ac.uk/pdf-stem_cell_lines_code_draft.pdf (date accessed: April 16, 2004)

The framework and content of this draft Code of Practice are based on the principles of good research practice as applied to the use of human stem cell lines for basic and clinical research leading to the development of therapeutic interventions. These principles should be followed if the work is to be conducted within a transparent, regulated and ethical framework. The draft Code has been developed by the Steering Committee for the UK Stem Cell Bank and for the Use of Human Stem Cell Lines.

Belgique/Gouvernement, *Projet de loi relatif aux expérimentations sur la personne humaine,* Bruxelles, 10 février 2004, *http://www.lachambre.be/FLWB/pdf/51/0798/51K0798001.pdf* (date consultée: le 16 avril 2004)

La légitimité de l'expérimentation humaine n'est pas évidente, de par le risque d'instrumentalisation du participant qu'elle comporte. De ce fait, l'expérimentation ouvre non seulement un débat éthique mais également un débat juridique, et particulièrement eu égard aux lacunes du cadre légal actuel.

L'intervention du médecin, en vertu du droit belge, n'est légitime que dans l'intérêt du patient et uniquement dans un but préventif, diagnostique ou curatif: l'expérimentation humaine n'est pas prévue.

Le principe de base étant évidemment que, sans un consentement préalable éclairé de la personne, aucun essai clinique ne peut être effectué sur elle.

FAQ

The HumGen website will soon launch a "frequently asked questions" or FAQ section. It aims to provide accessible information on the ethical, legal and social implications of human genetics. In this issue of GenInfo, we present to you a sample of the questions that will be found in this section; the first, discusses the notion of informed consent in research involving human participants, and the second, the topic of population genetics.

Q Can knowledge acquired through genetic studies expose tested persons to risks of discrimination and stigmatization?

A The acquisition by third parties (such as insurance companies or employers) of information about a risk or a precise genetic diagnosis may lead to discrimination or stigmatization of individuals that participate in research. The biological family members of a tested person, whether or not they participate in research, can also experience this risk because they share similar genetic traits. However, one has to understand that this possibility exists for all medical information related to specific risk factors (i.e. hypertension, high blood cholesterol, contagious diseases). The medical file of a Quebec health system user is confidential in accordance with the law. There is not, at present, any empirical data demonstrating the existence of genetic discrimination in Canada.

The Tri-Council Policy Statement, which frames research in Canada and which was produced by three Canadian research funding organisations, recognises the existence of risks of discrimination and stigmatization. This Statement asks for the disclosure of these risks by researchers who undertake genetic research projects with families.

According to the UNESCO International Committee on Bioethics, "No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity.." (art. 6, Universal Declaration on the Human Genome and Human Rights, 1997)

Q What is confidentiality?

A Confidentiality is linked to the right to privacy and to the fact that personal information about an individual - like an address, the health status or genetic information - is privileged and private since it is held by a professional with whom the person has a special relationship.

Q Why is it important to protect the confidentiality of personal information about an individual, such as genetic information?

A According to the Tri-Council Policy Statement, (see above), the protection of confidentiality of personal data is viewed as essential to human dignity.

Laws which protect the confidentiality of personal information also protect an individual's mental and psychological integrity under the principle of respect for privacy.

Your Feedback

As we believe that information exchange is a two-way process, we would appreciate some feedback concerning your thoughts on this new format for the GenInfo Newsletter. The following is a brief survey; your input through this questionnaire will allow us to tailor future newsletters to serve you better.

1. How would you describe yourself? Specify, if possible.

Professionnal Specify

2. How useful do you find the information that is provided by GenInfo?

Not useful Very useful

○ ○ ○ ○ ○ ○ ○ ○ ○ ○

1 2 3 4 5 6 7 8 9 10

3. With the information that has appeared in GenInfo, have you taken any of the following measures after reading it? (Check all that apply)

You have :

- searched for more extensive information
- used it for your work
- passed it on to others colleagues
- used it to help construct a bibliography
- used it to help launch a research project
- used it to inform your decision making
- used GenInfo as a principal resource for policy documents
- used for your updates on current news, events and publications related to soci-ethical and legal implications of human genetics

Other

4. How could we improve GenInfo so that it better responds to your needs?

Submit

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