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As evidenced by the number of policies and guidelines presented in this issue of GenInfo, fall once again brings a resumption of normative activity in the field of human genetics. On the international scene, we bring your attention to the new (non-official) English version of the South Korean *Bioethics and Safety Act* now available on the internet. At the national level, Genome Canada's new policy regarding data release and resource sharing should be of great interest to all Canadian researchers in the field of genetics.

We would like to welcome two new members to the GenInfo editorial team: Emmanuelle Lévesque (associate editor) and Guillaume Sillon (editorial assistant).

Feel free to submit any interesting new piece of information on the ethical, legal, or social issues of human genetics for inclusion in a forthcoming issue of GenInfo.

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NEWS

The "News" section of GenInfo provides a brief listing of events for the coming year (if organized by our team or partner organizations). We are also pleased to include a "Publications" section with a summary of books, articles and editorials published by members of our team.

EVENTS

OCTOBER 2005

Canadian Bioethics Society 17th Annual Conference and Meeting
"Money, Money, Money: Bioethics Confronts Dollars and Sense"

Date: October 20-23, 2005

Location: Lord Nelson Hotel, 1515 South Park Street, Halifax (Nova Scotia)

Information and registration: For additional information and to register, visit <http://www.bioethics.ca/CBSbrochure.pdf>

PUBLICATIONS

BOOK CHAPTERS & ARTICLES

Bartha Maria Knoppers and Madelaine Saginur, "The Babel of Genetic Data Terminology" (2005) 23(8) *Nature Biotechnology*, p. 925-927.

Abstract: Identifying genetic samples and data is a key problem both because the research community must be able to share data and because the public must have confidence in the robustness of confidentiality mechanisms to ensure genetic privacy. One major impediment to the implementation of a universal identification system for genetic samples is the proliferation of a bewildering array of terminologies at the national and international levels. We have used a survey of these frameworks and propose simpler terminology that could facilitate future policy and practice in this area.

Denise Avard and Emmanuelle Lévesque, " Discrimination génétique et discrimination fondé sur le handicap : comparaison internationale des différentes approches normatives " (January-June 2005) 105/106 *Handicap : Revue des sciences humaines et sociales*, p. 71-86. [French version only]



GENEDIT

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

CURRENT ISSUE

Volume III No.1 (2005)

Populational Genetic Databases: Is a Specific Ethical and Legal Framework Necessary?"

Anne Cambon-Thomsen, Clémentine Sallée, Emmanuelle Rial-Sebbag, Bartha Maria Knoppers

PAST ISSUES

Volume II No.3 (2004)

Newborn Screening, Banking and Consent

Claude Laberge, Linda Kharaboyan, Denise Avard

Volume II No.2 (2004)

Genetics and Life Insurance : A Comparative Analysis

Trudo Lemmens, Yann Joly and Bartha Maria Knoppers

Volume II No.1 (2004)

Protecting Genetic Information: A Comparison of Normative Approaches

Patricia Kosseim, Martin Letendre and Bartha Maria Knoppers

Volume I No.1 (2003)

Stem Cells in a Pluralistic Society: Consequences of Proposed Canadian Legislation

Dorothy C. Wertz, Marie-Hélène Régnier and Bartha Maria Knoppers



NEW LAWS & POLICIES

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

We are constantly searching for documents to enrich our databank. If your organisation has published policy statements relating to genetics, or if you are aware of such new publications, kindly send us the relevant information and we will consider including it in the databank.

National Society of Genetic Counselors (NSGC), *National Society of Genetic Counselors Supports the Senate's Passage of Genetic Non-Discrimination Bill*, Wallingford, February 18, 2005, http://www.nsgc.org/newsroom/pr_021805.pdf (date accessed: June 22, 2005).

The National Society of Genetic Counselors (NSGC) fully supports the Senate's passage of the Genetic Non-Discrimination Bill (S.306). Fear of genetic discrimination has been a factor preventing individuals and families at risk for genetic disease from pursuing valuable testing and participation in research. NSGC believes that the passage of this bill will alleviate these fears.

Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), *An Analysis of the Adequacy of Current Law in Protecting Against Genetic Discrimination in Health, Insurance and Employment*, Bethesda, May 2005, http://www4.od.nih.gov/oba/sacghs/reports/legal_analysis_May2005.pdf (date accessed: August 1, 2005).

One of the findings in the bill entitled, "Genetic Information Nondiscrimination Act of 2005", as introduced in the current sessions of the House and Senate, is that Federal law addressing genetic discrimination in health insurance and employment is incomplete in both the scope and depth of its protections and that State genetic nondiscrimination laws vary widely with respect to their approach, application, and level of protection. This analysis examines pertinent Federal statutes and constitutional protections to determine the extent to which they provide for the confidentiality of genetic information and protect against genetic discrimination and briefly reviews the coverage of State laws.

Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), *SACGHS Letter to the Secretary of Health and Human Services*, Bethesda, May 3, 2005, http://www4.od.nih.gov/oba/sacghs/reports/letter_to_Sec_05_03_2005.pdf (date accessed : June 29, 2005).

Coalition for Genetic Fairness, *Letter to Senate*, Washington, February 7, 2005, <http://www.geneticfairness.org/senateltr.html> (date accessed: June 29, 2005).

United States, *Statement of Administration Policy, S.306 - Genetic Information Nondiscrimination Act of 2005*, Washington, February 16, 2005, <http://www.whitehouse.gov/omb/legislative/sap/109-1/s306sap-s.pdf> (date accessed : June 29, 2005).

The Administration favors enactment of legislation to prohibit the improper use of genetic information in health insurance and employment.

Commission d'accès à l'information (CAI), *Mémoire sur le Projet de Loi no 83, Loi modifiant la Loi sur les services de santé et les services sociaux et d'autres dispositions législatives*, Québec, January 2005, [http://www.cai.gouv.qc.ca/06_documentation/01_pdf/Memoire-PL%2083%20\(final\).pdf](http://www.cai.gouv.qc.ca/06_documentation/01_pdf/Memoire-PL%2083%20(final).pdf) (date accessed: August 24, 2005). [French version only].

Australia, National Health and Medical Research Council, *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research*, Canberra, September 2004, http://www.nhmrc.gov.au/publications/_files/e56.pdf (date accessed: August 1, 2005).

These revised guidelines, which replace the 1996 guidelines, have been issued to continue to promote ethical practice in ART as follows.

- With respect to clinical practice, the guidelines will remain a key element in the accreditation processes for ART clinics.
- With respect to research, the guidelines will be used by HRECs and researchers who apply for ethical approval of any research involving ART participants, human gametes or embryos, and by researchers who wish to make an application to the Licensing Committee for a licence.

Australia, Department of Health and Ageing, Therapeutic Goods Administration, *Regulatory Impact Statement for Human Cell, Tissues and Cellular and Tissue-Based Products*, Canberra, September 2004, <http://www.tga.gov.au/consult/2004/hctpris.pdf> (date accessed: August 1, 2005).

In July 2002, the Australian Health Ministers conference (AHMC) recommended that the Therapeutic Goods Administration (TGA) introduce a national regulatory framework for human tissues and emerging biological therapies and that the therapeutic goods legislation be amended to accommodate therapeutic goods manufactured from viable human and animal tissues. This RIS addresses the issue of human cell, tissue and cellular and tissue-based products (HCT/Ps) specifically.

Genome Canada, *Data Release & Resource Sharing Policy*, Ottawa, July 1, 2005, <http://www.genomecanada.ca/GCgenomeCanada/politiques/DataReleasePolicy.pdf> (date accessed: August 2, 2005).

Genome Canada is committed to the principle of rapid data release and sharing of unique resources to the scientific community. Genome Canada-funded projects must follow the data release and resource sharing principles of a "community resource project" defined as "a research project specifically devised and implemented to create a set of data, reagents or other material whose primary utility will be as a resource for the broad scientific community."

European Commission, European Society of Human Genetics and European Society of Human Reproduction and Embryology, *The Interface Between Medically Assisted Reproduction and Genetics: Technical, Social, Ethical and Legal Issues*, Seville, June 3, 2005, <http://www.eshg.org/BGDDocuAfterSevilla030605etAnnexes.pdf> (date accessed: August 2, 2005).

The Public and Professional Policy Committee (PPPC) of the European Society of Human Genetics (ESHG) found it necessary to create professional recommendations on how to use IVF techniques safely and reliably from the genetic point of view. Also, guidelines are needed on acceptable (genetic) goals of IVF treatment and on how these expensive treatments should be prioritised in the European health care systems. Accordingly, the purpose of the present paper was to outline a framework for development of guidelines for the interface between genetics and ART.

South Korea, *Bioethics and Safety Act*, South Korea, January 1, 2005, <http://www.ruhr-uni-bochum.de/kbe/Bioethics&BiosafetyAct-SouthKorea-v1.0.pdf> (date accessed: August 29, 2005) [unofficial English translation].

This act aims to enhance the health of human beings and the quality of human life by creating conditions that allow for the development of life sciences and biotechnologies that can be used to prevent or cure human diseases. Additionally, this act aims to protect human dignity and to prevent harm to human beings by ensuring that the life sciences and biotechnologies are developed safely and in accordance with the principles of bioethics.

European Commission, *Report from the Commission to the Council and the European Parliament: Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering*, Brussels, July 14, 2005, http://europa.eu.int/comm/internal_market/en/indprop/invent/com_2005_312final_en.pdf (date accessed: August 29, 2005).

This is the second report pursuant to Article 16c of the Directive 98/44/EC1 of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions and bears the title "Developments and implications of patent law in the field of biotechnology and genetic engineering" (hereinafter the "second 16c Report").

Its purpose is to set out the key events which have occurred since publication of the first 16c Report2 and to comment on two issues identified in the latter: the scope of patents on sequences or partial sequences of genes which have been isolated from the human body and the patentability of human stem cells and cell lines obtained from them. The Commission's analysis is based on the Commission staff working paper SEC(2005)943.

Human Genetics Commission, *Choosing the Future: Genetics and Reproductive Decision-Making, Analysis of Responses to the Consultation*, London, May 2005, <http://www.hgc.gov.uk/UploadDocs/Contents/Documents/Analysis%20of%20responses%20to%20the%20HGC%20consultation.pdf> (date accessed: August 15, 2005).

This report collates the responses with respect to the areas set out in the terms of reference in the consultation document:

- past, current and future developments in genetic services related to reproduction within the current legal framework and in terms of the technology and public attitudes towards its use;
- advances as they relate to prenatal genetic screening services, prenatal genetic diagnosis and preimplantation genetic diagnosis; and
- genetic services and possible future developments in the area of genetics and reproduction.

New Zealand, *Memorandum to Cabinet Policy Committee, Report Back with Recommendations and Options for Addressing Genetic Material Patents*, Wellington, May 2005, http://www.med.govt.nz/buslt/int_prop/genetic-material/cabinet/memo/memo.pdf (date accessed: August 10, 2005)

This report back presents recommendations on the issues and possible options for addressing concerns over patents on genetic material.

American Society of Clinical Oncology, *Federal Funding for Embryonic Stem Cell Research, Position Statement*, Alexandria, March 2005, http://www.asco.org/asco/downloads/stem_cell_research_3.2005.pdf (date accessed: August 16, 2005).

(PMC), *Comments on SACGHS Draft Report "Coverage and Reimbursement of Genetic Tests and Services"*, Washington, May 11, 2005, http://www.personalizedmedicinecoalition.org/sciencepolicy/public-policy_sacghs-position.php (date accessed : August 15, 2005).

Founded to advance genomic medicine, the PMC has a keen interest in the current state of coverage and reimbursement of genetic/genomic tests and services as well as any and all efforts to improve patient access through a revamped test evaluation and reimbursement process. We encourage the Committee to focus on potential private sector solutions when it assesses historically inadequate methodology for establishing appropriate reimbursement for genetic/genomic services. In particular, it should seek to encourage the development of sophisticated new tests and services by recommending the establishment of adequate reimbursement policies.

Personalized Medicine Coalition (PMC), *PMC Statement on Genetic Non-Discrimination*, Washington, April 28, 2005, http://www.personalizedmedicinecoalition.org/sciencepolicy/public-policy_patients-rights-position.php (date accessed : August 15, 2005).

We believe that all genetic information, including family history, deserves strong and enforceable protections against misuse in health insurance and employment. Such safeguards will ensure confidentiality of genetic information of the individual and their family.

Organization for Economic Co-operation and Development (OECD), *Quality Assurance and Proficiency Testing for Molecular Genetic Testing: Survey of 18 OECD Member Countries*, Paris, May 1, 2005, <http://www.oecd.org/dataoecd/25/12/34779945.pdf> (date accessed: August 22, 2005).

This report presents recommendations for action to assure the quality of human genetic testing and the proficiency of those that carry out such tests. It provides the first detailed information about the availability and extent of molecular genetic testing throughout the OECD member countries as well as existing quality assurance practices in use in testing laboratories, including policies regarding samples and genetic data handling, and transborder flow of specimens. It also provides some insight into the level of proficiency of those offering genetic tests. It reports the results of a survey 18 OECD countries, with responses from 827 laboratory directors.

Medical Research Council, *Medical Research Council Position Statement on Research Regulation and Ethics*, London, May 2005, http://www.mrc.ac.uk/pdf-mrc_statement_regulations_ethics_may_2005.pdf (date accessed: July 13, 2005).

Some recent events have raised concerns within the medical research community about the level of regulation. This paper summarises the Medical Research Council's (MRC) views about the need for regulation and the balance that needs to be struck between this and the importance of not impeding vital medical research to improve individual and public health.

Aetna Inc., *Clinical Policy Bulletins: Genetic Testing*, Hartford, April 22, 2005, <http://www.aetna.com/cpb/data/CPBA0140.html> (date accessed: July 13, 2005).

Aetna Inc, *Clinical Policy Bulletins - Genetic Counseling*, Hartford, April 15, 2005, <http://www.aetna.com/cpb/data/CPBA0189.html> (date accessed: August 22, 2005).

Québec, Ministry of Health and Social Services, *L'organisation des services de génétique au Québec - Plan d'action 2005-2008*, Québec, april 2005, <http://publications.msss.gouv.qc.ca/acrobat/f/documentation/2005/05-917-01.pdf> (date accessed : august 1, 2005). [French version only].



DRAFTS

United States Senate, *Genetic Information Non-Discrimination Act (bill S. 306)*, Washington, February 17, 2005, <http://thomas.loc.gov/cgi-bin/query/z?c109:S.306>: (date accessed: August 1, 2005).

United States House of Representative, *Genetic Information Nondiscrimination Act of 2005 (Introduced in House)*, H.R. 1227, Washington, March 10, 2005, <http://thomas.loc.gov/cgi-bin/query/z?c109:H.R.1227>: (date accessed: August 1, 2005).

United States House of Representatives, *A Bill to Amend Title 35, United States Code, Relating to the Procurement, Enforcement, and Validity of Patents*, H.R. 2795, 109th Congress, 1st Session, Washington, June 8, 2005, <http://www.govtrack.us/data/us/bills.text/109/h2795.pdf> (date accessed: August 2, 2005).

The President's Council on Bioethics, *A White Paper: Alternative Sources of Human Pluripotent Stem Cells*, Washington, May 2005, http://www.bioethics.gov/reports/white_paper/alternative_sources_white_paper.pdf (date accessed: August 15, 2005).

Alternative Sources of Human Pluripotent Stem Cells is a White Paper of the President's Council on Bioethics, which was created by President George W. Bush on November 28, 2001, by means of Executive Order 13237. The Council's purpose is to advise the President on bioethical issues related to advances in biomedical science and technology. In connection with its advisory role, the mission of the Council includes the following functions:

- To undertake fundamental inquiry into the human and moral significance of developments in biomedical and behavioral science and technology.
- To explore specific ethical and policy questions related to these developments.
- To provide a forum for a national discussion of bioethical issues.
- To facilitate a greater understanding of bioethical issues.

United Nations Educational, Scientific and Cultural Organization (UNESCO), *Universal Draft Declaration on Bioethics and Human Rights*, Paris, June 24, 2005, http://portal.unesco.org/shs/en/file_download.php/11445d5a75d2306d7437f0626f35e1c1Draft_EN.pdf (date accessed: September 1, 2005)

The second session of the intergovernmental meeting of experts aimed at finalizing a draft declaration on universal norms on bioethics took place at UNESCO Headquarters in Paris from 20th to 24th June 2005.



FAQ

The judicial, ethical and social concerns raised in the regulative texts that provide the framework for human genetics are complex. Our goal, with the Frequently Asked Questions (FAQ), is to approach these questions in such a way as to render them accessible.

Q Can insurance providers require that a person submit to a genetic test before being eligible for insurance?

A In Canada, the policy of the insurance providers is not to require insurance applicants to undergo genetic testing. This policy was developed by the Canadian Life and Health Insurance Association

This non-mandatory policy could be modified at any time.

Currently, in Canada, no legislative provisions specifically address the issue of genetic tests as a prerequisite for insurance.

For more FAQs, visit HumGen's FAQ section at <http://www.humgen.umontreal.ca/int/faq.cfm?lang=1>



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