

January-February 2005

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Happy New Year! This first "GenInfo" issue of 2005 contains several new policy documents on the topics of population genomics and pharmacogenomics, likely a harbinger of the direction of policy making in the coming year. In addition to the items listed below, I want to bring to your attention a South Korean law allowing therapeutic cloning, a German law on biotechnology patenting and a Ukrainian law banning reproductive cloning (all three laws being unavailable in official English translation at press time).

**NEWS**

The "News" section of GenInfo provides a brief listing of events for the coming year (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

JANUARY 2005

Conference: "Research Ethics Committee in Europe : Facing the Future Together"

Date: January 27-28th, 2005

Location: Brussels, Belgium, Charlemagne Building, rue de la Loi 170, B-1040

Host: European Commission

Informations and registration: For more information, consult http://europa.eu.int/comm/research/conferences/2005/recs/index_en.htm

FEBRUARY 2005

Conference: AAAS Annual Meeting

Date: February 17-21st, 2005

Location: Washington D.C.

Informations and registration: For more information, consult http://www.aaas.org/meetings/Annual_Meeting/01_REG/Register.shtml.

MARCH 2005

Conference: "Using Blood Spots in Research : Moving Beyond Screening and Treatment"

Date: March 1st 2005

Guest Speaker: Denise Avard

Location: University of Ottawa, Faculty of Medicine, Epidemiology and Community Medicine, 451, Smyth Rd., Ottawa, Ontario.

Informations and registration: The conference is free. For more information, contact: Ms France Gagnon at (613) 562-5800 ext. 8262.

PUBLICATIONS

BOOK CHAPTERS & ARTICLES

Joly, Y., Knoppers, B.M. and Nguyen, M.T., "Stored Tissue Samples : Through the Confidentiality Maze", (2005) 5, *The Pharmacogenomics Journal*, 2-5.

Abstract: If the public is to fully reap the benefits of pharmacogenomics, policy makers must learn to recognize the specificity of this type of research. Established ethical principles demand that data banks and samples be protected, but guidelines for confidentiality levels ought to reflect and correspond to the reality and needs of protecting research participants and of productive research. In this paper, the authors propose elements for consideration for researchers and IRBs to determine appropriate levels of protection of genetic data in pharmacogenomics research.



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.

AVAILABLE SOON

Volume III No.1
Biobanks: Need for a specific ethical and legal framework?
Anne Cambon-Thomsen, Clémentine Sallée, Bartha Maria Knoppers

PAST ISSUES

Volume II No.3
Newborn Screening, Banking and Consent
Claude Laberge, Linda Kharaboyan, Denise Avard

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

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 Régner and Bartha Maria Knoppers



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 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.

United States Department of Health and Human Services, Food and Drug Administration, *Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products*, Washington, March 2004, <http://www.fda.gov/oc/initiatives/criticalpath/whitepaper.pdf> (date accessed: January 18, 2005).

FDA is issuing this report to address the growing crisis in moving basic discoveries to the market where they can be made available to patients. The report evaluates how the crisis came about and offers a way forward. It highlights examples of Agency efforts that have improved the critical path and discusses opportunities for future efforts. Finally, the report calls for a joint effort of industry, academia, and the FDA to identify key problems and develop targeted solutions.

International Bioethics Committee (IBC), UNESCO, *Fifth Meeting of the IBC Drafting Group for the Elaboration of a Declaration on Universal Norms on Bioethics: Final Report* (October 27-28, 2004), Paris, November 15, 2004, http://portal.unesco.org/shs/en/file_download.php/8be80fc111574e6f99db5edae9796626Rap_Gred5_en.pdf (date accessed: December 9, 2004).

With a view to further refining the text of a declaration on universal norms on bioethics, the Drafting Group of the International Bioethics Committee (IBC) held its fifth meeting at UNESCO Headquarters (Paris) on 27 and 28 October 2004.

American Academy of Pediatrics, "Ethical Consideration in Research With Socially Identifiable Populations", (2004) 113:1 *Pediatrics*, p. 148-151, <http://pediatrics.aappublications.org/cgi/reprint/113/1/148> (date accessed: December 10, 2004).

Community-based research raises ethical issues not normally encountered in research conducted in academic settings. In particular, conventional risk-benefits assessments frequently fail to recognize harms that can occur in socially identifiable populations as a result of research participation. Furthermore, many such communities require more stringent measures of beneficence that must be applied directly to the participating communities. In this statement, the American Academy of Pediatrics sets forth recommendations for minimizing harms that may result from community-based research by emphasizing community involvement in the research process.

Ontario/Government, *Personal Health Information Protection Act, 2004*, S. O., c. 3, Sched. A, Ontario, http://www.e-laws.gov.on.ca/DBLaws/Statutes/French/04p03_f.htm (date accessed: December 13, 2004).

Council of Europe, *Additional Protocol in the Convention on Human Rights and Biomedicine Concerning Biomedical Research*, Strasbourg, June 30, 2004, http://www.coe.int/T/E/Legal_Affairs/Legal_co-operation/Bioethics/Activities/Biomedical_research/Protocol_Biomedical_research-1.pdf (date accessed: December 20, 2004).

The Additional Protocol to the Convention on Human Rights and Biomedicine on Biomedical Research is intended to build on the principles embodied in the Convention, with a view to protecting human rights and dignity in the specific field of biomedical research. Its purpose is to define and safeguard fundamental rights in biomedical research, in particular of those participating in research.

The fundamental principle for research involving human beings, as in the Convention itself, is the free, informed, express, specific, and documented consent of the person(s) participating. It is foreseen that the Protocol will address issues such as risks and benefits of research, consent, protection of persons not able to consent to research, scientific quality, independent examination of research by an ethics committee, information to be submitted to the ethics committee, information for research participants, confidentiality and the right to information, dependent persons, undue influence, safety, duty of care, and research in states not Party to the Protocol.

The Council of Canadians With Disabilities, *Community Consultation on the United Nations Effort to Comprehensive and Integral International Convention on the Protection and Promotion of the Rights and Dignity of Persons With Disabilities*, Ottawa, February 29-March 1, 2004, <http://www.ccdonline.ca/publications/CCDconsultation/CCDconsultation.htm> (date accessed: December 20, 2004).

From February 29 to March 1, 2004, the Council of Canadians with Disabilities (CCD) held a national community consultation to discuss the draft UN Convention on the Human Rights of Disabled People. The goals of the meeting were to introduce participants to the convention and some of the key issues surrounding it, and to look specifically at the draft text formulated by the UN Ad Hoc Committee's Working Group in January 2004.

Participants heard briefings outlining the history of human rights for people with disabilities, both in Canada and at the UN, and received advice from representatives of the International Commission of Jurists and Mines Action Canada on how Canadian NGOs could work to influence this convention. Delegates then discussed the convention's objectives and principles, as well as the options for monitoring and implementation.

Morocco/Government, *Industrial Property Law, No 17.97*, Morocco, June 7, 2004, [electronic copy not available]

Morocco issued Decree No. 2.00.368 dated June 7, 2004 stipulating on implementing Law No. 17.97 concerning Industrial Property Protection. The Decree was published in the Official Gazette No. 5222 dated June 17, 2004. The law provides protection for trademarks, patents, topography of integrated circuits, industrial designs and models and industrial awards and trophies. Pharmaceutical compositions, pharmaceutical products and/or remedies including the processes, will now become patentable.

European Federation of Pharmaceutical Industries and Associations (EFPIA), *Pharmacogenetics in Medicinal Product Research and Development, Position Paper*, September 2004, http://www.efpia.org/4_pos/sci_regu/Pharmacogenetics%20Sept%202004.pdf (date accessed: January 05, 2005).

Greenpeace, *The True Cost of Gene Patents. The Economic and Social Consequences of Patenting Genes and Living Organisms*, Berlin, March 2004, http://weblog.greenpeace.org/ge/archives/1Study_True_Costs_Gene_Patents.pdf (date accessed: January 5, 2005).

The patenting of living organisms continues to be extremely controversial in Europe. Whereas the German Association of Research-Based Pharmaceutical Manufacturers (Verband forschender Arzneimittelhersteller, VFA) accords the highest priority to implementing EU Biotech Patents Directive 98/44, large sections of the general public and politicians continue to reject the patenting of genes and living organisms. The present documentation is one in a series of various topical publications that all demand substantial restriction of or a complete end to the patenting of genes and living organisms. The documentation covers three areas: The patenting of microorganisms, human genes and seeds.

The World Medical Association, *Workgroup Report on the Revision of Paragraph 30 of the Declaration of Helsinki*, Tokyo, January 5, 2004.

Following the adoption by the World Medical Association Assembly in October 2000 of a substantially revised version of the Declaration of Helsinki (DoH), concerns were voiced about a few of its provisions, especially paragraph 29 dealing with the use of placebos in clinical trials and paragraph 30 on continuing care of research subjects. Para. 29 was addressed in a note of clarification adopted by the Assembly in October 2002. This report deals with para. 30.

Intellectual Property Institute (IPI), *Patents for Genetic Sequences: the Competitiveness of Current UK Law and Practice*, May 2004, London, http://www.dti.gov.uk/5397_DTi_Patent_Study.pdf (date accessed : December 23, 2004).

The results of the study have shown a high degree of consistency and support anecdotal evidence that current UK law and practice regarding patents for genetic sequences are generally meeting the needs of those currently active in this research area. The study indicates that this is true for both public and private sectors.

Canadian Biotechnology Advisory Committee, *Biotechnology and the Health of Canadians*, Ottawa, December 2004, <http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/ah00488e.html#mes> (date accessed : January 5, 2004)

This report describe some of the current and emerging opportunities and challenges associated with biotechnology-based health innovation. It proposes a policy framework along with a series of initiatives that would enhance Canada's capabilities and performance in research and development, regulation and commercialization, and technology assessment and uptake; and would contribute to the realization of Canada's potential as an effective and responsible leader in this important field.

European Commission, *Pharmacogenetics: Technical, Social, Legal and Ethical Issues*, Sevilla, 25-26 March 2004, <http://www.epposi.org/Epposi%20sevilla%20workshop%5B1%5D.pdf> (date accessed: January 5, 2005).

Most of the work undertaken by the IPTS is in response to specific requests for assistance from EU institutions, mainly the European Commission and the European Parliament. The Institute combines two perspectives in its work: a focus on emerging technologies, and a focus on technoeconomic, policy-relevant options which involve technology. This unique partnership provides added insight, not only through empirical analysis of available data, but prospective exploration of the future characterizing the specificity of the Institute's mission. The main objectives are to monitor and analyze science and technology developments and the impact they have on different sectors of society and pharmacogenetics is one of these developments. In this context, this workshop presented a great opportunity to identify some of the potential impacts of pharmacogenetics in Europe and co-organizing it with the ESHG and EPPOSI gave IPTS the opportunity to access the main stakeholders in the process. Mr Sorup ended by thanking the organizing committee and stressing how pleasant the co-operation had been during the workshop preparation.

India/Government: Department of Biotechnology: Ministry of Science & Technology, *Guidelines to Develop Proposals in the Area of Pharmacogenomics*, New Delhi, 2004, <http://dbtindia.nic.in/policy/format/Pharmacogenomics.pdf> (date accessed: January 6, 2005).

Scientists in India are increasingly undertaking pharmacogenomic studies. The Department of Biotechnology (DBT) has been many receiving proposals for funding such studies. The scientific aspects of these proposals do not often address all the major issues that need to be taken into account before initiating pharmacogenomic studies. This document, therefore, provides some guidelines regarding the major scientific issues for consideration by scientists planning to undertake such studies.

German National Ethics Council, *The Patenting of Biotechnological Inventions Involving the Use of Biological Material of Human Origin, Opinion*, Berlin, October 6, 2004, http://www.ethikrat.org/_english/publications/Opinion_patenting_of_biotechnological_inventions.pdf (date accessed: January 7, 2005).

Swiss Society of Medical Genetics (SSGM), *Projet de modification de la Loi fédérale sur les brevets d'invention: Position Statement*, Lausanne, October 31, 2004, http://www.ssgm.ch/sections/pdf/2004/SSGM_prise_de_position.pdf (date accessed: January 7, 2005).

La SSGM estime que, dans le domaine de la biotechnologie, les prestations intellectuelles sont par principe dignes de protection et doivent permettre de promouvoir les progrès et l'innovation. Cependant, étant donné les particularités du matériel génétique et des inventions biotechnologiques, elle est d'avis que l'octroi et l'utilisation d'un brevet dans ce domaine requièrent des exigences clairement définies tant des points de vue biologiques et médicaux que juridiques, sociaux et éthiques.

International HapMap Project, *Guidelines for Referring to the HapMap Populations in Publications and Presentations*, United States, July 30, 2004, <http://www.hapmap.org/citinghapmap.html> (date accessed: November 16, 2004)

It is important to exercise care when labeling the populations whose samples were used to develop the HapMap in any publications and presentations that describe the Project or use Project data. This document provides guidelines on how to refer to the populations and includes other relevant background information about each population.

Australia/Government, Department of Health and Ageing, Therapeutic Goods Administration, *Regulatory Impact Statement For the Regulation of Human Cell, Tissue and Cellular and Tissue-Based Products*, Woden, September 2004, <http://www.tga.gov.au/consult/2004/hctpris.pdf> (date accessed: December 10, 2004)

A RIS is a mandatory document for all reviews of existing legislation, proposed new or amended regulation and proposed treaties involving regulation which will directly affect business, have a significant indirect effect on business, or restrict competition. It is prepared by the agency responsible for a regulatory proposal following consultation with affected parties. The RIS that has been developed in relation to the proposed regulatory framework for Human Cell, Tissues and Cellular and Tissue - based Products, reviews the options available to the TGA to address the recommendation by the Australian Health Ministers' Conference (2002) that these products should be subject to regulatory control by the TGA.

UK Newborn Screening Programme Centre, *Communication Guidelines for Discussing Newborn Blood Spot Screening With Parents*, London, 2004, http://www.ich.ucl.ac.uk/newborn/download/communication_guidelines.pdf (date accessed: December 20, 2004)

These guidelines have been developed to support midwives (or other health professionals) discussing newborn blood spot screening with parents. They should be used alongside the national pre-screening leaflet on newborn blood spot screening. The leaflet and guidelines have been developed by the UK Newborn Screening Programme Centre with input from parents and health professionals with experience of newborn screening.



DRAFTS

International Bioethics Committee (IBC), UNESCO, *Elaboration of the Declaration on Universal Norms on Bioethics: Fourth Outline of a Text*, Paris, July 27, 2004, http://portal.unesco.org/shs/en/file_download.php/377486e581fab8658319802f8269dbd0PublicOutline4_en.pdf (date accessed: December 20, 2004).

Quebec/Government, *An Act respecting clinical an research activities as regards assisted human reproduction and amending other legislative provisions*, (bill), Quebec, December 16, 2004, <http://www.assnat.qc.ca/eng/37legislature1/Projets-loi/Publics/04-a089.htm> (date accessed: January 10, 2005).



FAQ

Q What is the goal of population genetic research?

A Population genetic research allows researchers to identify genetic and non genetic factors involved in the development of complex or common diseases. Conditions, such as asthma and various cardiovascular illnesses, are caused by the interaction of several genes, and also by environmental factors and often linked to lifestyle, for example diet and exercise.

Q In Quebec, a large scale human population genetic research project called "Cartagene" is planned. What does this project entail?

A CartaGene is a population genetics research project that would allow the identification of genetic variations within the population of Quebec. Cartagene researchers are interested in identifying the role of genetic variation in the development of complex or common diseases, such as asthma or cardiovascular illness. CartaGene will collect the DNA of 60,000 to 65,000 citizens, from 24 to 75 years of age (1.5% representative of the whole of the Quebec population). This project would create a research tool for Quebec and others around the world. It would also help determine the demographic composition of Quebec so as to facilitate the adaptation of health services to their needs.

Q Are other large scale human population genetics projects planned or underway elsewhere in the world?

A Human population genetics research projects are planned or underway in several countries, for example in Iceland, the United Kingdom, Sweden and Estonia. These projects intend to study the link between genetic factors, non genetic factors (environmental factors and lifestyle), the development of illness, and health.



Your Feedback

We believe that information exchange is a two-way process and we would appreciate some feedback, especially your thoughts on the new format of the GenInfo Newsletter. Completing the following brief survey will allow us to tailor future newsletters to serve you better.

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

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 :

Other

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



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