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It is already time for the last "GenInfo" of 2004. I take this opportunity, on behalf of every member of the Genetics and Society Project, to wish everyone an excellent holiday. Since this was a year of transformation for "GenInfo," we would greatly appreciate your comments on the new format of our newsletter. You can give us your comments via the survey that is at the end of the newsletter or, directly at the following internet address: humgen@droit.umontreal.ca.

This month, I direct your attention to two documents I feel are especially interesting. First, the Report by the Director-General on the Drawing-up of a Declaration on Universal Norms on Bioethics, presented at the 170th session of the Executive Council. This report deals with the advancement of the work of UNESCO's International Bioethics Committee in the framework of this Declaration and includes in annex a third draft of the text. Next is the *french law on Bioethics* (french version available only), which was finally implemented on August 6th, 2004 after 3 years of development. The principal innovation introduced by this law concerns the fields of cloning (therapeutic and reproductive), medically assisted reproduction, organ donation, biotechnology patenting and stem cells.
Enjoy reading!



The News section of GenInfo provides a brief listing of events for the coming year (organized by our team or linked 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

NOVEMBER 2004

7th World Congress of Bioethics Special Symposium "Building a Movement for a Responsible Global Governance of the New Genetic Technologies: New Voices, New Perspectives"

Date: November 11, 2004 at 11h00 am

Location: Sydney, Australia

Host: International Association of Bioethics

Presenters: Rupsa Mallik, (India), Merry Osemwegie (Nigeria), George Annas, (USA), Isasi, Rosario (Canada).

Description: Presenters will discuss the urgent need for a global movement to bring the new human genetic and reproductive technologies under a governance regime committed to human rights, social justice and inclusion, if the benefits of these technologies are to be realized and a new era of high-tech, free-market eugenics is to be averted.

Informations and registration: For informations contact info@bioethicsworldcongress.com and for registration consult <http://www.bioethicsworldcongress.com/registration.asp>.

<http://www.bioethicsworldcongress.com/>

PUBLICATIONS

BOOK CHAPTERS & ARTICLES

B.M. Knoppers and R.M. Isasi, "Regulatory Approaches to Reproductive Genetic Testing," Human Reproduction, *European Society of Human Reproduction and Embryology*, September 2004, p.1-7, <http://humrep.oupjournals.org/cgi/reprint/deh505v1>, (date accessed: October 25, 2004).

Abstract: This report analyzes the ethical aspects of reproductive genetic testing in 11 countries (Australia, Austria, Canada, France, Germany, India, Israel, Japan, The Netherlands, Switzerland and the UK). The legal status of reproductive genetic testing in the countries under analysis is difficult to generalize due to the different regulatory systems adopted. These approaches are a reflection of the legal traditions and cultural and socio-religious beliefs which inform and shape public policy on assisted reproductive technologies and genetic testing. We divide approaches into two groups: public ordering (legislative, top-down approach) and private ordering (non-legislative, bottom-up approach). Even limiting our analysis to a number a countries that span the range from restrictive to pragmatic approaches, there is remarkable symmetry in both the substantive requirements (i.e. gravity, health indications generally) and procedural safeguards (i.e. informed consent, counseling, confidentiality, civil status, oversight and accreditation) surrounding reproductive genetic testing. Indeed, irrespective of whether a country adopts a prohibitive or a permissive approach through legislation or self-regulation or a mix of both, the ultimate decision is and should continue to be a medical one. Nowhere is this more evident than in the substantive requirements.

EDITORIALS

D. Avard, "Ethics, industry and "animal farm"", (November 2004) vol. 22, no 11, *Nature biotechnology*, p. 1348.



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 legal, social and ethical analysis.

CURRENT ISSUE

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

Newborn screening (NBS) programs are implemented as government sponsored public health initiatives. They aim to identify infants affected by inborn disorders that can result in mortality or lifelong disability if left untreated. This edition of GenEdit critically examines how existing guidelines and policy statements have addressed (I) consent to screening for treatable diseases; (II) consent for untreatable diseases/ and a wider range of disorders; (III) consent to storage; and (IV) consent to future uses of stored samples. Finally, we conclude with a few recommendations to help address the issues of informed decision-making.

PAST ISSUES

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 data bank.

National Society of Genetic Counselors, *Position of NSGC on Somatic Cell Nuclear Transfer (SCNT) or Cloning for Therapeutic and Reproductive Purposes*, Wallingford, 2004, <http://www.nsgc.org/about/position.asp> (date accessed: November 1, 2004).

Somatic cell nuclear transfer (SCNT) is defined as the process of removing the nucleus from a somatic donor cell and placing it within an enucleated ovum. Its use is being considered for two distinct purposes: research into potential therapies and reproduction.

Canadian Biotechnology Advisory Committee, *Protecting Privacy in the Age of Genetic Information*, Ottawa, August 2004, 91 p., [http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwapj/Privacy_Report_final_e.pdf/\\$FILE/Privacy_Report_final_e.pdf](http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwapj/Privacy_Report_final_e.pdf/$FILE/Privacy_Report_final_e.pdf) (date accessed: November 4, 2004).

With this publication, consisting of the two background papers and the synthesis paper, CBAC provides background and some possible answers, informed opinion and recommendations to guide legislators and others as they grapple with these issues.

Office for Human Research Protections, *Department of Health and Human Services, Guidance on Research Involving Coded Private Information or Biological Specimens*, August 10, 2004, <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf> (date accessed: November 1st, 2004)

This document applies to research involving coded private information or human biological specimens (hereafter referred to as "specimens") that is conducted or supported by HHS.

GeneWatch, *Bar-coding Babies: Good for Health?*, Buxton, August 2004, <http://www.genewatch.org/Publications/Briefs/brief27.pdf>, (date accessed: October 21, 2004).

Last year, in its White Paper on genetics in the National Health Service (NHS) the Government included the idea of screening babies at birth "to produce a comprehensive map of their key genetic markers, or even their entire genome." This briefing considers the implications of the genetics screening of newborn babies.

GeneWatch, *Genetic Tests and Health: The Case for Regulation*, Buxton, September 2004, <http://www.genewatch.org/Publications/Briefs/brief28.pdf>, (date accessed: October 21, 2004).

The completion of the Human Genome Project has opened some new avenues for medical research. It has also led to the marketing of genetic tests which identify parts of the sequence of an individual's genome. Genetic tests are marketed over the internet via alternative healthcare providers or private GPs or via the health service. Tests may be accompanied by health advice or products which are supposedly tailored to the customer's individual genetic make-up. One day, people may even be able to buy a scan of their whole genetic make-up. This briefing considers the case for regulating these genetic tests. Some important questions are

1. Will people taking genetic tests be given reliable and accurate information?
2. Will the products and advice supplied with genetic tests be good for health?
3. Are controls in place to prevent misleading marketing by commercial companies? [...]

External Advisory Committee on Smart Regulation, Government of Canada, *Smart Regulation: A Regulatory Strategy for Canada*, Ottawa, September 2004, http://www.smartregulation.gc.ca/en/08/part_1.asp, (date accessed: October 21, 2004).

The External Advisory Committee on Smart Regulation recommends major shifts in perspective and practice in this report. The Committee believes that the federal government must use regulation more strategically in the 21st century to advance Canadian interests and priorities. The way we regulate should be clearly seen to support national policies. As illustrated in Part II of the report, this means ensuring that our regulatory system supports the best health outcomes for Canadians, encourages innovation, sustainability and investment opportunities in Canada's manufacturing and natural resources sectors, enables First Nations economic development, and helps promote important new industries like biotechnology.

Office of Biotechnology Activities, National Institutes of Health (NIH), *NIH Guidance on Informed Consent for Gene Transfer Research*, February 17, 2004, http://www4.od.nih.gov/oba/rac/ic/pdfs/temp_pdf.pdf, (date accessed: October 26, 2004).

Since before the first clinical gene transfer trial began enrolling subjects, the National Institutes of Health (NIH) and its Recombinant DNA Advisory Committee (RAC) have sought to assist investigators in developing good consent forms and processes for clinical gene transfer research. Appendix M sections M-III and M-IV were added to the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) to address points and issues related to informed consent that would benefit from particular attention.

The Danish Council of Ethics, *Patenting Human Genes and Stem Cells: A Report*, London, 2004, http://etisk.inforce.dk/graphics/03_udgivelser/engelske_publicationer/patenting_human_genes/patents04/patenting_human_genes.pdf (date accessed: October 18, 2004).

The Danish Council of Ethics is sending out its report on the ethics of patenting human genes and stem cells. The report is a follow-up to the Council's 1993 report *Patenting Human Genes*, and the present report thus deals with the developments in the field that have taken place in the past 10 years.

Centers for Disease Control and Prevention, "Newborn Screening for Cystic Fibrosis: Evaluation of Benefits and Risks and Recommendations for State Newborn Screening Programs", Atlanta, October 15, 2004, 53: RR13, p.1-36, <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5313a1.htm>, (date accessed: October 22, 2004).

In November 2003, CDC and the Cystic Fibrosis Foundation cosponsored a workshop to review the benefits and risks associated with newborn screening for cystic fibrosis (CF). This report describes new research findings and outlines the recommendations of the workshop.

Genomics Working Group, Task Force on Science, Technology and Innovation, UN Millennium Project, "Genomics and Global Health," 2004, 79p., <http://www.cid.harvard.edu/cidbiotech/genomics.pdf>, (date accessed: October 25, 2004).

The idea for this report was born out of conversations between the Task Force on Science and Technology of the United Nations Millennium Project (commissioned by the United Nations Secretary-General Kofi Annan) and researchers at the University of Toronto who had recently authored a study on the top 10 biotechnologies for improving health in developing countries. The result explores the relationships between genomics and the Millennium Development Goals (MDGs) and shows how cutting-edge science closely aligns with the UN's development agenda.

Swiss National Advisory Commission on Biomedical Ethics, *Opinion no. 6/2003, On the Regulation of Living Donation in the Transplantation Law*, Bern, March 2004, http://www.nek-cne.ch/en/pdf/stellungnahme6_en.pdf, (date accessed: October 26, 2004).

Living donation is playing an increasingly important role in transplantation medicine. Not only the kidney, but also parts of the liver, lung and small intestine, as well as bone marrow and other tissues, can now be obtained from living donors and successfully transplanted; the risks involved are low or, if more substantial, possibly still acceptable. The ethical issues identified in this field by the Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE) are here presented in context.

Executive Board, United Nations Educational, Scientific and Cultural Organization (UNESCO), *Report by the Director-General on the Drawing up of a Declaration on Universal Norms on Bioethics*, 170th Session (170 EX/9), August 20, 2004, <http://unesdoc.unesco.org/images/0013/001360/136013e.pdf>, (date accessed: October 26, 2004).

Pursuant to 169 EX/Decision 3.6.2 and in accordance with the timetable approved by the Executive Board at its 169th session in the same decision, the Director-General submits this progress report on the work carried out by UNESCO concerning the drawing up of a declaration on universal norms on bioethics. An addendum to this document will contain the outline of the text of the declaration drafted by the International Bioethics Committee at its eleventh session (23-24 August 2004) and the decision proposed to the Executive Board thereon.

American College of Medical Genetics, "Second Trimester Maternal Serum Screening for Fetal Open Neural Tube Defects and Aneuploidy," (2004), 6(6): *Genetics in Medicine*, <http://www.acmg.net/resources/policies/pol-031.pdf>, (date accessed: October 26, 2004).

Maternal serum screening has been modified during the past 25 years and is now widely utilized during the second trimester to identify women at risk for fetal open neural tube defects (ONTDs), anencephaly, and trisomies 21 and 18. This statement replaces the 1994 and 1996 ACMG position statements on serum screening and discusses clinical guidelines for screening that complement the sections of ACMG's *Standards and Guidelines for Clinical Genetics Laboratories* entitled "Prenatal Screening for Open Neural Tube Defects" and "Prenatal Screening for Down Syndrome."



DRAFTS



FAQ

Q What is a Research Ethics Board (REB)?

A A Research Ethics Board (REB) is the local Canadian entity that evaluates research projects, including genetic research, involving human beings. The *Tri-Council Policy Statement* and the FRSQ's *Guide d'éthique de la recherche et d'intégrité scientifique*, are documents produced, respectively, by the three Councils that finance research in Canada and by the organization that finances research in Quebec (FRSQ). The documents address the question of the composition of an REB and specify that an REB is composed of at least five people: two people experienced in the methods or discipline of the research under evaluation, one person experienced in ethics, one person with legal expertise and one representative of the public. The *Tri-Council Policy Statement* and the FRSQ's *Guide d'éthique* also indicates that an REB must be independent of any and all financial or material gains that could result from the research.

Q What is the role of Research Ethics Boards (REBs) in Quebec?

A In Quebec, the principal role of Research Ethics Boards (REBs) is to protect research participants. REBs are charged with the evaluation of research involving human beings, including genetic research. REBs evaluate the projects from a scientific and ethical standpoint. They ensure that the research projects meet applicable norms. They carry out an annual follow-up of approved research projects. The Research Ethics Boards can also have a training mandate (of the researchers, students or REB members).

Q Do genetic research projects with human participants require evaluation by an ethics committee?

A International norms suggest that all research projects involving humans must be evaluated by an ethics committee. In Quebec and in the rest of Canada, organizations financing or regulating research (such as for example the FRSQ, Health Canada or the Ministry of Health and Social Services in Quebec) require evaluation of genetic research by Research Ethics Boards (REBs). In Quebec, all experiments involving minors, or adults who lack capacity to provide consent, must be evaluated by a designated ethics committee (*Civil Code of Quebec*, article 21). These ethics committees must be named by the Minister of Health and Social Services.



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. The following is a brief survey: and your opinion 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 responds to your needs?



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