
Professional Ethics Report

Publication of the American Association for the Advancement of Science
Scientific Freedom, Responsibility & Law Program in collaboration with
Committee on Scientific Freedom & Responsibility
Professional Society Ethics Group

VOLUME XV

NUMBER 1

WINTER 2002

CANADA PRODUCES REPORT AND POLICY RECOMMENDATIONS FOR GENE PATENTING

By Rachel J. Gray

Patents for Human Genes

The patenting of human genes has raised and continues to raise considerable international debate, even 22 years after the landmark U.S. Supreme Court Case¹ that effectively established the legal basis for the patenting of genes. Much of the ongoing debate originally focused on whether and/or to what extent patents on isolated human genes or DNA sequences can and/or should be granted. Along with the ethical, legal and social issues surrounding human gene patenting, new issues are arising in health care. Such issues pertain to scientific freedom, market monopolies, overly stringent or expensive licensing regimes, and the ability of publicly funded healthcare to afford the costs that will inevitably come with new genetic technologies.

Current Situation²

United States

Many U.S. scientists have voiced concerns that gene patents create an atmosphere of scientific secrecy due to the pressure to patent. Furthermore, some claim that patents are chilling research since many universities and commercial laboratories fear patent infringement or lack the funding required for royalty and/or licensing fees associated with genetic research on genes that may be patented. In fact, one study showed that 48% of laboratories surveyed decided not to develop genetic tests based on patented genetic materials.³

Europe

In Europe, there is opposition to a U.S. company's patent held on breast cancer genes (BRCA 1 and 2). Led by France, the opposition is based on the European Patent Office's "ordre public" clause that states that a patent - even after being granted - can be challenged if it is against public morality. In recent months, Belgium and the Netherlands have joined this opposition. In addition to this, the Council of Europe is calling for improved legislation on human gene patenting.

Canada

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In Canada, Canadian policymakers are pro-actively discussing how human gene patents and the patenting of genetic tests will affect Canada's publicly funded healthcare system. There is concern that if issues surrounding human gene and genetic testing patents are not discussed and/or resolved across Canadian jurisdictions, patents may block the availability of many genetic services and/or products. The possible inclusion of a comparable 'ordre public' clause in the Canadian Patent Act is being considered, among other changes that are discussed below.

Patenting 101

Since genes are part of the shared commonality of humankind and raw products of nature are human genes patentable? Are the techniques used to isolate human genes, DNA, SNPs (single nucleotide polymorphisms) or ESTs (expressed sequencing tags) subject to intellectual property rights? Are the tools, diagnostic or otherwise, that can be derived from isolation of the genetic information patentable? The answers to these questions are dependent upon whether the criteria for patent applications are met. The four criteria to determine whether something is patentable vary little on a global scale. The criteria are: 1) the invention must be useful in a practical sense and its useful purpose must be identified in the patent application; 2) the invention must be new/novel, in that the product claimed is/was not previously known, used or available in the claimed form before the filing of the patent application; 3) the invention must be non-obvious, not simply an improvement that is easily made by someone trained in the relevant area; and 4) the invention must be described in sufficient detail to allow someone skilled in the relevant field to use it for the purpose stated in the application. Once an application is filed, patent priority is given based on the first to file principle in all countries except the U.S., where the first to invent principle is utilized.

Canadian Consensus on Report and Recommendations

In Canada, the province of Ontario has led policy work on human gene and genetic test patenting. This stems from the fact that the Premier of Ontario, Mike Harris, raised the issue of human gene patenting at a gathering of all Canadian Premiers in August 2001. At that point, Ontario was charged, through the Ministry of Health and Long-Term Care, to produce a report surveying the multitude of issues surrounding human gene patenting and genetic testing and to develop recommendations to address the issues. The report, *Genetics, Testing and Gene Patenting: Charting New Territory in Healthcare*, was presented on January 25, 2002 at a special Premiers' meeting on healthcare. In an extraordinary occurrence, complete consensus was reached by all Canadian Premiers surrounding the report and its key recommendation for the development of a coordinated, cross-jurisdictional framework on genetics in healthcare. The report was hailed as an innovative comprehensive plan and all jurisdictions supported inter-governmental cooperation and a

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coordinated approach to prepare all health systems for the upcoming changes related to genetics and gene patents.

The report addresses human gene patenting, the use of genetics in medicine, the ethics of genetic testing and patenting, public demand for genetic tests, and direct to consumer marketing. It also surveys and analyzes the economic impact, capacity to deliver genetic services in terms of human resources, oversight and regulation. The report provides a set of recommendations for dealing with gene patents in Canada over the short-to-long-term.

An important focus of the report is gene patenting; the report provides nine areas for possible action regarding patent reform. Some include ensuring appropriate protections from patent infringement for healthcare professionals and institutions when using genetic materials in research, developing new guidelines for the Canadian Patent Office, clearly defining patentable subject matter and excluding broad-based genetic patents, clarifying experimental and non-commercial use exceptions, expanding the "methods of medical treatment" exclusion in the Patent Act, adopting an "ordre public" or morality clause in light of human cloning and stem cell research, and introducing a nine-month opposition period for new gene patents.

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The *Professional Ethics Report* is published quarterly by the Scientific Freedom, Responsibility and Law Program in collaboration with the Committee on Scientific Freedom and Responsibility and the Professional Society Ethics Group, American Association for the Advancement of Science, 1200 New York Avenue, NW, Washington, DC 20005, (202) 326-6792; Fax (202) 289-4950; E-mail ssiang@aaas.org; WWW <http://www.aaas.org/spp/dspp/sfirl/sfirl.htm>. Back issues of *Professional Ethics Report* are now on-line at <http://www.aaas.org/spp/dspp/sfirl/per/per.htm>

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ISSN: 1045-8808

The other areas of recommendation in the report include the development of an inter-jurisdictional framework and coordinating body, public and professional education and engagement, genetic technology assessment, service delivery in terms of quality control and human resources, privacy, disability and discrimination, the coordinated availability of testing, and support for the biotechnology sector.

Full contents of *Genetic, Testing and Patenting: Charting New Territory in Healthcare*, including the recommendations, can be found on the WWW at: <http://www.gov.on.ca/health/english/pub/ministry/geneticsrep02/genetics.html>.

The Biotechnology Industry

The Canadian genomics industry is rapidly growing, second only to that of the US. No jurisdiction in Canada has opposed gene patenting outright and there is general recognition that patents constitute important intellectual capital for the biotechnology industry and they are seen as an important incentive for innovation.

That said, there are concerns that legislation has not kept pace with science, and many have urged that the Canadian Patent Act be modernised, looking forward in order to retain and strengthen its capacity to innovate, lead and provide optimum healthcare to Canadians. In other words, to better balance patient care with the needs of the industry. According to Ontario Premier Mike Harris, "the human genome is our common heritage, so the benefits of genetic research belong to us all...there must be a balance between rewarding innovation and making these technologies accessible and affordable."

Are Human Genes Being Patented Now?

In Canada, gene patents are regularly being granted on information contained in human genes and DNA fragments. The same is true for the U.S. According to a recent U.S. study, approximately 9,000 patents on genes, gene sequences and gene patents have been granted and tens of thousands more applications are under consideration by the U.S. Patent and Trademark Office.

Many of the gene patents granted in North America confer the patent holder(s) with a very broad scope of ownership rights. In fact, numerous patents have been granted which give the patent holder(s) rights to any information that may be developed from research on their patented material, including rights to unforeseen products stemming from patented material, such as

Letters to the Editor: The editors welcome comments from our readers. We reserve the right to edit and abridge letter as space permits. Please address all correspondence to the deputy editor.

diagnostic tools and not yet known tools and/or uses.

Case in Point - Patenting Stem Cells

Patents are being granted on embryonic stem cells. In fact, very recently a U.S. research foundation and a commercial company reached a patent licensing agreement on embryonic stem cells types and technology. The research foundation has patents on 5 of the 72 stem cell lines approved for U.S. federally funded research and the commercial company holds the licensing rights to some of the technologies used to derive, culture, and maintain those cells. The agreement reached gives exclusive rights to the commercial company to develop products from stem cells derived from nerve, heart and pancreas cells and non-exclusive rights to the use of blood, cartilage and bone cells. It also narrows academic and government researchers' use of the patented technology without a licensing fee as long as the work is for research rather than product development.

The patenting of stem cells might mean that exclusive royalty fees will have to be paid in the future for replacement organs and tissues, raising significant implications both ethically and financially for publicly funded healthcare. This situation illustrates some of the concerns and problems surrounding human gene patenting.

Conclusion

It is estimated that approximately 60% of Canadians will experience a disease with a genetic component during their lifetime. Genetic research promises to improve human health and the delivery of healthcare, and genetic-based medicine and technology have the potential to re-define medical care. If patents are granted on each gene, gene sequences or ensuing technologies and are not able to be challenged, the perceived positive advances from genetic research and development may not be accessible. Patents may increasingly become obstacles to realizing potential benefits of the genetic revolution if the issues surrounding gene patenting are not examined presently, possibly on an international scale.

References

¹ *Diamond v. Chakrabarty*

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² For a full jurisdictional review see Appendix 1 in *Genetics, Testing and Patenting: Charting New Territory in Healthcare*, January 2002 on the WWW at: <http://www.gov.on.ca/health/english/pub/ministry/geneticsrep02/genetics.html>.

³ Cho. M. Ethical and Legal Issues in the 21st Century in Preparing for the Millennium. *American Association for Clinical Chemistry*. 1998; 47-53.

IN THE NEWS

JOURNAL PULLS PAPER

A paper examining the genetic origin of Palestinians and other Mediterranean populations led to an unusual action from *Human Immunology*, the journal that originally published the paper, and a great deal of controversy concerning both the paper and the actions of the journal.

The published study analyzed the genetic variability in the HLA complex of immune genes among Palestinians and other populations, concluding that Palestinians are genetically very close to Jews and other Middle East populations. In September 2001, the paper was published in a special issue of *Human Immunology* devoted to comparative population genetics under the supervision of guest editor Antonio Arnaiz-Villena of the Department of Immunology and Molecular Biology at the University of Complutense of Madrid, Spain. Shortly thereafter, under a barrage of complaints and the threat of mass resignations from the American Society for Histocompatibility and Immunogenetics (ASHI), which publishes the journal, editor-in-chief Nicole Sucio-Foca had all electronic versions of the article removed and a letter was sent by the publishing company to subscribers and librarians asking them to ignore the article "or, preferably, to physically remove the relevant pages."

The controversy arose over the content of the introduction, which included a summarized history of occupation in the region Israel and Palestine. This introduction included references to Jews living in the Gaza strip as "colonists" and Palestinians as living in "concentration camps." The decision of the editorial board to expunge the paper completely was based on the political bias of the paper, citing it as "inappropriate use of a scientific journal

for a political agenda." In a letter to ASHI members on October 3, 2001, president at the time, Dolly Tyan, wrote that the society is "offended and embarrassed."

Arnaiz-Villena, also lead author of the paper, asserted that the paper underwent the proper peerreview process and was approved by two reviewers. However, Sucio-Foca claims the article did not go through peer-review. In response to this incident, the editorial board has revised its policy to allow the editor-in-chief to supervise all future work by guest editors. Arnaiz-Villena has said that he was shocked by the unexpected removal of his paper, and that he never intended to offend anyone.

The editors of *Human Immunology* have invited Arnaiz-Villena to resubmit a new version of the paper, and are now considering the revised version for publication. PM

EUROPEAN PARLIAMENT REJECTS HUMAN GENETICS REPORT

On November 29th, 2001, the European Parliament (EP) voted to reject the recommendations of a report on the ethical, legal, economic, and social implications of human genetics. The report was the culmination of an eleven month effort by the Temporary Committee on Human Genetics and Other New Technologies in Modern Medicine to assess the role of the European Union in encouraging competitive development of the biotechnology industry in accordance with ethical principles. It was the first attempt to create regulatory guidelines to govern scientific and technological procedures throughout Europe.

The formation of the Temporary Committee by the EP in December 2001 stemmed from concern over the effect of novel biomedical research on the public's health, safety, and human rights. The report addressed these issues by providing a framework for the protection of genetic confidentiality and non-discrimination, international training on good clinical practices, nonpatentability of human embryos, and proposals for the EU Framework Program for Research.

Among the controversial recommendations was a ban on all human embryo cloning and embryonic stem cell research, both of which are permitted in the UK under the 1990 Human Fertilization and Embryology Act. Related activities prohibited by the recommendations included human reproductive cloning, production of hybrids or chimeras, and human germ line

modification. In addition, debate was fueled by ambiguity regarding evaluation of gene patents.

During the full parliamentary hearing, attempts were made to salvage the report's recommendations. But the 230 additional amendments adopted only created internal document contradictions and general confusion. The recommendations were rejected by a vote of 316 to 37 (with 47 abstentions).

The European Parliament is the 626 Member legislative body of the EU. Independent from member state national parliaments, the EP is responsible for appointment of the EU Commission, deciding the budget, and approval of international agreements. For more information on this report, see <http://www.europarl.org.uk/news/NWSindexmain.htm> SL

BECKONING A CALL: DISCLOSING CONFLICTS OF INTEREST

For many scientists maintaining quality and integrity in research is a main concern. In early February, this issue was the thrust behind a group of scientists' letter campaign urging science journal editors to toughen their policies regarding disclosure of conflicts of interest.

The letter targeted over two hundred science journals, including *Science* and *Proceedings of the National Academy of Sciences*. The list of endorsements includes more than two dozen prominent scientists and academics spanning several disciplines, and two former editors of *The New England Journal of Medicine* and a former editor of *The Journal of the American Medical Association*. The group is endorsing a more complete disclosure policy by urging journal editors to additionally publish alongside studies, reviews, editorials and letters:

- authors' sources of funding for the published study or review;
- the financial interests of authors and their families in the last 5 years in industries that have financial interest in the study;
- the specific contribution of each author of the published paper.

The letter comes at a time when clinical researcher-industry partnerships and university-industry partnerships are expanding at unprecedented levels. The marriage of clinical and university research with industry has concomitantly increased the

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influence industry has over scientific research. The tie that bonds this unlikely matrimony is money. These partnerships can take many forms: an industry-supported grant, research patent arrangements, researchers as paid consultants, researchers serving as members on advisory boards, and others. There are concerns that the financial relationship shared between an industry and a researcher can subtly influence scientific judgment. The group hopes to engage science journal editors in broader editorial oversight to reduce the risk of research bias.

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NIH DEVELOPS DRAFT STATEMENT ON DATA SHARING

The National Institutes of Health has announced a draft statement on data sharing that will allow scientists to “expedite the translation of research results into knowledge, products and procedures to improve human health.”

Data from NIH-supported studies should be shared in order to encourage the free exchange of scientific ideas and inquiries. A diversity of analyses and opinions will not only help educate researchers, but can promote new research or give rise to the testing of new or alternative hypotheses and methods of research. Researchers may also be turned on to topics of research never before explored, or may collaborate data with other researchers to create new data sets. Sharing data can also prevent the duplication of expensive data collection activities. Consequently, the NIH will be able to support more investigators.

Scientists seeking to conduct NIH-supported basic research, clinical studies, surveys and other types of research will be required to submit an application that includes a plan for data sharing or why data sharing is not possible. Ways that research data can be made available to the scientific community is through publications, public archives and web sites.

The NIH recognizes those instances in which sharing data may not be feasible. Data about human subjects research must never breach confidentiality or disclose linkages to the identity of participants in order to assure that the rights and privacy of human subjects are protected. NIH also recognizes that restrictions may be imposed by third parties, and that certain data may be patented or exclusively owned. In some cases, studies using very small

samples will not need to be subjected to data sharing.

Data-sharing is a topic that goes beyond NIH policy. On February 25, a select group of scientists and journal editors convened at the National Academies of Science with the objective of providing guidance for data sharing in scientific publishing.

One idea presented was that industry should have to release all data, as does academia, and not engage in “partial data release.” Another perspective stressed that people must “recognize the importance of the emerging biotechnology industry, and avoid adopting a set of ‘feel-good’ data-release policies that suit mainly academics.” Industry and academia should be synergistic in their goal to further the scientific enterprise, and many participants at the meeting felt that setting such types of policies will only drive the two apart.

See http://grants.nih.gov/grants/policy/data_sharing/index.htm Comments period for the draft policy ends on June 1, 2002. NIH expects to finalize a new policy by August 1, 2002 with a proposed effective date of January 1, 2003.

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ETHICS, LAW AND PUBLIC POLICY

HUMAN CLONING ATTEMPT PROMPTS GOVERNMENTAL REACTIONS

By Brent Garland

In November, 2001, biotechnology company Advanced Cell Technologies (ACT) announced that it had successfully “cloned” a human being through somatic cell nuclear transplant, resulting in a number of two-, four-, and a single six-cell embryo(s).¹ The announcement fast-tracked debate in the U.S. Congress over the ethics and legalities surrounding human cloning and cloning research.

The U.S. House of Representatives rapidly passed the “Human Cloning Prohibition Act of 2001”² by a substantial majority. Cloning to create another human person (“reproductive cloning”), as well as experimentation that sought to understand more fully cellular processes and mechanisms (“research cloning”), would be illegal and, by the terms of the act, criminal offenses.³ In addition, the act would prohibit importation of cloned embryos or any deriva-

tives therefrom, such as stem cells or medical treatments derived from cloned embryos. An identical bill has been proposed in the Senate,⁴ and several other bills have been proposed that would place lesser restrictions on human cloning research.⁵ In addition, some have called for a moratorium, which would automatically expire, rather than a complete ban, which would require repeal.⁶ While a debate is scheduled to come to the Senate floor in March, it is likely that it will be held after the Easter recess.

There have been a number of hearings during the second session of the 107th Congress on cloning, with impassioned and reasoned arguments in support of both the total ban and the narrower ban on reproductive cloning alone. The arguments for those favoring a narrower ban tend to be based in the potentialities of the research—possible cures, treatments and therapies that may result from cloning research. In addition, opponents to the total ban express concern about a law which would make certain types of research punishable as a crime, as the House bill would if enacted into law. Those favoring a total ban tend to base their arguments around preserving the genetic uniqueness of humans, the moral status of the embryo, and concerns about possible unintended consequences of cloning. In additions, some of those opposing cloning in any form have expressed concerns that cloning research might lead to the commercial exploitation of low-income women by creating a market for human ova harvested by health-threatening hormone treatment and surgery.

The President has indicated that he supports the House bill,⁷ which calls for a total ban, and which is mirrored in the Senate by the bill sponsored by Sens. Brownback and Landrieu. In support for the bill, the White House released the following statement: “The Administration supports a ban on the cloning of human beings by somatic cell nuclear transfer. The Administration unequivocally is opposed to the cloning of human beings either for reproduction or for research.”⁸

The Administration’s position has created some political tension. The United Nations recently hosted the first meeting of the United Nations Ad Hoc Committee on an

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International Convention against the Reproductive Cloning of Human Beings. The Ad Hoc Committee was created to draft a U.N. convention to ban reproductive human cloning.⁹ With the cloning issue still legislatively open in the U.S., the U.S. Delegate to the U.N., Carolyn Willson, called on the Ad Hoc Committee members to draft a “global and comprehensive ban” on human cloning, including research cloning.¹⁰

If the U.S. enacts legislation which allows for research cloning, but bans reproductive cloning, the Executive branch will be in the awkward position of asking all other member nations of the U.N. to refrain from doing what U.S. scientists will be able to do.¹¹ The absolute ban that the U.S. has called for in the U.N. Ad Hoc Committee¹² faces opposition from a number of nations that favor research cloning for possible therapeutic developments. The call for a global, comprehensive ban will be harder to justify if the U.S. is conducting research cloning, and reaping what scientific, medical, and therapeutic benefits may be found—a case of “do as I say, not as I do.”

The diversity of legal positions on cloning in the Federal Legislative and Executive branches (essentially five choices: a total or narrow ban, crossed with civil and/or criminal penalties; or a moratorium of some sort) is reflected in the cloning bans already enacted into law by a number of states.¹³ Several states have enacted total bans, while others have enacted reproductive cloning bans that would permit research cloning.¹⁴ It is worth noting that while several states have set civil penalties for violation of their anti-cloning statutes, it appears that only one state, Michigan, has criminalized the act.¹⁵ The impact of the federal legislation will depend on what is finally enacted, but it seems likely that there will be some conflicts between the state and federal statutory schemes.

What the current hasty debate over cloning makes absolutely clear is the value of having a scenario-driven, pro-active approach to addressing the questions likely to arise in the face of developing technologies. The announcement of the cloned sheep Dolly, delivered by live birth in 1996,¹⁶ surely presaged the attempts to clone humans. Rather than being buffeted by the storm of “human cloning” as its feasibility drew near, stakeholders should have begun the dialogue over implications and possible policies and laws five years

ago. While there were some who did act early to begin the dialogue, including the National Bioethics Advisory Commission,¹⁷ the current debate clearly needs to be broadly-based and inclusive of the public.

¹ See Cibelli, J.B., Lanza, R.P., West, M.D., and Ezzell, C., “The First Human Cloned Embryo,” *Scientific American*, <http://www.sciam.com/explorations/2001/112401ezzell/>. See also, Cibelli, J.B., Kiessling, A.A., Cunniff, K., Richards, C. Lanza, R.P., West, M.D., “Somatic Cell Nuclear Transfer in Humans: Pronuclear and Early Embryonic Development” (Rapid Communication), e-biomed: *The Journal of Regenerative Medicine*, Volume 2, November 26, 2001, <http://www.liebertpub.com/ebi>.

² See H.R. 2505.

³ The criminalization of research is an unusual step, with unsettling implications. Obviously, some scientific research can violate existing criminal laws (negligent homicide, for example), but typically the restrictions that lawmakers place on *specific areas* of research do not involve federal criminalization. Creation of a federal crime is itself a noteworthy event, as the vast majority of criminal statutes are typically left to the individual states to define and enforce.

⁴ See S. 1899, sponsored by Sens. Brownback and Landrieu.

⁵ Generally, the proposed legislation would ban “reproductive cloning” but allow “research cloning.” Sens. Feinstein and Kennedy have introduced one such bill and Sens. Harkin and Specter have introduced another. For an article exploring the legislative posture on cloning as of the time of this writing, see “Senate Braces for Cloning Debate,” in the February 2002 issue of *Science and Technology in Congress*, a publication of the Center for Science, Technology and Congress at AAAS (online at <http://www.aaas.org/spp/cstc/stc/stc02/02-02/cloning.htm>). The Center also maintains an excellent resource page on cloning at <http://www.aaas.org/spp/cstc/issues/cloning.htm>.

⁶ For example, bioethicist and former Commissioner of the National Bioethics Advisory Commission, Alexander Capron has called for a moratorium on all types of cloning research. See Mestel, R., “Panel Urges State to Limit Human Cloning to Research, Therapy; Science: Report calls for a ban on using the process to produce babies,” *Los Angeles Times*, January 12, 2002. Similarly, Brent Blackwelder, President of Friends of the Earth, recently testified to Congress in support of a moratorium. See, Weiss, R., “Cloning Creates Odd Bedfellows,” *The Washington Post*, February 10,

2002.

⁷ See, the White House press release of the President’s statement of support, <http://www.whitehouse.gov/news/releases/2001/07/20010731-12.html>. In addition, see the transcript of the March 28, 2001 press briefing by Ari Fleischer, the President’s Press Secretary, <http://www.whitehouse.gov/news/briefings/20010328.html#Cloning-Humans>.

⁸ The July 30, 2001 news release, in support of Rep. Weldon’s proposed ban, H.R. 2505 (subsequently approved in the house), is archived at <http://www.whitehouse.gov/news/releases/2001/07/20010730-8.html>.

⁹ The initiative for such a ban came from the member nations of France and Germany. See, the U.N. press release, “Committee Charged with Elaborating Convention to Ban Human Cloning Concludes First Session at Headquarters,” <http://www.un.org/News/Press/docs/2002/12996.doc.htm>.

¹⁰ See, Lynch, C., “U.S. Seeks to Extend Ban on Cloning,” *Washington Post*, February 27, 2002, at <http://www.washingtonpost.com/wp-dyn/articles/A8119-2002Feb26.html>.

¹¹ This assumes that the President does not veto such legislation, or that Congress can override such a veto.

¹² Joined by the Holy See and Spain, among others. See, Wurst, J., “CLONING: U.N. Debate Centers On Total Ban Or Allowance For Research,” *UN Wire*, February 28, 2002 at <http://www.unwire.org/unwire/2002/02/28/current.asp#24242>.

¹³ The National Conference of State Legislatures reported that as of January 29, 2002, five states had enacted cloning bans of some scope. They maintain a web page that tracks these statutes at <http://www.ncsl.org/programs/health/genetics/rt-shcl.htm>.

¹⁴ See, for example, VA CODE §§32.1-162.21 and 32.1-162.22, and CA Business and Professions Code §16105 and CA Health and Safety Code §§ 24185-24189.

¹⁵ Michigan has made it a felony to “intentionally engage in or attempt to engage in human cloning.” See Michigan Penal Code §750.430a. See also the National Conference of State Legislatures web page at <http://www.ncsl.org/programs/health/genetics/rt-shcl.htm>

¹⁶ See Campbell, K.H.S., McWhir, J., Ritchie, W.A., & Wilmut, I. (1996), “Sheep cloned by nuclear transfer from a cultured cell line,” *Nature*, 380, 64-66

¹⁷ Even the National Bioethics Advisory Commission’s prominent study of the cloning issue was rushed—President Clinton asked for a report within 90 days of when he asked NBAC to consider the issue. The ultimate impact of the NBAC Report has yet to be determined, though some feel

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that the greatest service NBAC did was in communicating clearly and directly to the public the complicated issues involved in cloning. See, for example, Russo, E., "A Look Back at NBAC," *The Scientist*, Oct. 11, 1999, at http://www.the-scientist.com/yr1999/oct/russo_p4_991011.html.

IN THE SOCIETIES

UNIVERSAL DECLARATION OF ENGINEERS' RIGHTS

Since 1997, an Institute of Electrical and Electronic Engineers (IEEE) listserv and discussion group has been the sounding board for many engineers on the topic of engineering responsibilities and rights. The comments resulting from the listserv, in addition to thoughts expressed in relevant publications were captured and compiled into the Universal Declaration of Engineers' Rights. The most recent, version 3.2, was published online on December 5, 2001.

The responsibilities of a Licensed Professional Engineer, clearly delineated in the obligatory Engineering Code of Ethics, include the responsibility to ensure the public safety and welfare through proper practice and application of technologies. These moral responsibilities often conflict with the professional or political interests of employers, presenting difficult ethical dilemmas.

The "employment at will" doctrine, which governs US employment (excluding government and labor union employees), gives employers the absolute right to terminate any employee, "at will" for any reason. Because of the immediate and universal impact of their work, an engineer's ability to make professional, scientific decisions must not be influenced by any threat of reproof or termination.

The Declaration states that, "in order to be able to practice ethically, and to be held accountable either to the legal or a society's code [of ethics]...engineers must be conferred certain rights, or, freedoms of independence to practice, free from coercion, harassment or wrongful discharge, to balance these imposed responsibilities."

Though specifically addressing engineers, the principles of the Declaration may be applied towards scientists of any discipline. Version 3.2 of the Universal Declaration can be viewed at <http://>

home.cfl.rr.com/welden/engineers_rights.html. Reviews and editing of the Declaration have been planned for the future. Comments may be sent directly to Walter L. Elden, welden@cfl.rr.com. For further discussion on the rights and responsibilities of practicing engineers, visit <http://www.nspe.org/ethics/eh1-res.asp>.
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NEW ALLIANCE TO PROMOTE PUBLICATION ETHICS IN CANADA

In November, editors of twenty-two Canadian peer-reviewed health science journals held a conference to promote discussion on ethical issues involved in scientific research, editing and publication. Sponsored by the *Canadian Medical Association Journal (CMAJ)* and the Canadian Institutes of Health Research (CIHR), the conference focused on the extent to which ethical and scientific misconduct is under-reported in the scientific community.

Those who attended proposed creating an independent committee to act as a resource for editors confronted with issues of ethical and scientific misconduct in evaluating manuscripts, including deliberate plagiarism, and fabrication and falsification of data. The charge of the committee would be to promote a concise editorial policy that cogently outlines research publication ethics while maintaining research objectivity, to uphold ethical behavior in research and publishing, and to develop educational resources for editors and peer reviewers. An essential part of its task would be to establish a database cataloguing case examples of unethical behavior, to provide guidelines for reporting misconduct, and to assist editors confronted with ethical issues.

The CMAJ Web site at <http://www.cma.ca/cmaj/> will post deliberations of the committee in a new Publication Ethics section that will provide online access to publication ethics for editors and researchers. The CMAJ Publication Ethics section can be found at <http://www.cma.ca/cmaj/publicationethics/index.asp>
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RESOURCES

RESEARCH INTEGRITY VIDEOS

The American Association for the Advancement of Science (AAAS) has re-released its popular videos on "Integrity in Scientific Research." This set of five video vignettes (ranging from 7-10 minutes each) dramatizes realistic situations confronting scientists, highlighting "gray areas" in research that will stimulate discussions on ethical behavior. Viewers are challenged to define ethical problems, identify options for responding to those problems, and to assess those options in light of their own experience and the norms and practices that govern the conduct of research. The videos are accompanied by a revised and updated *Discussion and Resource Guide*, which includes a compendium of resources on the teaching of research ethics and on issues central to research integrity and misconduct. For more information or to place an order, call (202) 326-6216 or visit WWW <http://www.aaas.org/spp/video>.
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AN ETHICAL CAREER IN SCIENCE AND TECHNOLOGY

Many scientists and engineers are faced with ethical or political dilemmas during their careers. Scientists for Global Responsibility published a summary of a report that explores some of the wider issues that scientists and engineers must deal with in the current state of global change.

Edited by Stuart Parkinson and Vanessa Spedding, *An Ethical Career in Science and Technology* will be published in 2002. The report includes contributions that introduce major scientific controversies and testimonies from current scientists. The prevailing theme throughout the report is that scientists must take responsibility for their work. In the introduction, 1995 Nobel Peace Prize Laureate Joseph Roblat states that "Scientists can no longer claim that their work has nothing to do with the welfare of the individual or with state politics," and that scientists should also concern themselves with the ethical implications involved in the application of pure science.

General topics covered include reasons why ethics should be taught at an earlier age, and how to deal with ethical dilemmas that may arise in certain scientific fields. These fields are environmental sciences, military sciences, and biological sciences. More specific issues include climate

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change, arms, militarisation of space, genetics and animal experiments. The report then outlines ways that research in these fields can be harmful to society and advises that scientists should be conscientious of and take responsibility for this impact, both directly and through indirect application of their research.

The report goes on to present more advice about how scientists can cope with ethical dilemmas and suggests how to avoid these dilemmas in current and future careers. Further issues that are touched upon include the funding of science and ethics and the world wide web. The summary is at WWW http://www.sgr.org.uk/AnEthicalCareer_cover.pdf
JS

ANNOUNCEMENTS

Conference- The **XIII Annual Strategy Conference**, convened by U.S. Army War College, will be held on April 9-11, 2002 in Carlisle, PA at Carlisle Barracks. The three-day event, with a follow-on "Teaching Strategy Workshop," will bring together representatives from Congress, national security strategists, senior military leaders, media, academia and the policy making community. Discussions will relate to issues concerning U.S. national security strategy and its moral dimensions. Contact Lt. Colonel Lawrence Painini (717) 245-4125; Email lawrence.papini@carlisle.army.mil

Conference- The **Eight Annual Trainer-of-Trainers Conference** on "Teaching Survival Skills and Ethics" will be held at Snowmass, CO on June 3-8, 2002. The conference will provide faculty and administrators with the background and materials needed to establish or improve instruction in research ethics and in a broad range of professional skills, such as effective communication, fund-seeking, and mentoring. Contact The Survival Skills and Ethics Program, University of Pittsburgh, 4K26 Posvar Hall, Pittsburgh, PA 15260; (412) 624-7098; fax (412) 624-7241; Email survival@pitt.edu; WWW <http://www.edc.gsph.pitt.edu/survival/teach.html>

Conference -The **Seventh National Communication Ethics Conference** will be held at Western Michigan University in Kalamazoo, MI, on May 30-June 2, 2002. The conference aims to promote research and teaching relating to ethical issues and standards in all aspects of human communication and to facilitate exchange among teachers and scholars of communication

ethics. Contact Cynthia Bergeon, Department of Communication, Western Michigan University, Kalamazoo, MI 49008; (616) 387-3130; fax (616) 387-3990; Email cynthia.bergeon@wmich.edu, WWW <http://www.wmich.edu/communication/ethics/>

Call for Papers - The **Society for Social Studies of Science (4S)** will hold its 26th Annual Meeting at the Hilton Hotel Milwaukee City Center, from November 7-10, 2002. The program committee encourages the submission of paper proposals on all subjects connected to the social and cultural analysis of science, technology and medicine. Authors should submit a one-page abstract (about 300 words) and a \$25 processing fee per submission by May 15, 2002. Contact Tom Gieryn, Engineering Professional Development, University of Arizona 1224 N Vine Ave, Tucson, AZ 85719; (520) 621-3054; fax (520) 621-1443; Email epd@engr.arizona.edu

Call for Abstracts - The **2nd Research Conference on Research Integrity (RCRI)**, sponsored by the U.S. Office of Research Integrity, will be held at the William F. Bolger Center for Leadership Development, in MD on November 16-18, 2002.

Abstracts for papers, poster sessions, panel discussions and working groups that discuss research on research integrity are welcomed. Research areas of particular interest include: authorship and publication, clinical research, human or animal subjects, conflict of interest, data management, institutions (universities or societies), mentoring, teaching responsible conduct, research climate, and research misconduct. In addition, papers and posters are welcomed on programs to promote research integrity, and ways to assess their effectiveness. Abstracts are due April 8, 2002 and will be peer reviewed. Contact Nicholas H. Steneck, Office of Research Integrity, DHHS, 5515 Security Lane, Suite 700, Rockville, MD 20852; (301) 443-5300; Email nsteneck@umich.edu; WWW <http://ori.dhhs.gov/html/programs/RCRIConf2002.asp>

Call for Papers - The **Journal of the Philosophy of Surgery and Medicine** invites submission of scholarly manuscripts, books for review and letters to the editor on topics relating, but not limited to, methodology and knowledge acquisition, certification and training, professional values, ethics, technology, concepts of disease and disability and resource allocation. Particular attention will be given to emerging scholars and clinically active physicians. The Journal is a semi-annual peer reviewed publication that provides a fo-

rum for the philosophic investigations of areas of import to the modern practice of surgery and medicine. Contact J Scott Isenberg, Editor-in-Chief *JPSM*, 216 NW 16th Street, Oklahoma City, Oklahoma 73103

Conference - The **Cleveland Clinic Foundation** and the **Office of Research Integrity (ORI)** are co-sponsoring Promoting Integrity in Clinical Research on May 2-3, 2002 in Cleveland, OH. The conference will focus on the ethical, institutional, and scientific issues related to integrity in the design and conduct of clinical research. The conference will address the unique questions regarding the responsible conduct of research when the subjects of research are also patients receiving medical care. Attendees of the conference will have the opportunity to learn about best ethical practices in the context of clinical research, principal investigator and institutional responsibilities for management of clinical research records, mentorship problems and responsibilities, current standards for authorship and publication of the results of clinical investigations, as well as ways of meeting emerging federal standards for research ethics education. See WWW <http://www.clevelandclinic.meded.com/courses/research2002.asp>

Workshop - The **Illinois Institute of Technology** will host Ethics Across the Curriculum, A Practical Workshop on how to integrate ethics into technical courses from July 30-August 6, 2002 in Chicago, IL. Application consists of a) a short letter describing reasons for wanting to take the workshop, applicant background, and the courses applicant will be teaching next fall; b) a CV; and c) a letter of commitment from the appropriate administrator indicating that the applicant's institution will pay its share of the \$2000 stipend if accepted. **Deadline for application has been extended to April 15, 2002.** Contact Michael Davis, Center for the Study of Ethics in the Professions, Illinois Institute of Technology, Chicago, IL 60616-3793; (312) 567-3017; fax (312) 567-3016; Email davism@iit.edu

Conference - the **Office of Research Integrity** and **Washington University in St. Louis** are co-sponsoring a conference on Conflicts of Interest and Research Integrity on April 16-17, 2002 at the Washington University School of Medicine in St. Louis, MO. Many universities are working to integrate institutional policies involving conflict of interest with other policies involving the ethical conduct of

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Professional Ethics Report

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research, particularly with regard to the protection of human subjects. This conference will discuss how conflict of interest, human subject protections and research integrity issues overlap and how conflict of interest and research integrity policies and administrative practices might be integrated. See WWW <http://research.wustl.edu/oc/news/conflicts.html>.

Call for Chapters - *Virtual Research Ethics: Issues and Controversies* is a book edited by Elizabeth A. Buchanan, University of Wisconsin-Milwaukee focusing on the use of the Internet/WWW as a medium for conducting research. Representative topics include but are not limited to the following: traditional research ethics and IRB protocols; philosophical dilemmas of

online research ethics; conducting online research; ethical codes of conduct for online research; IRB guidelines for human subject protection; and case studies of online research in action. Researchers and practitioners are invited to submit on or before June 1, a 2-5 page manuscript proposal clearly explaining the mission and concerns of the proposed chapter. The book will be published by Idea Group Inc., publisher of the Idea Group Publishing, Information Science Publishing and IRM Press imprints. Contact Elizabeth Buchanan, University of Wisconsin-Milwaukee, Milwaukee, WI 53211; (414) 229-4707; fax (414) 229-4848; Email eliz1679@uwm.edu

Support From the Following Societies and Organizations is Gratefully Acknowledged:

American Anthropological Association
American Association of University Professors
American Political Science Association
American Psychological Association
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