REGULATION OF HUMAN STEM CELL RESEARCH IN JAPAN AND CANADA: A COMPARATIVE ANALYSIS

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Introduction

Stem cell research, particularly research involving stem cells derived from human embryos, continues to generate worldwide controversy and debate. Various events throughout 2004 underscored the contentious nature of such research. For example, in February 2004, South Korean researchers announced they had successfully used a cloned human embryo to create stem cells.[1] In August, Britain's Human Fertilisation and Embryology Authority granted that country's first license to create human embryonic stem cells through a cloning technique.[2] Stem cell research figured prominently in the 2004 United States presidential election. Voters in the State of California broke new ground by supporting the allocation of $3 billion in public funding to stem cell research.[3] In October, Harvard University researchers sought ethics approval to produce cloned embryos for stem cell research.[4] In November, a United Nations legal committee finally abandoned efforts to pass a comprehensive ban against both reproductive and research cloning in favour of a declaration only against cloning for reproduction.[5]

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[1] See Woo Suk Hwang *et al.*, "Evidence of a Pluripotent Human Embryonic Stem Cell Line Derived from a Cloned Blastocyst", published online February 12, 2004, Science <http://www.sciencemag.org/cgi/content/abstract/1094515>.

[2] Human Fertilisation and Embryology Authority Press Release, "HFEA grants the first therapeutic cloning licence for research" (11 August 2004).

[3] Jonathan Knight, "Joys match fears as California agrees to stem-cell proposal" (2004) 432 Nature 135.

[4] G. Cook, "Harvard Team Wants OK to Clone: Human Cell Work Would be First in Nation" *Boston Globe* (13 October 2004) A1.

[5] Susan Mayor, "UN delays decision on human cloning" (2004) 329 British Medical Journal 1258.

These events have triggered renewed controversy regarding legal regulation and ethical oversight of human embryonic stem cell research. As one commentator observes, advances in stem cell research reveal that "it takes more than scientific breakthroughs to develop new medical therapies – a supportive regulatory framework and public backing are also crucial for such work."[6]

Stem cells, which can be obtained from embryos at early stages of development, aborted fetal tissue, umbilical cord blood, and adult tissues, have the capacity to divide and grow into various kinds of tissues.[7] Embryonic stem ("ES") cells, the focus of this commentary, are currently considered the most versatile in their potential to differentiate into various types of cells. This "pluripotentiality" suggests ES cells hold the most promise for developing neural, cardiac and other cells to offer treatment for a range of conditions including spinal cord injuries, Parkinson's disease, heart disease and diabetes.

Two sources for human ES cells are surplus embryos left over from fertility treatment and embryos created specifically for research purposes. Creation of embryos for research involves a cloning process referred to as somatic cell nuclear transfer ("SCNT"). In this procedure, the nucleus of an egg cell is removed and replaced with the nucleus of a somatic (body) cell, such as a skin cell, and then stimulated to begin dividing and growing. At approximately six days development (the blastocyst stage), embryonic stem cells may be extracted to develop cell lines that may ultimately result in new tissues or organs.[8] This process, commonly referred to as therapeutic or research cloning, destroys the embryo.

Since scientists first succeeded in deriving stem cells from early human embryos in 1998,[9] researchers around the world have targeted their work in this promising area of study, impelling governments to consider appropriate legal and policy mechanisms to regulate this ethically controversial domain. The purpose of this short paper is to comment on the current state of human ES cell research regu-

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[6] Jess Buxton, "Embryos, The Law and Medical Advances in 2004" BioNews (20 December 2004) online: <http://www.bionews.org.uk/commentary.lasso?storyid=2391>.

[7] For an overview of stem cell science, see Abdallah S. Daar & Lorraine Sheremeta, "The Science of Stem Cells: Some Implications for Law and Policy" (2002) 11 Health L.R. 5 and Canadian Institutes of Health Research, *Human Stem Cell Research: Opportunities for Health and Ethical Perspectives – A Discussion Paper* (Ottawa: Canadian Institutes of Health Research, 2001) online: Canadian Institutes for Health Research <http://www.cihr-irsc.gc.ca/e/publications/pdf_14370.htm>.

[8] If the egg and somatic cells come from the same person, the hope is that any tissues or organs developed from the embryonic stem cells and transplanted into the person will avoid immune rejection problems.

[9] See J.A. Thomson et al, "Embryonic Stem Cell Lines Derived from Human Blastocysts" (1998) 282 Science 1445 and M.J. Shamblott *et al.*, "Derivation of Pluripotent Stem Cells from Cultured Human Primordial Germ Cells" (1998) 95 Proceedings of the US National Academy of Sciences 13726.

lation in Japan and Canada. I describe the development of policy recommendations, laws and guidelines in the two countries and comment on three key areas: (1) activities involving ES cells that are subject to regulation; (2) sanctions for non-compliance with prevailing rules; and (3) the ease with which the regulatory regime can be adjusted.[10] I conclude by discussing some key differences and similarities between the Japanese and Canadian regulatory models.[11]

The Japanese situation

In February 2000, the Japanese government's key science policy organization, the Council for Science and Technology, released a draft report regarding human ES cell research.[12] This report sanctioned the use of human ES cells for research purposes and recommended an approval process that would apply to both publicly and privately funded researchers.[13] The report recommended that stem cell research only be conducted on surplus embryos remaining from fertility treatment with informed consent of donors.[14] Further, the report explicitly proscribed the use of ES cells for human reproductive cloning and mandated the establishment of institutional review boards to assess and approve research proposals.[15]

On November 30, 2000, the Japanese government passed the *Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques* ("the *Human Cloning Law*").[16] This law bans human reproductive cloning and prohibits the transfer of certain embryos, referred to as "Specified Embryos", to a human

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[10] I thank an anonymous reviewer who helpfully suggested structuring my discussion on these dimensions.

[11] For additional comparative discussion of regulatory approaches to ES cell research, see Timothy Caulfield, "The Regulation of Embryonic Stem Cell Research: A Few Observations on the International Scene" (2003) Health L.J. Special Ed. 87, Marie-Hélène Régnier & Bartha Maria Knoppers, "International Initiatives" (2003) 11 Health L.R. 67, and Lori P. Knowles, "A Regulatory Patchwork – Human ES Cell Research Oversight" (2004) 22 Nature Biotechnology 157. For a comparative survey of human cloning regulation worldwide, see Shaun D. Pattinson and Timothy Caulfield, "Variations and Voids: The Regulation of Human Cloning Around the World" (2004) 5 BMC Medical Ethics, online: <http://www.biomedcentral.com/content/pdf/1472-6939-5-9.pdf.>

[12] The human embryo research panel, a subcommittee of the bioethics committee of the Council for Science and Technology, prepared this report. See Japan Ministry of Education, Culture, Sports, Science and Technology, Press Release, "Basic Concepts of Human-Embryo Research – CST Published Subcommittee's Draft Report" (2 February 2000), online: <www.mext.go.jp/english/news/2000/02/s000202.htm>.

[13] For further summary of and commentary on the report's recommendations, see Dennis Normile, "Stem Cells: Report Would Open Up Research in Japan" (2000) 287 Science 949.

[14] *Ibid.*

[15] *Ibid.*

[16] An English translation of this law is available online at: <http://www.mext.go.jp/a_menu/shinkou/seimei/eclone.pdf.>

or animal uterus. The Specified Embryos are: human somatic clone embryos; human-animal amphimictic[17] embryos; human-animal chimeric embryos; and human-animal hybrid embryos.[18] Penalties for violating these bans range from up to 10 years in prison or fines of up to 10 million yen.[19] The law does not impose an outright ban on creating the Specified Embryos, but requires the Minister of Education, Culture, Sports, Science and Technology to implement guidelines regulating their creation and use.[20]

The *Guidelines for Derivation and Utilization of Human Embryonic Stem Cells* ("the Guidelines")[21] were established in 2001 based on recommendations of the Council for Science and Technology's Subcommittee on Human Embryo Research. The Guidelines authorize ES cell research on surplus embryos for certain purposes, but do not permit creation of embryos solely for research.[22] Before deriving ES cells from permissible sources, researchers must obtain specific governmental approval,[23] which requires two levels of research ethics approval: the first by an institutional

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[17] "Amphimictic" refers to "an individual which cannot be clearly classified as a human or an animal." See Article 1, *Human Cloning Law*.

[18] See Article 3, "Prohibited Acts".

[19] This is equivalent to approximately $120,000 Canadian dollars.

[20] See Article 4.

[21] The Guidelines are available online at:
<http://www.mext.go.jp/a_menu/shinkou/seimei/2001/es/020101.pdf.>

[22] Article 6 of the Guidelines states:

> A human embryo used for derivation of human ES cells shall
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> 1. be the human fertilized embryo which has initially been created for the purposes of fertility treatment, but is planned not to be used any longer for the purposes, and, hence is surely intended to be discarded by its donors,
> 2. be accompanied by an appropriate IC [informed consent] concerning its use for the derivation of human ES cells,
> 3. have been stored frozen, and
> 4. be used within 14 days after the fertilization, not counting any time during which it has been stored frozen.
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> Article 26 sets out the purposes for which human ES cells may be used in research:
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> Utilization of human ES cells shall be allowed only when the following requirements are satisfied:
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> 1. Its purpose is basic research contributing to
>   (a) clarification of the function of human development, differentiation and regeneration, and
>   (b) development of a new method to diagnose, prevent or treat diseases or of medicines, drugs and so on; and
> 2. The utilization of human ES cells in the research prescribed in 1 above is both scientifically necessary and rational.

[23] See Article 16.

review board and the second by a sub-committee of the Council for Science and Technology.[24] Failure to comply with the Guidelines will provoke public censure by the government.[25]

The establishment of this regulatory regime made Japan one of the first countries worldwide to officially sanction research with human ES cells.[26] The use of guidelines is viewed as a more flexible regulatory mechanism as they can be changed relatively quickly. As one commentator notes:

> The most striking feature of the Japanese regulation is that it is governed by a two-layered system, consisting of the law and the guidelines. One of the implications is that the guidelines can be swiftly altered when the circumstances surrounding human cloning technologies greatly change. ... Extraction of ES cells from a human somatic clone embryo is currently prohibited, but if many countries begin research on therapeutic cloning of this kind, the Ministry may revise the guidelines swiftly and allow researchers to study ES cells acquired from a human somatic clone embryo.[27]

The Guidelines expressly require periodic evaluation by the responsible government Minister, taking "into consideration the progress of research in life science, social trends and so on...."[28]

In early 2002, two centres were established in Japan to focus on stem cell research. One centre, situated at the Institute for Frontier Medical Science at Kyoto University, aimed at using spare embryos left over from fertility treatment to create stem cell lines.[29] The second, the Centre for Developmental Biology in Kobe, was

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[24] Article 33 establishes that the institutional review board of the institute where ES cells will be used must "review the overall ethical and scientific propriety" of the research protocol and Article 36 empowers the Minister to accept or reject the protocol following consultation with a Bioethics and Biosafety Commission.

[25] Article 40 provides: "The Minister shall announce officially if there is a certain instance of derivation or utilization of human ES cells that is recognized by the Minister of its non-compliance with the Guidelines."

[26] Ryuichi Ida, "Ethical questions of the human embryonic stem cells research" (2002) Rinsho Shinkeigaku 1147. [This article is in Japanese; an English abstract is available on PubMed.]

[27] Masahiro Morioka, *The Ethics of Human Cloning and its Legal Regulation in Japan*, paper prepared for presentation at the conference "Cross-Cultural Issues in Bioethics: The Example of Human Cloning", December 4-6, 2003, Germany. Online at: <www.lifestudies.org/cloning01.html>.

[28] *Supra* note 21 at Additional Rules, Article 2, "Reexamination of guidelines."

[29] CellNews, *Japan's Stem Cell Research* (29 August 2002) online: CellNews <http://www.geocities.com/giantfideli/CellNEWS_Japans_Stem_Cell_Research.html>. In March 2002, a Japanese government panel approved this research and was reportedly the first approval in Japan regarding research on human ES cells.

opened as an initiative of RIKEN, Japan's Institute of Physical and Chemical Research, to focus on basic research.[30] In May 2003, researchers at Kyoto University announced they had successfully established stem cell lines that would be made available to other Japanese researchers who had obtained government ethics approval for their work.[31]

Overall, the Japanese regulatory regime for ES cell research is characterized by strict ethics approval and consent requirements, yet government-established guidelines are the primary mode of regulation rather than legislative prohibitions. Although this approach may permit regulatory flexibility over time, certain issues remain divisive. For example, the creation of embryos specifically for research purposes remains a matter of debate in Japan and many believe other sources of ES cells should be pursued first before deliberately creating embryos to derive cells.[32] In addition, some argue therapeutic cloning ought not be permitted as it will lead to reproductive cloning, a practice clearly considered repugnant under the *Human Cloning Law*. Although theological influences are not as strong in Japan as in other countries,[33] some opposition to stem cell research comes from religious groups, as well as naturalists who oppose a range of technologies, including *in vitro* fertilization and genetic modification, which are considered "contrary to nature".[34]

Indeed, human embryo cloning for research remains controversial as the embryo would be created solely for deriving ES cells. The bioethics committee of the Council for Science and Technology has been considering the issue of permitting research use of cloned embryos. An interim report released in late 2003 indicated a lack of consensus among panel members, with about half supporting research using cloned embryos and the other half either completely opposed or urging temporary suspension of such research pending further public consultation.[35] It has been report-

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[30] *Ibid.*

[31] David Cyranoski, "Japanese team makes stem cells" (2003) 423 Nature 577. See also, "Japanese institute produces human embryo stem cells" *Associated Press* (16 January 2004).

[32] Interview of Shin-ichi Nishikawa, MD, PhD, Group Director, Laboratory for Stem Cell Biology, Centre for Developmental Biology, Kobe, Japan (6 December 2003). Dr. Nishikawa pointed out that Japanese researchers are focusing on cord blood as a source of stem cells.

[33] A recent analysis of Asian advances in ES cell research makes the following observation: "Because obtaining ES cells involves the destruction of very early stage embryos, many Western governments have placed heavy restrictions on the work. But across Asia, there is little of the conflict with prevailing religious and ethical beliefs that has Western countries hesitating." Dennis Normile & Charles C. Mann, "Asia Jockeys for Stem Cell Lead" (2005) 307 Science 660 at 660.

[34] *Ibid.*

[35] See "Cloning panel at odds over stem cells" *The Japan Times* (29 November 2003) online: The Japan Times < http://www.japantimes.co.jp/cgi-bin/getarticle.pl5?nn20031129a9.htm> and Eriko Arita, "Homegrown embryonic stem cells in offing" *The Japan Times* (27 December 2003).

ed that "[s]ome 300 people – an unusually large number – responded to the committee's request for comments, with 64% in favor of therapeutic cloning."[36] Throughout June and July 2004, the committee met for continued discussion, with one member suggesting the committee "... may take the unusual step of forwarding both majority and dissenting recommendations to the full council."[37] If the majority favours permitting therapeutic cloning, at least by a small group of researchers under tight oversight, the council may endorse the recommendation. A final report is planned for release in mid-2005.[38]

The Canadian Situation

Efforts to establish a legal regime governing stem cell research in Canada have been protracted. Until the enactment of the *Assisted Human Reproduction Act* in March 2004, Canada lacked legal regulation of stem cell research. To address this void, the Canadian Institutes of Health Research ("CIHR"), the key federal health funding agency in Canada, established the *ad hoc* Working Group on Stem Cell Research in fall 2000 to consider whether ES cell research should be eligible for funding. The Working Group sought to consider the application of existing rules set out in the Tri-Council Policy Statement[39] ("TCPS") to stem cell research. The Working Group's January 2002 final report[40] recommended that human ES cell research be funded only if it uses surplus embryos left over from fertility therapy, where the donors consent and no commercial transaction is involved.[41] The report also stated that SCNT research with human egg cells for the purpose of deriving ES cells should be ineli-

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[36] Dennis Normile, "Japan Faces Decision as Moratorium Expires" (2004) 304 Science 1729 at 1729. However, it is noted that "...the results may have been tipped by advocates for particular diseases, who are hoping for cures." *Ibid.*

[37] *Ibid.*

[38] Knowles, *supra* note 11.

[39] Canadian Institutes of Health Research, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, online: Canadian Institutes for Health Research <http://www.pre.ethics.gc.ca/english/pdf/TCPS%20June2003_E.pdf>. The TCPS applies to researchers at institutions that receive funding from one of three national research councils: the Canadian Institutes of Health Research (CIHR), the Social Sciences and Humanities Research Council (SSHRC), and the Natural Sciences and Engineering Research Council (NSERC).

[40] Canadian Institutes of Health Research, ad hoc Working Group on Stem Cell Research, *Human Pluripotent Stem Cell Research: Recommendations for CIHR-Funded Research – Report of the ad hoc Working Group on Stem Cell Research* (January 2002) online: Canadian Institutes for Health Research <http://www.cihr-irsc.gc.ca/e/1489.html>. The final report followed the release of a discussion paper in spring 2001: see Canadian Institutes of Health Research, *Human Stem Cell Research: Opportunities for Health and Ethical Perspectives – A Discussion Paper* (March 2001) online: Canadian Institutes for Health Research <http://www.cihr-irsc.gc.ca/e/publications/pdf_14370.htm>.

[41] Recommendation 4.1.

gible for funding,[42] a recommendation consistent with the TCPS prohibition against any method of human cloning, including SCNT. As Article 9.4 of the TCPS provides:

> It is not ethically acceptable to create human embryos specifically for research purposes. However, in those cases where human embryos are created for reproductive purposes, and subsequently are no longer required for such purposes, research involving human embryos may be considered to be ethically acceptable...[43]

Additionally, the report advocated the immediate creation of a National Stem Cell Oversight Committee to review funding applications and monitor approved research.[44] Research proposals would also require approval of a local Research Ethics Board. The report also urged the CIHR to review stem cell research guidelines on a regular basis to expand or restrict permissible areas of research, as appropriate.

The Guidelines for CIHR-funded human stem cell research[45] came into effect on March 4, 2002 and adopted the Working Group recommendation that human ES cell research only be permitted using surplus embryos and prohibited the creation of human embryos specifically to derive stem cells. CIHR-funded researchers would be subject to audit and those who contravened the guidelines risked funding withdrawal. The Guidelines recognized the need for ongoing review and revision of the rules as needed.

After introducing various draft laws, the federal government finally enacted the *Assisted Human Reproduction Act* on March 29, 2004.[46] This statute, which comes into force in phases, prohibits specified activities and imposes a regulatory regime regarding other activities and research in the realm of assisted reproductive technologies. Prohibited practices include creating a human clone for any purpose (that is, reproductive or therapeutic purposes) and creating human/non-human com-

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[42] Recommendation 4.9.

[43] *Supra* note 41.

[44] Recommendation 8.1.

[45] Canadian Institutes of Health Research, *Human Pluripotent Stem Cell Research: Guidelines for CIHR-Funded Research* (4 March 2002) online: Canadian Institutes of Health Research <http://www.cihr-irsc.gc.ca/e/1487.html>.

[46] *An Act respecting assisted human reproduction and related research*, S.C. 2004, c. C-6. See also Health Canada, News Release, "Assisted Human Reproduction legislation becomes law" (30 March 2004) online: < http://www.hc-sc.gc.ca/english/media/releases/2004/2004_12.htm>. The federal government initially proposed legislation in 1996. See Health Canada, News Release, "Comprehensive national policy on management of New Reproductive and Genetic Technologies proposed (14 June 1996) online: <http://www.hc-sc.gc.ca/english/media/releases/1996/96_44e.htm>. The draft legislation went through various reviews and introductions in the federal legislature until finally being passed into law in March 2004.

binations for reproductive purposes.[47] In addition to outright bans on these practices, the legislation regulates other human reproductive activities and related research including the collection, alteration, manipulation or treatment of any human reproductive material for the purpose of creating an embryo (e.g. *in vitro* fertilization) and the storage, handling and use of reproductive materials and embryos.

The legislation also establishes the Assisted Human Reproduction Agency to be responsible for licensing, monitoring and enforcement. This Agency will report to the federal Minister of Health[48] and be comprised of up to 13 members.[49] The *Act* does not stipulate the timing for the creation of the Agency and until it is operational, CIHR-funded researchers must continue to observe the requirements set out in the CIHR Guidelines.

The harshest penalties under the *Act* include fines of up to $500,000 or imprisonment for up to ten years for persons convicted on indictment for knowingly engaging in prohibited activities.[50] Lesser penalties - $100,000 fine or two year imprisonment on summary conviction - may be imposed on those who violate legislative provisions regarding controlled activities.[51] A prosecution under the *Act* may only proceed with consent of the Attorney General of Canada,[52] a provision that would help ensure consistent enforcement of the legislation across the country.

The *Act* is subject to mandatory review by Parliamentary committee within three years of the creation of the Assisted Human Reproduction Agency.[53] The review committee must submit recommendations within a year of undertaking its review, though the reporting period may be extended.[54]

The Canadian legislative ban on therapeutic cloning has met with mixed reaction. Some argue the ban is justified and suggest therapeutic cloning is "not neces-

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[47] Other prohibited activities include: identifying the sex of an embryo created for reproductive purposes, except for medical reasons such as sex-linked disorders; paying a woman a financial incentive to be a surrogate mother (commercial surrogacy); paying a donor for their sperm or eggs, or providing goods or services in exchange; and, selling or buying human embryos, or providing goods or services in exchange. See section 5(1).

[48] See ss. 20, 21. The Assisted Human Reproduction Agency would also maintain a donor/offspring registry and provide information on assisted human reproduction to Canadians.

[49] See s. 26.

[50] See s. 60.

[51] See s. 61.

[52] See s. 63.

[53] See s. 70.

[54] *Ibid.*

sary to harness the potential benefits of stem cell therapies."[55] Others argue the ban, based on a "fear of abusive, dangerous, and unsafe use of cloning techniques and [a] need to find a political compromise,"[56] will inhibit valuable research. At least two legal scholars believe the prohibition may violate constitutionally protected rights by stifling scientific freedom.[57]

Discussion

Unlike Canada's legislation, the Japanese *Human Cloning Law* is not part of comprehensive legislation regarding human reproductive technologies. Some commentators have suggested this is due to the fact that the Science and Technology Agency of the Ministry of Education, Culture, Sports, Science and Technology has no jurisdiction over human reproductive medicine, an area that falls under the purview of the Ministry of Health and Wellness.[58]

Japan's regulatory regime applies to all research, both in the public and private sectors. While the *Assisted Human Reproduction Act* applies in both spheres, the CIHR Guidelines apply only to institutions that receive CIHR funding. It has been argued that a national legislative regime remedies this "patchwork" approach to regulation:

> The benefits of a consistent national approach to human embryo research would be considerable. Researchers would be governed by one set of rules, not two or more depending on the source of funding. There would be a level playing field for Canadian researchers, and no built-in incentive for researchers to move their research to the private sector.[59]

However, despite the logical arguments in favour of a consistent regulatory regime, the form that regulation takes through Canada's legislation has been criticized as it

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[55] Françoise Baylis, "Canada Bans Human Cloning" (May-June 2004) Hastings Center Report 5 at 5.

[56] Louise Bernier & Dominic Grégoire, "Reproductive and Therapeutic Cloning, Germ Line Therapy and Purchase of Gametes and Embryos: Comments on Canadian Bill C-13 Governing Reproduction Technologies" (March 2003) online: < http://jme.bmjjournals.com/cgi/data/28/2/DC1/17?ck=nck> at 4.

[57] Barbara Billingsley & Timothy Caulfield, "The Regulation of Science and the Charter of Rights: Would a Ban on Non-Reproductive Human Cloning Unjustifiably Violate Freedom of Expression?" (2004) 29 Queen's L.J. 647 and Timothy Caulfield, "Scientific Freedom and Research Cloning: Can a Ban be Justified?" (2004) 362 Lancet 124.

[58] See Robert Triendl, "Japan to permit stem cell research" (2000) 6 Nature Medicine 239, where he notes: "Efforts to establish more comprehensive reproductive medicine legislation have been blocked by officials at ... the Science and Technology Agency (STA), who say this would be too time-consuming and might bring the agency into conflict with the Minstry of Health and Wellness."

[59] Françoise Baylis, "Betwixt and Between Human Stem Cell Guidelines and Legislation" (2002) 11 Health L.R. 44 at 45.

imposes criminal bans on numerous practices, including therapeutic cloning. The concern is that criminal prohibitions "are blunt, inflexible, and require a good deal of time and political energy to change...."[60] In this sense, the Japanese model may be one that allows a more responsive regulatory approach in a rapidly-changing field.

Despite these differences, there are some clear similarities between the Canadian and Japanese approaches. Both are premised on similar principles, including concern with human health, safety and dignity. For example, section 2 of the *Assisted Human Reproduction Act* expresses concern with "taking appropriate measures for the protection and promotion of human health, safety, dignity and rights in the use of these technologies and in related research."[61] In Japan, Article 1 of the *Human Cloning Law* emphasizes the "preservation of human dignity, safety for human life and body, and maintenance of social order."[62] The preface to the Japanese Guidelines explicitly notes that the policy "attempt[s] to appropriately promote research on human ES cells, by providing fundamental rules to be observed from bioethical points of view so that human dignity may never be violated in association with derivation or utilization of human ES cells."[63]

Numerous international documents explicitly express concern regarding the impact of biotechnological advances, including cloning technologies, on human dignity, though most address reproductive cloning while remaining silent on therapeutic cloning. For example, UNESCO's *Universal Declaration on the Human Genome and Human Rights* asserts that cloning for reproductive purposes is contrary to human dignity but does not address therapeutic cloning.[64] In 2001, UNESCO's International Bioethics Committee noted that ES cell research holds promise but

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[60] Timothy Caulfield, "Clones, Controversy, and the Criminal Law: A Comment on the Proposal for Legislation Governing Assisted Human Reproduction" (2001) 39 Alta. L.R. 335 at 337. See also Timothy Caulfield, "Bill C-13 *The Assisted Human Reproduction Act:* Examining the Arguments Against a Regulatory Approach" (2002) 11 Health L.R. 20. For an argument in favour of criminal regulation, see Angela Campbell, "Defining a Policy Rationale for the Criminal Regulation of Reproductive Technologies" (2002) 11 Health L.R. 26.

[61] *Supra* note 48.

[62] *Supra* note 16.

[63] *Supra* note 21.

[64] United Nations Educational, Scientific and Cultural Organization, *Universal Declaration on the Human Genome and Human Rights* (Paris: UNESCO, 1997) online: <http://www.unesco.org/shs/human_rights/hrbc.htm >. Article 11 states: "Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organizations are invited to co-operate in identifying such practices and in taking, at national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected."

ought to be carefully considered by national governments.[65] The World Health Organization has similarly condemned reproductive cloning as a violation of human dignity[66] but has recognized the potential value of cloning techniques to create tissues and organs.[67] Although concerns with human dignity infuse the debate at international and domestic levels, there is little agreement on the meaning of dignity and the value of the concept in policy-making.[68]

The current Japanese system, as well as the CIHR Guidelines and the Canadian legislation all require that embryos be left over from fertility treatment, that donors give informed consent, and there be no commercial inducement to donate embryos. Both regimes require two levels of ethics review: one at the institutional level and the other at the governmental level.

In addition, facilitating domestic research access to stem cell lines is an important consideration in both countries. The CIHR have committed to establishing a national registry of human ES cell lines developed in Canada. As a condition of funding, researchers must agree to participate in the registry and make cell lines available to other Canadian academic researchers at cost. Likewise, the Japanese guidelines require researchers to distribute ES cells they have derived to other researchers who obtain approval to use the cells.

Finally, both regimes recognize the need for ongoing review in this area, though the Japanese regulatory model will likely prove easier to amend over time, in contrast with the Canadian approach of inscribing prohibitions and controls into law. Penalties for non-compliance with the *Human Cloning Law* and the *Assisted Human*

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[65] UNESCO, *The Use of Embryonic Stem Cells in Therapeutic Research: Report of the IBC on the Ethical Aspects of Human Embryonic Stem Cell Research* (Paris: UNESCO, 2001) online: <http://unesdoc.unesco.org/images/0013/001322/132287e.pdf >. The conclusion to this report states that "[t]he IBC recognizes that human embryonic stem cell research is a subject on which it is desirable for a debate to occur at national level to identify which position on this issue is to be adopted, including abstaining from this research. It urges that debates be conducted at appropriate national regulatory levels, enabling expression of a range of views, and whenever possible allowing a consensus to be reached on the limits of the permissible in this important new therapeutic research field." (at 13).

[66] World Health Organization, *Ethical, scientific and social implications of cloning in human health* (Geneva: World Health Organization: 1998) online: <http://www.who.int/gb/ebwha/pdf_files/EB101/pdfangl/angr25.pdf >.

[67] World Health Organization, *Cloning in Human Health – Report by the Secretariat* (A52/12) (Geneva: World Health Organization 1999) online: <http://www.who.int/gb/ebwha/pdf_files/WHA52/ew12.pdf>, see paragraph 16.

[68] For a critique of dignity-based arguments against human cloning, see Timothy Caulfield, "Human cloning laws, human dignity and the poverty of the policy making dialogue" (2003) 4:3 BMC Medical Ethics, online at: <http://www.biomedcentral.com/1472-6939/4/3>. For an effort to articulate the meaning of human dignity in the context of bioethics, see John Harris and John Sulston, "Genetic equity" (2004) 5 Nature Reviews Genetics 796.

Reproduction Act are stringent and will likely serve as effective deterrents to impermissible activities.

Conclusion

As recent scientific advances and regulatory responses reveal, stem cell research is clearly an area of exciting development, yet is one that raises challenging legal and ethical concerns. The ongoing United Nations debate over human cloning highlights the challenge of attempting to gain agreement on these contentious issues.[69] However, international dialogue on appropriate regulatory regimes, as well as efforts to learn from experiences of other nations, can serve to guide legal and policy development in our own country.

[69] *Supra* note 5.