

The Regulation of Embryonic Stem Cell Research: A Few Observations on the International Scene

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1. Introduction

Few areas of scientific inquiry have generated as much social controversy as embryonic stem cell research. Almost as soon as the first major stem cell breakthroughs were announced in 1998,¹ there were calls for the development of some kind of regulatory response. Though few countries have actually developed legislative schemes to govern stem cell research, it remains an area of intense policy debate.

In this brief article, I provide an overview of the relevant laws in several countries. This is not meant to be a comprehensive analysis of the complex social factors at play in the regulation of embryonic stem cell research. Rather, I merely seek to provide the reader with a sense of how policy makers have reacted to this controversial area of research. More broadly, I make a few observations about the nature and timing of the regulatory response and the challenges associated with making laws in this context.

2. Stem Cell/Cloning Laws: An International Overview

Despite a great deal of international policy debate which has surrounded embryonic stem cell research and related technologies, there are, in fact, few countries with laws designed to specifically address the unique issues associated with this area. Indeed, most countries in the world do not have “stem cell” or even “cloning” legislation. Even the technology of human reproductive cloning remains, from an international perspective, largely unregulated.² As noted by Professor Bonnicksen: “Many of the nations with advanced scientific infra structure have

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¹James A. Thomson *et al.*, “Embryonic Stem Cell Lines Derived from Human Blastocysts” (1998) 282 *Science* 1145; M.J. Shambloott *et al.*, “Derivation of Pluripotent Stem Cells from Cultured Primordial Germ Cells” (1998) 95 *Proc. Nat’l. Acad. Sci.* 13726.

²Shaun D. Pattinson, *Influencing Traits Before Birth* (London: Ashgate, 2002).

laws or policies to preclude reproductive cloning. Taken overall, however, few of the world's nations have cloning laws".³

That said, many developed nations do now have or are now developing regulatory schemes.⁴ The following is a review of some of the existing laws.

i) Restrictive/Prohibitive Approaches

A number of countries already have laws that create a very restrictive environment for research involving human embryos. For example, Ireland and Austria have laws that limit research on and the creation of human embryos to situations involving reproduction. In countries with a strong and broad ban, particularly in Ireland, the laws are often founded on a clear and relatively consistent and publically accepted religious mandate. These laws were not developed with embryonic stem cell research in mind – indeed, they were enacted before the major stem cell advances had occurred. Nevertheless, because the laws restrict what can be done with human embryos, there is little doubt of their application in this context; embryonic stem cell research is, in a practical sense, outlawed.⁵

Germany and the United States stand as examples of jurisdictions with rather inconsistent approaches to the regulation of embryonic stem cell research. Both countries have invested in biotechnology but also have regulatory schemes that make publicly funded embryonic stem cell research problematic. In the US, a jurisdiction where the policy making enterprise is often dominated by abortion politics, the government has restricted funding to research involving existing stem cell lines.⁶ In Germany, embryo research is essentially banned, but the importation of existing stem cell lines is permitted.⁷

³ Andrea L. Bonnicksen, *Crafting A Cloning Policy: From Dolly to Stem Cells* (Washington: Georgetown University Press, 2002).

⁴ Marie H el ene R egnier & Bartha Maria Knoppers, "International Initiatives" (2002) 11 Health L. Rev. 13; George J. Annas, Lori B. Andrews & Rosario M. Isasi, "Protecting the Endangered Human: Toward and International Treaty Prohibiting Cloning and Inheritable Alterations" (2002) 28 Am. J. L. & Med. 151; Bonnicksen, *supra* note 3; Pattinson, *supra* note 2; Aurora Plomer, "Beyond the HFE Act 1990: The Regulation of Stem Cell Research in the UK" (2002) 10 Med. L. Rev. 132; Stephen P. Marks, "Human Rights Assumptions of Restrictive and Permission Approaches to Human Reproductive Cloning" (2002) 6 Health & Hum. Rts. 81; Steven Malby, "Human Dignity and Human Reproductive Cloning" (2002) 6 Health & Hum. Rts. 103.

⁵ Shaun D. Pattinson, "Reproductive Cloning: Can Cloning Harm the Clone?" (2002) 10 Med. L. Rev. 295.

⁶ President George W. Bush, "Remarks by the President on Stem Cell Research" (Washington D.C.: Office of the Press Secretary, 2001), online: The Whitehouse <<http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html>>.

⁷ Sabine Steghaus-Kovac, "Stem Cell Project Wins Final Approval" (2001) 299 Science 31.

ii) “Middle Ground” Approaches

A more moderate approach is emerging in a variety of jurisdictions. For example, some countries are considering or have already adopted what has been called a “cautious” approach.⁸ In general, these schemes allow research on “spare” embryos left over from assisted reproductive procedures, such as *in vitro* fertilization. However, the creation of embryos for research purposes and all forms of somatic cell nuclear transfer involving human embryos, including “therapeutic cloning,” are banned. Canada’s proposed law, Bill C-13, *The Assisted Human Reproduction Act*,⁹ stands as a good example of this approach. If passed, the law would create an oversight entity that would govern all research that involves human reproductive material. This would capture research involving human embryonic stem cells. “Therapeutic cloning” and the creation of embryos for research purposes are, however, criminalized by specific statutory provisions.

France has adopted a similar stance. Research on surplus embryos is permitted, subject to the issuance of a licence, so long as there is a medical goal to the research and there is no other way to do the research. The creation of embryos for research purposes and therapeutic cloning are prohibited. Similarly, the Australian government recently proposed a law that would allow research on embryos but criminally bans therapeutic cloning and the creation of embryos for research.¹⁰

iii) “Flexible”, “Liberal” or “Pragmatic” Approaches

At the other end of the regulatory spectrum lie the jurisdictions that either explicitly allow or have not explicitly excluded the possibility of a full range of research activities, including therapeutic cloning and the creation of embryos for research purposes. The regulatory framework present in the United Kingdom is undoubtedly the best known of these approaches. The UK has a licencing scheme which regulates all research involving embryos; this includes the possibility of therapeutic cloning and the creation of embryos.¹¹

Recently, the State of California decided to proceed in a similar manner. This will be the first US jurisdiction with a law “explicitly allowing scientists to derive human embryonic stem cell lines as well as to clone embryos to study and treat diseases”.¹² Other countries which have a regulatory environment that has the potential to allow this type of research include Singapore, Japan and Israel.¹³

⁸ Régnier & Knoppers, *supra* note 4.

⁹ 2nd Sess., 37th Parl., 2002 (1st reading 9 October 2002) [Bill C-13].

¹⁰ Brendan Gogarty & Dianne Nicol, “The UK’s Cloning Laws: A View from the Antipodes” (2002) 9 Murdoch University Electronic Journal of Law, online: Murdoch University <www.murdoch.edu.au/elaw/issues/v9n2/gogarty92_text.html

¹¹ *Human Fertilisation and Embryology Act 1990* (U.K.), c. 37 [HFEA]; Plomer, *supra* note 4.

¹² Constance Holden, “California Flashes A Green Light” (2002) 297 Science 2185.

¹³ Régnier & Knoppers, *supra* note 4; Annas, Andrews & Isasi, *supra* note 4.

3. The International Scene: A Few Observations

Though few countries have enacted laws that are specific to the area of stem cell research, I believe a number of broad trends can be observed. First, many of the applicable laws were, in fact, enacted prior to many relevant scientific developments. And many of these laws, such as those in Germany, Spain, Austria, and Ireland, are among the most prohibitive. Indeed, other than the UK, there are no jurisdictions that had a potentially permissive scheme in place prior to the birth of Dolly. Many of these prohibitive laws seem closely tied to a specific cultural or historic context, such as Ireland's strong Catholic tradition and Germany's eugenic past. These laws were not the product of public or political debates about the benefits or risks associated with stem cell research, but were based on other, longer standing, policy considerations.

Second, among those laws that were developed after the birth of Dolly and the major stem cell advances, we see much more variation. Though virtually every country that has enacted or is in the process of enacting laws in this area has chosen to ban reproductive cloning,¹⁴ there are some stark differences in the manner in which research involving human embryos, and therefore stem cell research, is addressed. As I will argue below, this variation is hard to justify on a cultural basis alone, and seems, more than anything, to highlight the ad hoc nature of many of the existing and proposed schemes.

It is also worth noting the impact of the chronology of scientific events. Scientific advances often unfold in an unpredictable manner. How the public reacts to a given advance or application undoubtedly has an impact on how future related technologies are received. Had the atomic bomb not been the lay public's introduction to the potential of atomic energy, perhaps the public's view of nuclear power stations would have, rightly or not, been much different. Likewise, the context in which embryonic stem cell research has emerged seems likely to have had a significant impact on public perception and, more importantly, regulatory policy.

The first stem cell advances, in 1998, came at a time when there was a degree of general anxiety about the need to control biotechnology.¹⁵ Indeed, since the start of the Human Genome Project in approximately 1990, there were calls for greater oversight of genetic research and the commercialization process,¹⁶ including concern about human gene patents, genetic discrimination, and the inappropriate alteration of the human genome.¹⁷ Then, in 1997, came Dolly, the first successfully cloned mammal. With her announcement also came the introduction of the practical

¹⁴ Pattinson, *supra* note 2.

¹⁵ Timothy Caulfield, "Underwhelmed: Hyperbole, Regulatory Policy & the Genetic Revolution" (2000) 45 McGill L. J. 437.

¹⁶ Robert Mullan Cook-Deegan, *The Gene Wars: Science, Politics and the Human Genome* (New York: Norton & Co., 1994).

¹⁷ Caulfield, *supra* note 15.

use of somatic cell nuclear transfer technology.¹⁸ While this advance was met with scientific praise, the public's reaction was that of concern and a call for regulatory control.¹⁹

Shortly after, in 1998, the first major breakthroughs in embryonic stem cell research were announced. This was followed closely by scientific speculation about the potential application of the Dolly technique to stem cell research, a method often referred to as "therapeutic cloning".²⁰ Again, these scientific advances generated excitement among most of the research community and for many in the lay public. However, they also created a tremendous amount of policy making activity and, in some cases, the enactment of specific laws. Often, these policy discussions seemed to combine concerns about reproductive cloning and the potential abuses of genetic research with debates about how to regulate embryonic stem cell research and therapeutic cloning. As a result, many of the emerging laws deal with these issues within the same piece of legislation (e.g., Canada's Bill C-13 addresses a broad range of issues even though it was meant to be a law regulating reproductive technologies).²¹

Further, the historical context has had an impact on the scope and tone of existing and emerging laws. For example, the technique of therapeutic cloning seems to be an obvious victim of the chronology of scientific events. Had there not been such an international and largely adverse reaction to the possibility of human cloning, it is unlikely that the use of somatic cell nuclear transfer for research and therapeutic purposes would now be the subject of specific criminal prohibitions, such as in Canada. Of course, many of these prohibitions have also been heavily influenced by the abortion debate and views of the moral status of the embryo and, therefore, therapeutic cloning would never be considered entirely benign by all in the lay public. But without the strong public reaction to Dolly, I believe that somatic cell nuclear transfer would not be the target of specific prohibitive legislation.

Paradoxically, in some jurisdictions, the chronology of events, specifically the advances in stem cell research, have introduced even greater moral ambiguity into the policy debate, thus making a regulatory response more challenging. As noted by Pattison: "...even though there is widespread acceptance of the view that creating a cloned child is immoral, the use of cloning technique for other purposes is far more controversial. This might explain why legislatures have been slow to pass new legislation in this area".²² For instance, the potential benefits associated with, for example, therapeutic cloning has caused a hesitation in the legislative process in a number of jurisdictions that appeared politically predisposed to a

¹⁸I. Wilmut, *et al.*, "Viable Offspring Derived From Fetal and Adult Mammalian Cells" (1997) 385 *Nature* 810.

¹⁹Caulfield, *supra* note 15.

²⁰M. Li *et al.*, "Generation of Purified Neural Precursors from Embryonic Stem Cells by Lineage Selection" (1998) 8 *Curr. Biol.* 971; Nadya Lumelsky *et al.*, "Differentiation of Embryonic Stem Cells to Insulin-Secreting Structures Similar to Pancreatic Islets" (2001) 292 *Science* 1389.

²¹Bill C-13, *supra* note 9.

²²Pattinson, *supra* note 5.

prohibitive approach to the issue of human cloning. In July of 2002, the US President's Council on Bioethics explicitly noted the lack of moral consensus stating that, therefore, a ban on all forms of human cloning was not justified and that a moratorium should be imposed to give time "to seek moral consensus".²³ Given the conservative stance of the Bush administration, this relatively moderate recommendation came as somewhat of a surprise. It is clear, however, that the scientific and therapeutic potential of somatic cell nuclear transfer had an impact on some members of the Council.²⁴

In total, much, but not all, of the international policy debate involves a balancing of concerns about the moral status of the embryo and reproductive cloning against the potential benefits of stem cell research and therapeutic cloning. The intense social debate around these issues has created, at least in most jurisdictions, a state of moral ambiguity. In other words, there is little or no social consensus about how the risks and benefits balance and, therefore, few countries have provided their legislators with a clear public mandate. The later the jurisdiction has chosen to regulate, the more intense this moral ambiguity seems to be.

4. "Therapeutic Cloning," Jurisdictional Variation and the Role of "Moral Ambiguity"

The international debate surrounding the acceptability of therapeutic cloning serves as a good example of how this moral ambiguity has played out in the development of policy. In Canada, for example, survey research has consistently shown a degree of public support for stem cell research and even the concept of therapeutic cloning. A recent poll found that six in ten Canadians approve of the creation of cloned human embryos for collecting stem cells.²⁵ This seems like a significant amount of support given that both the controversial terms "embryo" and "cloning" are used and the survey question makes no mention of potential therapeutic benefit. An early study that did relate the technique to potential treatments, specifically to the cloning of human organs for transplant, found that three quarters of respondents said it was either very or somewhat acceptable.²⁶ Despite such evidence, which is similar to work done in a variety of other jurisdictions, including the US and the UK,²⁷ a number of jurisdictions have prohibited or are likely going to prohibit the technology.

²³The President's Council on Bioethics, *Human Cloning and Human Dignity, Letter of Transmittal* (Washington D.C.: The President's Council on Bioethics, 2002), online: The President's Council on Bioethics <<http://www.bioethics.gov/reports/cloningreport/transmittal.html>>.

²⁴Janet D. Rowley *et al.*, "Harmful Moratorium on Stem Cell Research" (2002) 297 *Science* 923.

²⁵Ipsos-Reid, "Six in Ten (61%) Canadians Approve Creation of Cloned Human Embryos for Collecting Stem Cells" (22 October 2002), online: Ipsos-Reid <http://www.ipsos-reid.com/media/dsp_displaypr_cdn.cfm?id_to_view=1650>.

²⁶"Canadians Support Cloning of Human Organs, Survey Says" *Canada NewsWire* (20 February 2001).

²⁷Ipsos-Reid, "Stem Cell Research Debate Last Summer Paved the Way For Greater Acceptance of Human Cloning Research Today" (3 December 2001), online: Ipsos-Reid <http://www.ipsos-reid.com/media/dsp_displaypr_cdn.cfm?id_to_view=1368>.

This has led to a strange jurisdictional conflict where culturally similar countries have strikingly different regulatory approaches to therapeutic cloning. For example, Canada and Australia are set to criminally ban the technique with punishments ranging from 10 to 15 years in jail. Meantime, California and the UK permit therapeutic cloning. Since the available evidence indicates that all four of these jurisdictions can be characterized as having a similar degree of moral ambiguity (specifically, a population that is generally supportive of the science but with a vocal minority – in Canada, about 1 in 5 – who are strongly opposed), this discrepancy in regulatory approaches seems hard to justify.²⁸ Do Canadians and Australians really feel so differently about therapeutic cloning from their Californian and UK counterparts that a criminal sanction with a heavy prison sentence is required? Indeed, there are few other human activities that have met with such different regulatory responses from such culturally similar nations.

An examination of available policy documents reveals that in all of these jurisdictions the legislators seemed to have considered the same issues. For example, though the Report of the California Advisory Committee on Human Cloning is certainly more thorough and scientifically accurate than the Canadian Government's Report, both touch on the same basic topics: concern about the potential adverse impact of reproductive and therapeutic cloning and discussions regarding the moral status of the embryo.²⁹ Nevertheless, Canada concludes that statutory prohibitions are needed for all forms of somatic cell nuclear transfer while California recommends allowing research with close governmental oversight. Interestingly, Canada seems to base its decision, at least in part, on the existence of social consensus. In explaining the need for prohibitions, a document from Health Canada that accompanied an early version of the legislation argued that "[t]here is a broad consensus that the activities that would be banned under the proposed legislation are not acceptable in Canada".³⁰ But as we have seen above, this simply is not the case.

In the end, political and legal issues seem to have played the most significant role in the adoption of statutory prohibitions. For example, the constitutional framework of a jurisdiction may limit the regulatory options available to legislators. In Canada, health is a provincial matter, while criminal law lies within the

²⁸ Pollara Research & Earncliffe Research and Communications, *Public Opinion Research Into Biotechnology Issues, 5th Wave* (Ottawa: Biotechnology Assistant Deputy Minister Coordinating Committee, 2001), online: Canadian Biotechnology Strategy <<http://www.biotech.gc.ca/docs/engdoc/3Wavexec-e.html>>.

²⁹ California Advisory Committee on Human Cloning, *Cloning Californians? Report of the California Advisory Committee on Human Cloning*, online: Markkula Center for Applied Ethics <<http://www.scu.edu/ethics/publications/adbreport.html>>; Canada, House of Commons Standing Committee on Health, *Assisted Human Reproduction: Building Families* (Ottawa: House of Commons Canada, 2001) (Chair: Bonnie Brown M.P.), online: Parliament of Canada <<http://www.parl.gc.ca/InfoComDoc/37/1/HEAL/Studies/Reports/healrp01-e.htm>>.

³⁰ Health Canada, "Assisted Human Reproduction: Frequently Asked Questions" (May 2001), online: Health Canada: <http://www.hc-sc.gc.ca/english/media/releases/2001/2001_44ebk3.htm>.

jurisdiction of the federal government.³¹ As a result, it is easier for the federal government to claim jurisdiction over the area if it makes legislation grounded in the criminal power. In the UK, however, the national government does not have to contend with these jurisdictional issues and, as a result, may have more regulatory options available.

And, of course, the politics of abortion permeate much of the relevant discourse and policy making activity. Indeed, given the lack of scientific justifications for a ban and evidence of a public that is generally supportive of therapeutic cloning, one wonders if the ban adopted by the countries with a “cautious” approach (e.g., Canada, Australia and France) is primarily a political compromise meant to appease the vocal minority. In the US, the anti-abortion community has had an obvious and explicit impact on government policy, primarily because of the largely anti-abortion stance of the Bush administration. In the UK, an anti-abortion group led a legal action that sought to challenge the *Human Fertilization and Embryology Act's* (HFEA) authority over the regulation of “therapeutic cloning”.³² In countries like Canada and Australia, the impact is less obvious, though the lobby is certainly present.³³ By highlighting the presence and influence of this vocal minority I do not mean to discount its substantive relevance. On the contrary, discussions about the moral status of the fetus are present in virtually every policy document. However, in many jurisdictions, such as the UK, the US, Canada, and Australia, there is no social consensus on the moral or legal status of the embryo, and there never will be. In such a state, the adoption of prohibitive legislation appears inappropriate. As noted by Gogarty and Nicol: “The public tends to demand prohibition of conduct that is universally opposed, but expects issues of moral ambiguity to be regulated”.³⁴

5. Conclusion

For me, the variation we see in how jurisdictions address embryonic stem cell research, and especially somatic cell nuclear transfer, highlights the difficulty of regulating an area so permeated with moral ambiguity. One can certainly sympathize with governments throughout the world as they seek ways to face the unique challenges associated with this controversial research. But given the lack of social consensus about the technology (indeed, with the passing of time the moral ambiguity seems to be intensifying), the use of statutory prohibitions is surely a mistake. Whether one favours a more restrictive research environment or one that leaves room for activities like therapeutic cloning, a more responsive regulatory scheme seems only logical. Given the speed of scientific advance, the legal framework should be developed in a manner that allows a reasonably quick response to both new social concerns and scientific advances. As noted by Shaun

³¹ Martha Jackman, “Constitutional Jurisdiction Over Health in Canada” (2000) 8 Health L. J. 95.

³² Plomer, *supra* note 4.

³³ “Anti-Abortion March Focuses on Stem Cell Bill” *Edmonton Journal* (11 May 2002) A11.

³⁴ Gogarty & Nichol, *supra* note 10.

Pattison in his review of the international scene, "...legislative prohibitions can quickly become dated".³⁵ Whatever scheme is adopted, it should be crafted to meet the realities of stem cell research. There is never going to be moral consensus, science will move forward and create unique regulatory challenges, and new social concerns are going to emerge.

³⁵ Pattinson, *supra* note 5.

