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Legislating Limits on Human Embryonic Stem Cell Research

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Introduction

Research on embryonic stem cells has generated great intrigue in the scientific community. Many medical researchers consider stem cell-based therapies to have the potential of treating a host of human ailments and yielding a number of medical benefits. They are motivated by the possibility of treating incurable diseases or facilitating effective treatment methods. Their enthusiasm is shared by many of those who are afflicted with these debilitating diseases.

However, the methodology of this research raises numerous ethical and public policy concerns. The extraction of embryonic stem cells for research destroys the human embryo. This has generated a storm of debate about if, and in what circumstances, this research can be legally and ethically justified. The concerns are heightened further when embryos are created specifically for use in the very research that occasions their destruction. In response, numerous countries have passed legislation that attempts to control some of the more controversial aspects of embryonic stem cell research. For example, in May 2002, Canada introduced draft legislation that would govern and restrict a number of practices related to this fast-growing field of research.

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Assessing the legality of embryonic stem cell research, and whether there are any justifications to restricting this field, raises a number of challenging questions. What is the legal status of the unimplanted embryo? Is there a societal interest in protecting embryos from such research? If so, what legal balance is required when legislating in relation to embryos, given the potential medical benefits of stem cell research? These questions, and the broader legal debate surrounding stem cell research, will be the focus of this paper.

Part I. The Science of Embryonic Stem Cell Research

A. The Basics of Human Reproduction

Understanding what embryonic stem cells are and why they are so valuable for research requires a short primer on the basics of human reproduction. The human embryo has its origins in specialized gamete cells, known as the spermatozoon for males and the ovum for females.[2] Each gamete contains a set of 23 chromosomes, out of the 46 that comprise the entire human genome.[3] Chromosomes contain highly condensed DNA, short sequences which make up the genes that code for the synthesis of the different proteins that construct the human body.[4] The chromosomes are enclosed within a cellular organelle that in gametes are known as pronuclei. Conception arises upon the union of two gametes. The two pronuclei fuse, and a single cell known as a zygote is created.[5] This zygote contains a total of 46 chromosomes, half from each parent, and is therefore complete with the entire genetic makeup needed to direct the development of a genetically distinct human being.

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[2] *See, e.g.* Bruce Alberts et al., Essential Cell Biology: An Introduction to the Molecular Biology of the Cell 305 (1998).
[3] *See, e.g.* Anthony J.F. Griffiths et al., An Introduction to Genetic Analysis 2 (4th ed. 1989).
[4] *See, e.g.* Alberts et al., *supra* note 1, at 246-7.
[5] *See, e.g.* Alberts et al., *supra* note 1, at 306.

The zygote then undergoes a series of cell divisions known as cleavages, where the dividing cells, known as blastomeres, double in number following each cleavage event.[6] By the time the zygote has divided into sixteen cells, it is comprised of a compact sphere of blastomeres known as a morula. After five to seven days, it has developed into a blastocyst, at which stage a cavity has formed within the structure and two distinct cell types can be distinguished: a peripheral cellular layer known as a trophoblast, and an inner cell mass.[7] The trophoblast is destined to give rise to the placenta, which will nourish the embryo as it develops within its mother. In contrast, the inner cell mass will develop into the embryo, the fetus and eventually the fully developed child.

At about 14 days following conception, a structure within the inner cell mass known as the primitive streak is formed.[8] The primitive streak marks the longitudinal head-to-tail axis of the future embryo. This is what gives rise to an individual human's bilateral symmetry. The major organs of the body eventually differentiate along this axis, with tissue to the left and right of the streak developing into the left and right sides of the body, respectively.[9] The appearance of the primitive streak is widely regarded as a fundamental step in embryonic development, the significance of which will be discussed later in this paper.[10] By the time the main organs develop, usually eight weeks following conception, the embryo is scientifically termed a fetus.[11] This terminology should be

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[6] *See generally* William J. Larsen, HUMAN EMBRYOLOGY, (3rd ed. 2001) (overview of the sequence of cell divisions following fertilization).
[7] *See, e.g.* David F. Moffett et al., HUMAN PHYSIOLOGY: FOUNDATIONS & FRONTIERS 728 (2d ed. 1993).
[8] Kevin U. Stephens, Sr., *Reproductive Capacity: What Does The Embryo Get?* 24 S.U.L. REV. 263, 267 (1997).
[9] Kayhan Parsi, *Metaphorical Imagination: The Moral and Legal Status of Fetuses and Embryos*, 2 DEPAUL J. HEALTH CARE L. 703, 753 (1999).
[10] *See, e.g.* J. Marshall, *The Case Against Experimentation* in G. Basen, M. Eichler, A. Lippman, eds., MISCONCEPTIONS 2: THE SOCIAL CONSTRUCTION OF CHOICE AND THE NEW REPRODUCTIVE AND GENETIC TECHNOLOGIES 111 (1994).
[11] *See, e.g.* Michael Abercrombie et al., THE PENGUIN DICTIONARY OF BIOLOGY 113 (6th ed. 1977).

distinguished from that used in Canadian courts, which commonly refer to the unborn child at any stage of development as a fetus.

B. Human Reproduction and Stem Cells

The early embryo is comprised of stem cells. These can be characterized as those precursor cells, not yet specialized, that give rise to the more specialized cells of the human body.[12] The biological process by which cells specialize is known as differentiation. It occurs when some of the approximately 80,000 genes in the chromosomes of a cell are inactivated, while the remaining genes are selectively expressed.[13] The function of specific cells in the body will depend on which of these genes are selected for expression. Incidentally, each cell retains the full complement of the DNA that makes up the human genome throughout the differentiation process. It is for this reason that a specialized cell from an adult body can theoretically be used to clone an entire human.

Stem cells can be subdivided into three main categories, depending on their level of differentiation: totipotent, pluripotent and monopotent stem cells.[14] The least differentiated, totipotent stem cells, have unlimited developmental capacity (i.e. the potential to produce an entire human). Thus, the initial single-celled zygote described above is totipotent. In contrast, the inner cell mass of the blastocyst is comprised of pluripotent stem cells, which are more highly differentiated but can potentially specialize into almost any type of tissue. These cells specialize further into monopotent stem cells, which serve as the precursors of specific cell-types having particular functions. They

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[12] *See, e.g.* Moffett et al., *supra* note 6, at 10.
[13] *See generally* Griffiths et al., *supra* note 2, at 572-605 (discussion on the processes of cell differentiation).
[14] U.S.A., NATIONAL INSTITUTES OF HEALTH, STEM CELLS: A PRIMER (May 2000) [hereinafter STEM CELLS].

include blood stem cells, skin stem cells and stem cells of any of the 214 such cell-types of the human body.[15] It is these pluripotent and monopotent stem cells that researchers hope to isolate, culture and one day apply to therapeutic ends.

C. Stem Cells and In Vitro Fertilization

While the developmental stages outlined above typically occur in the female womb following coitus, the embryos used in embryonic stem cell research are created asexually via in vitro fertilization (IVF). This procedure was first developed for humans in the late 1970s to assist infertile couples with having children. The first step in the process requires obtaining human eggs from a female donor, who has usually been treated with drugs that induce the maturation of multiple follicles in her ovaries.[16] This increases the yield from a single ovulation cycle from one egg to as many as a few dozen eggs per month. The eggs are retrieved either surgically, or by suction through a process known as ultrasound-guided transvaginal aspiration.[17] The eggs are then artificially fertilized in a petri dish with donated sperm.

Biotechnology, through a process known as cryopreservation, now enables the freezing and storage of these artificially created embryos for future use, such as in fertility treatments. The embryos are first treated with a cryoprotectant solution to replace the water in the cells (which would otherwise expand upon freezing, leading to cell rupture).[18] They are then gradually cooled and transferred to liquid nitrogen, where they are stored at a temperature of minus 195 degrees Centigrade. They are then

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[15] *Id.*
[16] Carl H. Coleman, *Procreative Liberty and Contemporaneous Choice: An Inalienable Rights Approach to Frozen Embryo Disputes*, 84 MINN. L. REV. 55, 58 (1999).
[17] Luigi Brandimarte, *Comment, Sperm Plus Egg Equals One "Boiled" Debate: Kass v. Kass and the Fate of the Frozen Pre-Zygotes* (2000) 17 N.Y.L. SCH. J. HUM. RTS. 767, 771 (2000).
[18] Coleman, *supra* note 15, at 60.

gradually cooled and transferred to liquid nitrogen, where they are stored at a temperature of minus 195 degrees Centigrade.[19] The cryopreservation process is a cheaper, easier and more time efficient method of obtaining future embryos than repeating the IVF procedure.

D. The Medical Potential of Stem Cells

In vitro fertilization and cryopreservation have provided researchers with a convenient way of obtaining embryos that can supply stem cells for research goals. Human embryonic stem cells were first isolated in November 1998 by James A. Thompson of the University of Wisconsin, and John D. Gearhart of Johns Hopkins University.[20] They have since been successfully induced to self-replicate for mass production.[21] Thus, cultures of desired stem cell lines can be established for widespread potential medical application.

Research on stem cells has many benefits over research on other types of cells. For example, cultures of adult cells traditionally do not last very long and new cell cultures are constantly needed to replace old ones.[22] This has been partly attributed to the role played by chromosomal structures known as telomeres. Telomeres exist at the ends of chromosomes and function as protective caps.[23] They normally shorten with each replication of the chromosome (i.e. after every cell division cycle), a fact that is thought to contribute to the aging process. In the rapidly dividing stem cells of the embryo, however, there is a high expression of an enzyme known as telomerase, which helps

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[19] Brandimarte, *supra* note 16, at 773.
[20] James A. Thompson et al., *Embryonic Stem Cell Lines Derived From Human Blastocysts*, 282 SCIENCE 1145 (1998).
[21] Gregg Easterbrook, *Will Homo sapiens become obsolete?*, NEW REPUBLIC (March 1, 1999), at 20.
[22] Jason H. Casell, *Lengthening the Stem: Allowing Federally Funded Researchers to Derive Human Pluripotent Stem Cells from Embryos*,34 U. MICH. J.L. REFORM 547, 551-552 (2002).
[23] *See, e.g.* Alberts et al., *supra* note 1, at 249.

prevent telomeres from shortening.[24] Thus, cultures of desired embryonic stem cell lines could, at least theoretically, be capable of indefinite reproduction. This would make them ideal subjects of manipulation in medical research.

One of the potential medical applications of stem cells is in a procedure known as cell therapy, where stem cells are directly injected into the human body.[25] While the exact mechanisms are not yet clear, such cells are often able to target their corresponding organ or tissue types. In one experiment, for example, pig liver stem cells that were injected into humans were able to target the human liver.[26] In another experiment, mice that had suffered from heart attacks were injected with blood stem cells.[27] The cells migrated to the damaged regions of the heart, and even produced vessels to supply the new heart muscle with blood. Stem cells have also been shown to develop into brain tissue when injected into rats that had suffered stroke-related brain damage.[28]

Another exciting potential application of stem cell therapy is in the treatment of spinal injuries. Experiments at John Hopkins University have shown that some rats that had pluripotent stem cells injected into their spinal fluid regained partial leg movement.[29] Clearly, there is hope that the same success can be attained with paralyzed humans. Cell therapy is also an especially effective medical treatment because it utilizes the body's own curative abilities. This helps side-step some of the problems associated with transplantation, such as organ rejection.

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[24] *Id.* at 250.
[25] Khristan A. Heagle, *Should There be Another Ewe? A Critical Analysis of the European Union Cloning Legislation*, 17 DICK. J. INTL L. 135 (1998).
[26] *Id.*
[27] Stem cells repair heart attack damage, (March 31, 2001), *at* http://www.news.bbc.co.uk/hi/health/1251876.stm (date last visited April 2001).
[28] Stem cells repair stroke damage, (Feb. 17, 2001), *at* http://www.news.bbc.co.uk/hi/health/1174232.stm (date last visited March, 2001).
[29] Jonathan Knight et al., *Reach for the Prize*, NEW SCIENTIST (Nov. 18, 2000), at 11.

E. Possible Applications of Stem Cell Technology

Stem cells can also have much more specific medical applications. By identifying and administering the correct growth factors, scientists hope to someday be able to direct stem cells to differentiate along a specific path into desired cell or tissue types. These can then be transplanted into patients suffering from various physical ailments. In this way, it is hoped that embryonic stem cell research can provide treatments for a number of diseases.

Diabetes, for example, results when the immune system self-destroys pancreas cells that produce the insulin hormone.[30] Insulin is essential in maintaining blood sugar levels at a safe concentration. While insulin injections are available to diabetes sufferers, they are painful and need to be administered constantly to sustain life. A much more effective treatment would be to derive insulin-producing cells from pancreatic stem cells and directly transplant such cells into patients. The research looks promising. Scientists at the National Institutes of Health, for example, have successfully used the embryonic stem cells of mice to derive cells that express insulin and other pancreatic hormones in diabetic mice.[31]

Other diseases that stem cell research may help alleviate include Parkinson's, Alzheimer's and Huntington's disease. In each of these neurological diseases, there is a loss of neurons from a particular region of the brain.[32] Stem cell technology may help replace these lost neurons with ones cultured from brain stem cells. Still another possible candidate for stem cell therapy is DiGeorge's Syndrome. This disease is characterized by

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[30] Robert Berkow, ed., THE MERCK MANUAL OF DIAGNOSIS AND THERAPY 1037 (1982) [hereinafter MERCK MANUAL].
[31] Casell, *supra* note 21, at 554.
[32] *See generally* MERCK MANUAL, *supra* note 29.

the absence of immune cells in the thymus gland, increasing the patient's susceptibility to serious infections at an early age.[33] Again, the missing immune cells can be replaced by ones derived from precursor stem cells. One last example is leukemia and other blood diseases for which treatment may be found in blood stem cells. Similar stem cell therapies potentially exist for a number of other cell-based illnesses.

There is a wide array of other potential medical uses of stem cells. For example, stem cells may be able to yield cells that can help treat malignant tumors (which are created by cells that divide uncontrollably), or to provide cells that can generate bone marrow for chemotherapy patients.[34] Stem cell technology may even progress to a level where human organs can be directly grown for transplantation. This would help alleviate the severe shortage of donated organs that exists in Canada and in most parts of the world.[35] Moreover, if therapeutic stem cells are derived from embryos that are cloned from a patient, they will serve as a perfect genetic match for recipients, thus overcoming the problems of immune rejection.

There are also more general benefits to embryonic stem cell research. First, it can yield answers to the complex events that characterize human development, as well as to the root causes of various diseases and genetic disorders.[36] Second, it can help improve medications, through the creation of cell types that can serve as subjects for tests seeking to determine which drugs are safe and beneficial for human use.[37] Isolating human

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[33] Jose L. Gonzalez, *The Legitimization of Fetal Tissue Transplantation Research Under Roe v. Wade*, 34 CREIGHTON L. REV. 895, 908-909 (2001).
[34] Michael J. McDaniel, *Legal Perspectives on Cloning: Regulation of Human Cloning: Implications for Biotechnological Advancement*, 32 VAL. U.L. REV. 543, 553 (1998).
[35] *Id*. at 558.
[36] Department of Health and Human Services, Public Health Service, National Institutes of Health, Draft National Institutes of Health Guidelines for Research Involving Human Pluripotent Stem Cells, *at* http://www.nih.gov/news/stemcell/draftguidelines.htm (December 1999).
[37] *Id*.

embryonic stem cells, however, necessitates the destruction of a human embryo. This raises a host of legal and policy issues, a discussion of which will be the focus of the remainder of this paper.

Part II. The Legal Status of the Embryo

A. The Existing Jurisprudence on Prenatal Rights

The jurisprudence pertaining to the rights of the embryo or fetus in Canada fairly clearly outlines the legal status of the unborn child. That legal status was concisely summarized by the Supreme Court of Canada in *Winnipeg Child and Family Services (Northwest Area) v. G.(D.F.)*.:

> The position is clear. Neither the common law nor the civil law of Quebec recognizes the unborn child as a legal person possessing rights. This principle applies generally, whether the case falls under the rubric of family law, succession law or tort. Any right or interest the foetus may have remains inchoate and incomplete until the birth of the child.[38]

As the Court indicates, this principle has held true in all areas of law. In looking at criminal law, abortion has historically been allowed for various reasons, such as to protect the mother's health. Thus, in this example, it is apparent that the unborn child has not always held full rights as a person. In *R. v. Morgentaler*,[39] the Supreme Court of Canada found that the abortion-access provisions of the Criminal Code unduly infringed upon the constitutional rights of pregnant women. Additionally, in *R. v. Sullivan*,[40] the Canadian Supreme Court held that "person" in the criminal negligence provisions of the

[38] *Winnipeg Child and Family Services (Northwest Area) v. G.(D.F.)*, [1997] 3 S.C.R. 925 [hereinafter *Winnipeg*] at ¶ 15.
[39] *R. v. Morgentaler*, [1988] 1 S.C.R. 30 [hereinafter *Morgentaler*].
[40] *R. v. Sullivan and Lemay*, [1991] 1 S.C.R. 489.

Criminal Code held the same meaning as "human being," which the Code defines as a child that "has completely proceeded, in a living state, from the body of its mother."[41]

A civil law analysis leads to similar conclusions. In tort law, the Canadian Supreme Court recognized as early as 1933 in *Montreal Tramways Co. v. Leveille*[42] that there is a right or duty in tort owed by third persons to an unborn child. Any right of civil action, however, is contingent upon the child being born alive. Similarly, an analysis of estate and property law reveals no instance where property was passed to the heirs of a stillborn or aborted fetus. Furthermore, the Saskatchewan Court of Appeal in *Borowski v. Canada* (Attorney General) concluded generally that "there are no cases in Anglo-Canadian law giving the foetus qua foetus status."[43] It should be noted that some Canadian legislation, primarily in the area of family law, does include unborn children within its definition of "child."[44] Some courts have also found that a fetus is a "child" for purposes of some family law legislation.[45] However, other courts have reached precisely the opposite conclusion.[46]

Nor has the fetus ever been constitutionally recognized as a person under the Charter of Rights and Freedoms. Two Ontario courts have found that fetuses are not persons under the Charter.[47] In *Borowski*, the plaintiff argued that the therapeutic abortion provisions of the Criminal Code were in violation of the constitutional rights of the

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[41] Criminal Code, R.S.C. ch. C-46, § 223(1)(1985)(Can.).
[42] *Montreal Tramways Co. v. Leveille*, [1933] S.C.R. 456.
[43] *Borowski v. Canada* (Attorney General) 33 C.C.C. (3d) 402.
[44] *See, e.g.* the New Brunswick Family Services Act, where an "unborn child" is included within the definition of "child": Family Services Act, S.N.B. 1980, ch. F-2.2, § 1(g)(a)(1980)(Can.) *at* http://www.gnb.ca/acts/acts/f-02-2.htm.
[45] *See, e.g.* Re Children's Aid Society of City of Belleville and T, [1987] 59 O.R. (2d) 204, and Re Children's Aid Society for the District of Kenora and J.L. [1981] 134 D.L.R. (3d) 249.
[46] *See, e.g.* Re Baby R , 53 D.L.R. (45h) 69 (B.C.S.C. 1988), and New Brunswick v. N.H., 224 N.B.R. (2d) 80 (1996).
[47] *See, e.g.* R. v. L.(N.), 10 W.C.B. (2d) 582 (1990), and Campbell v. Attorney-Gen. of Ont., 58 O.R. (2d) 209 (1987).

foetus. However, the Saskatchewan Court of Appeal concluded that a fetus is not included within the definition of "everyone" in section 7, or "every individual" in section 15 of the Charter. A subsequent appeal to the Canadian Supreme Court was declined on the grounds of mootness, resulting from the striking down of all abortion provisions in the Criminal Code in Morgentaler, supra.

B. The Special Circumstances of In Vitro Embryos

The law pertaining the legal status of unborn children in Canada appears to be fairly settled. However, there is still no clear indication as to what rights, if any, an embryo might have as an independent entity (for instance, when it exists in an in vitro state). The cases discussed above are not as helpful in this regard. They comment only about the rights of unborn children who exist not as independent entities but as a biological part of their mothers. This fact presents a crucial contextual difference. Its significance with respect to female equality rights has been recognized by courts on numerous occasions. According to the Canadian Supreme Court in Winnipeg "[t]he potential for intrusions on a woman's right to make choices concerning herself is considerable. The foetus' complete physical existence is dependent on the body of the woman. As a result, any intervention to further the foetus' interests will necessarily implicate, and possibly conflict with the mother's interests."[48] The special nature of the maternal-fetal relationship that courts pay deference to is fundamentally different from that existing between the embryo or fetus and a third party.

This point was made clear in *Dobson v. Dobson.*[49] In *Dobson*, a tort action had been brought on behalf of a child for prenatal injuries it had suffered due to the allegedly

[48] *Winnipeg*, *supra* note 37, at ¶ 37.
[49] *Dobson v. Dobson*, 2 S.C.R. 753 (Sup.Ct.Can. 1999) at ¶ 29.

negligent acts of its mother. In ruling in favor of the mother, the Canadian Supreme Court pointed out that "it is the biology of the human race which decrees that a pregnant woman must stand in a uniquely different situation to her fetus than any third-party."[50]

Hence, it is unclear how to apply the principles derived from these cases to help define the legal status of the embryo in the special context of stem cell research. The jurisprudence has generated rules relating to unborn children. The problem, of course, is that this birth event cannot even be contemplated in the case of the unimplanted, in vitro embryos. With in vitro embryos, the complex physical and intensely personal relationship between the embryo and its mother that courts have frequently alluded to is absent. Any legal relationships that exist are essentially only between the embryos and third parties.

This conclusion suggests that the common law rules are rather lacking in providing guidance on those special situations created by artificial reproductive technologies and associated practices such as stem cell research. There is, therefore, a need to elucidate a different standard regarding the legal status of in vitro embryos. This standard will need to address the unique and largely unprecedented circumstances that characterize research on unimplanted embryos. It will also need to contemplate the indirect impact that conferring specific embryonic rights (in any context) may have on women's reproductive autonomy.

C. A Legislative Role in Protecting the Embryo

It will be the role of the legislators to determine the standard that ought to be applied to in vitro embryos. Courts have already suggested that Parliament has a legitimate role in conferring legal protections upon the embryo in clearly specified contexts. In

[50] *Id.*

Winnipeg, the Canadian Supreme Court stated that "if Parliament or the legislatures wish to legislate legal rights for unborn children or other protective measures, that is open to them, subject to any limitations imposed by the Constitution of Canada."[51]

And in *Morgentaler*, Justice Dickson found for the majority that the protection of the fetus would be a sufficiently important legislative objective under section one of the Charter. The Court was itself reluctant in *Winnipeg*, *supra*, to define specific prenatal rights. To do so, it feared, would place the courts "at the web of thorny moral and social issues which are better dealt with by elected legislators than by the courts […since] the courts would find it difficult to limit application of the new principle to particular cases."[52]

Lower courts had earlier already recognized a legislative role in protecting the embryo/fetus. Perhaps most tellingly, in *Borowski v. Attorney General of Canada et al*., Matheson J. of the Saskatchewan Court of Queen's Bench stated that "although rapid advances in medical science may make it socially desirable that some legal status be extended to fetuses, irrespective of ultimate liability, it is the prerogative of Parliament, and not the courts, to enact […the appropriate] legislation."[53] Thus, some courts seem to have already recognized a role for Parliament to legislate the use of embryos in such medical sciences such as stem cell research.

It is important to remember that the "particular cases" referred to in *Winnipeg*, *supra*, where Parliament may legislate, pertain to "unborn children" – a state, again, outside the context of stem cell research. However, each in vitro embryo is one that may potentially be implanted and turned into an unborn child, bringing it within the scope of

[51] *Winnipeg*, *supra* note 37, at ¶ 12.
[52] *Winnipeg*, *supra* note 37, at ¶ 24.
[53] *Borowski v. Attorney Gen. of Can.*, 4 D.L.R. (4th) 112 (1983).

the traditional prenatal legal analysis. Moreover, having already recognized in *Winnipeg*, *supra*, that legislators may further explicate prenatal rights, courts may also accept extending this legislative role into the realm of protecting young, in vitro embryos, subject to any limitations imposed by the Charter. To do so, however, will require a clear elucidation of the bases upon which legislative protections for the embryo can be justified. It will also require a balancing of the different, overlapping social interests that arise in that context.

Part III. Legislating Embryonic Stem Cell Research

A. General Legislative Considerations

A number of jurisdictions have introduced legislation that seeks to protect the in vitro embryo. In the United States, for example, several states including Massachusetts, Minnesota, North Dakota, Rhode Island and Louisiana have enacted laws that provide protections to embryos that exist outside the womb, such as prohibitions on embryo experimentation.[54] In Canada, legislation pertaining to this field was tabled in Parliament in May 2002.

It is essential for any future legislation to carefully balance the numerous and often conflicting social considerations that are implicated in the context of stem cell research. For example, it may be a purported threat to human dignity that serves as the basis for legislation that restricts various forms of embryo research. Indeed, the 2001 report of the Standing Committee on Health, discussed further in section VI below, recommends that an overarching consideration of "respect for human individuality, dignity and integrity" be included in a statutory declaration for forthcoming legislation on

[54] *See* M.S.A. § 145.421 (West 1989); M.G.L.A. 112 § 12J(a)(I)(West 1996); N.D.C.C. 14-02.2-01(1)(3)(West 1991); R.I.S.T. § 11-54-1(c) (West 1994).

genetic technologies.[55] Such a consideration will need to be balanced against the potential medical benefits that stem cell research may provide.

A better legislative approach may be to make in vitro embryos the subjects of some form of limited legal protection characterized by the specific context of experimental medical research. This determination could be made on the basis of some social interest, as opposed to an embryo's individual interest, in conferring such protection. Such a social interest can be found in the desire to protect the sanctity of [potential] human life. Protecting the potential for human life is different from saying that a rights-bearing entity already exists. By framing legislation in this way, such competing interests as women's or patients' rights can in some circumstances take priority over protecting an embryo.[56]

Moreover, although the in vitro embryo exists as an independent entity, consideration needs to be given to the fact that the recognition of any embryonic rights will likely have indirect implications for female reproductive liberty. For this reason, it may be inadvisable to introduce legislation that recognizes the embryo as a new legal individual with explicit rights. Such legislation can also outline and clarify certain duties that are owed to the embryo on a prima facie basis, but that can be overridden by other considerations.[57]

B. Possible Scientific Harms of Stem Cell Research

In addition to the numerous social considerations implicated by stem cell research as discussed below, there are also health and safety considerations associated with the

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[55] Canada, House of Commons, Standing Committee on Health, "*Assisted Human Reproduction: Building Families*" (December 2001) (Chair: Bonnie Brown, M.P.) [hereinafter *Building Families*].
[56] John A. Robertson, *Reproductive Technology and Reproductive Rights: In the Beginning: The Legal Status of Early Embryos*, 76 VA. L. REV. 437, 445-51 (1990).
[57] Parsi, *supra* note 8, at 705.

technology. These may provide another basis for restrictive legislation. Again, they will need to be balanced against the health benefits that this technology may provide.

It is now established that human embryos cannot remain frozen indefinitely without developing various abnormalities. The longest time that a human embryo has been successfully cryopreserved is two years,[58] though abnormalities may arise far sooner, even incidentally to the cryopreservation process. Until some method exists to detect when and why these abnormalities occur, it may be dangerous to put stem cells derived from such embryos to medical use.

Also, while the purported value of stem cells lies in the fact that they are relatively undifferentiated, scientists still do not understand all the biological processes necessary to direct stem cells to specialize into desired cell and tissue types. There is a risk that scientists may improperly signal the stem cells as they attempt to direct their specialization, leading to overgrowth.[59] Such uncontrolled cell growth can lead to the development of a tumor, and is the hallmark of cancer. Unsurprisingly, numerous animal studies have indeed identified increased rates of cancer among the recipients of stem cell-derived tissue. One of these studies, for example, showed that as much as three percent of mouse heart tissue that had been artificially cultured from stem cells became malignant after transplantation into mice.[60]

Concern has also been expressed about some of the specific practices that are employed in human stem cell research. For example, many of the human stem cell

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[58] Heidi Forster, *Recent Development: The legal and ethical debate surrounding the storage and destruction of frozen human embryos: A reaction to the mass disposal in Britain and the lack of law in the United States*, 76 WASH. U.L.Q. 759, 768-9.
[59] Daniel McConchie, *Using Stem Cells from Embryos will make Human Flesh Profitable* (June 29, 2001) Center for Bioethics and Human Dignity (Bannockburn, IL).
[60] Easterbrook, *supra* note 20.

cultures that are created in the laboratory are nourished by animal cell cultures. Mouse cells, for instance, are commonly used to help human stem cells replicate in vitro; bovine serum is also used to help in the derivation of specific colonies of human stem cells.[61]

It is feared that such practices can lead to the transfer of animal viruses and other diseases into the human cells. These viruses and diseases, in turn, could afflict any patients that are recipient to those stem cells. Thus, legislation may be appropriate to protect Canadians from these medical risks, at least until such further time that they are either alleviated, or when scientific advances have lowered their probability.

C. Competing Rights

i) Reproductive liberty rights:

One of the more obvious rights with which restrictions on embryo research may interfere, and that has already been frequently alluded to, is the right to reproductive liberty. This becomes an issue particularly where restrictions are imposed on the basis of safeguarding the well-being of the embryo. Simply put, "feminists are guarded about movements to accord rights to fetuses, since those rights are frequently invoked by those whose purpose is to regulate how women may behave when they are, or are liable to be, pregnant."[62] Some courts have been conscious of the linkage between banning embryo research and reproductive rights. In *Lifchez v. Hartigan*, for example, a U.S. federal district court held that a law that banned certain forms of fetal research was unconstitutional on the grounds that it constituted an infringement upon reproductive liberty.[63]

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[61] Will Dunham, *Experts Back Human Embryonic Stem-Cell Research*, REUTERS (September 11, 2001).
[62] Rebecca J. Cook, *Feminism and the Four Principles in Raanan Gillon, ed.*, PRINCIPLES OF HEALTH CARE ETHICS 195, 195-196 (1994).
[63] *Lifchez v. Hartigan*, 735 F. Supp. 1361 (N.D. Ill 1990).

One clear example of where conflict can arise is in a hypothetical case of a woman who decides to have an abortion to obtain access to stem cells that may help treat a disease-afflicted relative or friend. It can be argued that a clear separation ought to be made between the decision to abort, and the decision to donate aborted embryonic or fetal tissue for medical uses. It is unclear, however, if such a separation can be enforced. To question the motives behind an abortion may in itself be viewed as an interference with the right to reproductive liberty. Indeed, if abortion is considered to be a woman's fundamental right, then its motive can be seen to be of secondary concern, or even irrelevant.

Others might view restrictions on embryonic stem cell research, and on abortions carried out with the intent to benefit from such research, to be valid. After all, these restrictions do not compel a woman to carry an embryo or fetus to term. This line of reasoning would suggest that it is these negative procreative rights, i.e. rights that ensure bodily integrity, that constitute the essence of reproductive rights protections. This attitude is reflected in some of the different laws in this field. In the U.S., for example, researchers can legally use fetal tissue obtained from elective abortions only if those abortions were performed for reasons unrelated to the research. Moreover, the National Institutes of Health Revitalization Act of 1993 specifically prohibits abortions with the intent to provide fetal tissue for transplant.[64]

Typically, the option to donate is put forth to the patient only after she has made the decision to abort. Moreover, the woman does not have the option to direct that the

[64] National Institutes of Health Revitilization Act of 1993, Pub. L. No. 103-43.

donated tissue be used to benefit a particular person.[65] These U.S. measures attempt to strike a balance between protecting women's bodily integrity, and ensuring that an embryo/fetus is not created and/or terminated for research purposes. Canada may very well choose to follow a similar approach.

Another interesting debate that arises in the context of reproductive rights deals with whether or not there is a right to avoid having biological offspring. Some have pointed out, based on court cases dealing with contraception and other issues that such a right may exist.[66] If true, then it is possible that any law that interferes with the discard, or that freely allows the donation of those in vitro embryos used in stem cell research, may violate that right. This is because it would allow for the creation of biological offspring even where contrary to the wishes of one or both parents. Perhaps such a right, if it exists, would be restricted to cases where the parent(s) would also be charged with the burden of rearing the child.[67]

However, courts may consider that the mere knowledge that one has biological offspring somewhere would create a psychological burden that provides sufficient grounds for recognizing such a right. At any rate, this issue is yet another of the many issues to be considered in drafting legislation pertaining to stem cell and embryo research.

ii) Other competing rights:

Another potential right that may be infringed by restrictions on stem cell research is the right to conduct scientific research. Such a right can possibly be read into section

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[65] Lori P. Knowles, *Comparative Primordial Stem Cell Regulation: Canadian Policy Options*, (January 11, 2001), *at* http://www.cbac.gc.ca (date last visited Nov. 2001).
[66] Robertson, *supra* note 55, at 500.
[67] Id.

2(b) of the Canadian Charter of Rights and Freedoms, which protects freedom of expression. In *R. v. Keegstra*, the Supreme of Court of Canada stated quite clearly that "[a]t the core of freedom of expression lies the need to ensure that truth and the common good are attained, whether in scientific and artistic endeavors or in […] our political affairs [emphasis added]."[68] Earlier, the U.S. Supreme Court had adopted a similar position in *Miller v. California*, stressing that "the courts must always remain sensitive to any infringement on genuinely serious literary, artistic, political, or scientific expression [emphasis added]."[69]

These statements recognize the public benefit that scientific inquiry provides, and the crucial role it plays in maintaining the sanctity of knowledge. In keeping with this deference, Canadian courts appear to apply a primary presumption of liberty to pursue certain fields of scientific research.[70]

One last collection of rights that may compete with restrictions on stem cell research are those belonging to Canadians afflicted with diseases that stem cell research may help treat or cure. Indeed, some might see the treatment of these people as being a sufficient basis alone for permitting embryonic stem cell research. Embryo research and practices that inevitably destroy some embryos are already permitted for treating one illness: infertility. As mentioned earlier, this is largely because fertility and the generation of offspring are seen as desirable goals on both an individual and a societal basis. Can a similar desirability not be found in research that has the potential to cure debilitating diseases and save lives? Indeed, if the reasons for protecting the embryo were to be based on the principle of respecting human life, then can this end not also be

[68] *R. v. Keegstra*, [1990] 3 S.C.R. 697, at ¶ 88.
[69] *Miller v. California*, 413 U.S. 15 (1973).
[70] House of Commons, Evidence for the Standing Committee on Health (June 8, 1999).

achieved by helping improve the existing human lives of the thousands of disease-afflicted Canadians?

In fact, the life-threatening nature of many of these diseases suggests that Canadians may already have a constitutional right to stem cell therapies that are potentially life-saving.[71] Such a right may be embodied in section 7 of the Charter, which protects one's rights to "life, liberty and security of the person."[72] Section 15 of the Charter, which protects the equality rights of Canadians, may also be implicated. To many disease-suffering Canadians, stem cell research may be one of the only means by which they can attain a level of comfort and dignity comparable to that enjoyed by healthy Canadians. Indeed, "physical handicap" is one of the enumerated grounds of section 15 upon which an equality action can be raised. Moreover, these disease sufferers can also be considered to be a historically disadvantaged group. On account of their ailment, many have been denied the same opportunities in life that healthier Canadians have been able to enjoy. A finding of such "historic disadvantage" would assist in determining whether or not this group's section 15 rights would be violated.[73]

Moreover, government restrictions that, for example, prohibit public funding of research that leads to the destruction of an embryo may leave such research to be financed, and therefore controlled, by largely profit-seeking private companies. This could restrict access to stem cell therapies to wealthy individuals, further widening the existing inequalities between rich and poor Canadians.[74] Due consideration to all of these

[71] Sina Muscati, *Therapeutic Cloning and the Constitution – A Canadian Perspective*, 8 HEALTH L. CAN. 21 (2001).
[72] Canadian Charter of Rights and Freedoms, § 7, Part I of the Constitution Act, 1982, being Schedule B to the Canada Act 1982 (U.K.), 1982, ch. 11.
[73] *See e.g.* Law v. Canada (Minister of Employment and Immigration), [1999] 1 S.C.R. 497 at ¶ 39.
[74] Muscati, *supra* note 70.

competing rights will need to be given by the government when deciding what action to take regarding embryonic stem cell research.

D. Alternatives to Embryonic Stem Cell Research

Whether or not legal restrictions on embryonic stem cell research can be justified will depend partly on the availability of any real alternatives to it. Where such alternatives exist, they would undermine any claims that embryonic stem cell research alone can lead to the medical advances desired. This would make it even more difficult to justify the destruction of human embryos. Thus, an analysis of these more morally-unproblematic alternatives represents an alternate approach to evaluating embryonic stem cell research, one that side-steps the complex ethical debates, and focuses instead on whether such research is in fact necessary.

i) Adult stem cell research:

Perhaps the most promising possible alternative to embryonic stem cell research is ongoing research into the use of adult stem cells. As their name suggests, these cells exist in adult humans and share many of the properties of embryonic stem cells, including a low degree of differentiation. Adult stem cells are found primarily in the bone marrow, brain, intestines and skin; they are also found in the placenta and umbilical cords of newborn babies. Their main function is to repair the wear and tear that occurs in certain parts of the adult body. For example, they help in renewing the intestinal lining, revitalizing and repairing skin and reproducing new blood cells by continuously specializing into new cells that replace older ones.[75]

[75] U.S.A., Report and Recommendations of the National Bioethics Advisory Commission: Cloning Human Beings (Rockville, Maryland: June 1997).

It is hoped that adult stem cells can provide those same medical benefits that embryonic stem cells promise to provide. Many, however, have been critical of just how beneficial adult stem cells can be. They point out that such cells tend to be present in only minute quantities, and decrease in number with age.[76] Adult stem cells are also difficult to purify and have yet to be isolated for every type of tissue. Some research also suggests that adult stem cells may be able to divide only a limited number of times.[77] This would limit their use in creating sufficient numbers of specialized cells for medical application.

Despite such shortcomings, adult stem cell research has shown a lot of potential. Adult stem cells are being discovered for an increasing number of tissues, increasing the scope of their potential application. New research also indicates that these cells are much more adaptable than once believed. Scientists have encountered increasing success in specializing these cells into different tissue types as they begin to understand the chemical triggers that influence them. Italian scientists, for example, have succeeded in triggering adult nerve stem cells that produce nerve cells in one location of the body to produce muscle cells in another.[78]

Other researchers have triggered adult bone marrow stem cells to develop into brain neurons.[79] In August 2001, a team of Canadian researchers successfully transformed the adult skin stem cells of mice into various other cell-types, including brain cells, glial cells, muscle cells and fat cells.[80]

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[76] STEM CELLS, *supra* note 13.
[77] Casell, *supra* note 21, at 553.
[78] Italians Report Finding Alternative Stem Cell Research Method, Reuters (September 19, 2000).
[79] Stem cells repair heart attack damage, (March 31, 2001), at http://www.bbc.co.uk (date last visited March 2001).
[80] Carolyn Abraham, *McGill team harvests stem cells from skin*, THE GLOBE AND MAIL (August 13, 2001).

Adult stem cells may also have certain advantages over their embryonic counterparts. For example, the transfer of tissues derived from embryonic stem cells, unless cloned from the recipient, runs the same risks of immune rejection associated with transferring any foreign substance into the human body. Such rejection can be treated only by a potentially lifelong prescription of anti-rejection drugs. This problem is avoided in adult stem cells if they are obtained from the recipient him/herself such that they possess the same genetic makeup.

Adult stem cells have already been successfully used clinically, whereas embryonic stem cells have not. In one case, a man suffering from scleromyxedema, a potentially fatal skin disease, was reportedly free of symptoms following a transplant of adult stem cells isolated from his own bone marrow.[81] How much promise adult stem cell research shows will likely feature prominently in the debate over whether embryonic stem cell research can be justified.

ii) Xenotransplantation and animal stem cell research:

Another field of research that may provide similar benefits to those promised by embryonic stem cell research involves the cross-species transplant of certain animal cells and tissues. For example, rather than using embryonic stem cells to generate human organs, animal organs can be transplanted into humans, a process known as xenotransplantation, to address the current shortage of donated organs. The transplant of animal organs runs the risk, again, of immune rejection in the human recipient.

Scientists, however, are working to overcome this problem by the creation of transgenic animals. These are animals that have been genetically altered by the direct

[81] A.M. Feasel et al., *Complete remission of scleromyxedema following autologous stem cell transplantation*, 137 ARCHIVES OF DERMATOLOGY 1071-2 (2001).

injection of genes from other species, namely humans, into the fertilized egg. For example, the human body's rejection of certain pig organs has already been partially overcome by creating transgenic pigs that express certain human regulatory proteins.[82]

Another ongoing field of research lies in the use of stem cells that contain human DNA, but are extracted from embryos derived from mammalian eggs. Known as chimeras, these embryos are created by transferring the nucleus of a human cell (where nearly all DNA exists) to a mammalian egg cell whose nucleus has been removed. The procedure, known as somatic cell nuclear transfer, is the same procedure used in whole-organism cloning (in creating Dolly the sheep, for example). Because they are cloned, the derivative stem cells have the added benefit of providing an exact genetic match for the recipient. The procedure also has practical advantages, given the ample supply of mammalian eggs compared to human eggs. Scientists have already succeeded in using cow and pig eggs to create cow/human and pig/human chimeras. The embryos undergo a few cleavages, although they are still non-viable in the long-term.[83]

The use of chimeric embryos might side-step some of the ethical concerns associated with experimenting on human embryos. This is because chimeric embryos are technically not human, given that their cellular composition includes both human and animal components. However, the creation of chimeric embryos raises ethical issues relating to the mixing of human DNA and other cellular components with that of other species. Indeed, there is widespread concern that this practice represents an affront to human dignity. There are also safety concerns that arise when the biological products of another species are incorporated into the human body. Hence, it is unclear if the use of

[82] McDaniel, *supra* note 33.
[83] P. Cohen, *Cloning Report: Organs Without Donors*, NEW SCIENTIST 4 (July 1998).

chimeric embryos provides a truly viable alternative to human embryonic stem cell research.

iii) Other alternatives:

It was recently discovered that some of the stem cells found in fetuses can be as valuable for research as embryonic stem cells. For example, fetal bone marrow stem cells have been discovered to be highly adaptable, provoking low rates of immune rejection.[84]

Another valuable group of cells, known as embryonic germ cells, are also found in fetuses. These cells are destined to specialize into the eggs or sperm of the future adult.[85] They too have properties resembling those of embryonic stem cells. Fetal cells can even be isolated from spontaneously aborted or stillborn fetuses, again side-stepping the ethical concerns associated with the deliberate destruction of human embryos.

Other scientific breakthroughs are also promising new alternatives to embryonic stem cell research. For example, PPL Therapeutics, the same firm that cloned Dolly the sheep, is working on a method of converting ordinary cells into stem cells through a process known as de-differentiation.[86]

If successful, then ordinary cells may replace embryos as a primary source of stem cells. Also, a team of Canadian scientists has recently discovered a means to make non-embryonic stem cells reproduce in vitro as rapidly as embryonic stem cells.[87] This development will greatly facilitate research on developing alternatives to embryonic stem

[84] *On Human Embryos and Stem Cell Research: An Appeal for Legally and Ethically Responsible Science and Public Policy* (July 1, 1999) Center for Bioethics and Human Dignity (Bannockburn, IL).
[85] Knowles, *supra* note 64.
[86] McConchie, *supra* note 58.
[87] G. Bhardwaj et al., *Sonic hedgehog induces the proliferation of primitive human hematopoietic cells via BMP regulation*, 2 NATURE IMMUNOLOGY 172-80 (February 2001).

cells, as well as on the creation and maintenance of non-embryonic stem cell cultures for clinical use.

Part IV. The Canadian Legal Response to Stem Cell Research

A. The History of Legal Measures Against Reproductive and Genetic Technologies

The law in Canada pertaining to embryonic stem cell research is currently unclear. In 1989, the federal government established the Royal Commission on New Reproductive Technologies, which released its 1200 page final report in 1993. That report set out a number of recommendations, including the passage of laws to govern various reproductive technologies, and criminal prohibitions against specific activities that "conflict…sharply with the values espoused by Canadians, and are…potentially harmful to the interests of individuals and of society […]."[88] In response, the Minister of Health issued a voluntary moratorium in July 1995 against nine reproductive technologies.[89] These included the cloning of human embryos, the formation of animal-human hybrids and the creation of an artificial womb.[90]

In 1996, Bill C-47 (The Human Reproductive and Genetic Technologies Act) was introduced into the House of Commons, and passed first reading. The bill set out criminal prohibitions against a number of practices, including human cloning, sex selection and the selling of genetic material.[91]

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[88] *See, e.g.* Canada, *Final Report of the Royal Commission on New Reproductive Technology: Proceed with Care* (Ottawa: Minister of Government Services Canada, 1993) (Chairperson: P. Baird) at 1022.
[89] Owen Wood, *Reproductive Technologies Laws in Canada*, (December 2001) *at* http://www.cbc.ca/news/indepth/background/rgtech.html (date last visited January 2002).
[90] The other six prohibitions are sex-selection, commercial "surrogacy" arrangements, buying and selling eggs, sperm, and embryos, genetic alterations, retrieval of eggs from fetuses and cadavers, and egg donation in exchange for *in vitro* fertilization.
[91] Bill C-47, *An Act respecting human reproductive technologies and commercial transactions relating to human reproduction*, 2d Sess., 35th Parl., 1996, cl. 4 (1st reading 14 June 1996).

However, it was terminated after Parliament was dissolved following the federal election call of 1997. Later that year, Bill C-247 was introduced to ban human cloning. That bill was defeated following its second reading in the House of Commons. All this has left Canada without any legislation governing reproductive and genetic technologies

Proposed Canadian Legislation

The federal government recently revived attempts to pass new legislation governing reproductive and genetic technologies. Draft legislation (The Assisted Human Reproduction Act) was drawn up in May 2001, and tabled in the House of Commons as Bill C-56 in May 2002. The Bill proposes, again, complete prohibitions of various controversial research practices. These include the cloning of humans, the development of an in vitro embryo beyond fourteen days, the creation of embryos solely for research purposes and the use of human reproductive material previously transplanted into an animal.[92] The Bill also proposes that other, less controversial activities, be controlled by regulation. These measures are consistent with the proposals of the Canadian Institutes for Health Research (CIHR) regarding stem cell research.[93]

Earlier, in December 2001, the Standing Committee on Health had issued a report following its review of the draft legislation. It called for an even tougher set of laws than those proposed. The Standing Committee also noted that it was "struck by […the] tremendous gains in adult stem cell research in humans," recommending that no licence to experiment on surplus embryos be issued "unless the applicant clearly demonstrates

[92] Bill C-56, *An Act respecting assisted human reproduction*, 1st Sess., 37th Parl., 2002, cl. 5(1) (1st reading 9 May 2002).
[93] *Id.*

that no other category of biological material could be used for the purposes of the proposed research."[94]

Further, it recommended the development of "regulated standards in relation to the maximum number of embryos that may be produced, stored and transferred for in vitro fertilization procedures," as well as a prohibition on creating surplus embryos "once egg-storage techniques have been perfected and validated."[95] Bill C-56 will be subject to further review and its passage is expected to take several months. Several more months will be needed before any new regulatory body could begin to function.

Many aspects of the Bill and the Standing Committee's proposals are interesting. For example, they appear to recognize a moral distinction between embryos that are and are not created for research purposes. They also distinguish between embryos that are older and younger than fourteen days. The proposed requirement of having researchers demonstrate the necessity of experimenting on embryos is also significant. Clearly, this would give new importance to the many potential alternatives to embryonic stem cell research that were outlined earlier.

B. Comparing Proposed Canadian Measures to Those of Other Nations

The passage of Bill C-56 would make Canada the newest in a long list of nations to adopt measures intended to govern stem cell research. Some, including the United Kingdom, France, Germany and Japan have already passed laws and in some cases set up governing bodies to deal with genetic technologies.[96]

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[94] *Building Families, supra* note 54.
[95] *Id.*
[96] *See, e.g.*: the United Kingdom's *Human Fertilisation and Embryology Act 1990* (U.K.), 1990, ch. 37, which allows the creation of embryos for research for specified purposes up to the age of 14 days, and is administered by the *Human Fertilization and Embryology Authority;* France's *Loi no. 94-654 du 29 juillet 1994*, which bans cloning, the creation of chimeras and research using human embryos; Germany's *Embryo Protection Act* (1990), which defines every totipotent stem cell as an embryo, and criminalizes the

Specific measures, such as the fourteen-day limit on embryo research, would place Canada in a similar position to other countries, such as the U.K., which has adopted this same limit. The proposal to allow the use of surplus embryos also goes much further than the measures taken in other countries. In the United States, for example, President Bush announced in August 2001 that federal funding of stem cell research would be allowed only on existing embryonic stem cell cultures, where the decision to terminate the embryos had already been made.

The divergence from the U.S. position has some advantages. It avoids the seeming paradox of not funding research that creates embryonic stem cell cultures, but then funding research on those same cultures after they have been derived without the observance of any regulatory or ethical standards.[97] Access to existing embryonic stem cell cultures may also be restricted given that they are subject to private patent protection. Some groups, such as the U.S. National Academy of Sciences, have also suggested that the therapeutic potential of stem cell research can only be exploited if research is expanded beyond existing stem cell cultures.[98]

C. Critiques of the Proposals

i) Ambiguity and the problem posed by rapid scientific advances:

One of the most striking problems in the proposed legislation is that it is potentially ambiguous with respect to some of the scientific terms and processes described. Many of the phrases used, such as "alter the genome," are difficult to

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creation of embryos for research purposes and research on totipotent (but not pluripotent) stem cells; Japan's *Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques* (2000), which legalizes *in vitro* experimentation on human embryos.

[97] Knowles, *supra* note 64.

[98] Rick Weiss, *Broader Stem Cell Research Backed: Key Science Group Differs with Bush*, The Washington Post (September 11, 2001), at A01.

interpret. It is unclear, for instance, whether this phrase refers to all the DNA, or only parts of it. Would it encompass a change that affects a single DNA base pair, which represents one molecule out of approximately six billion? These are important determinations that will need to be made.

Another example is that while the text of Bill C-56 appears to renounce the idea of creating an animal/human hybrid, it is ambiguous as to whether the creation of those chimeric clones described earlier in the paper is absolutely prohibited. The legislation defines a chimera as a human embryo "into which a cell of any non-human life form has been introduced" or "that consists of cells of more than one embryo, fetus, or human being."[99] This definition would not include chimeric clones. They may be encompassed by the prohibition against creating human clones, defined as an embryo with the same nuclear DNA sequence as another human organism. However, an embryo is defined as a human organism, and it is unclear if embryos with cells having human nuclei but animal cellular components can be considered as such. The Standing Committee also found problems with the definitions provided for "gene," "genome," "embryo" and "embryo donor."[100] Clearly, there may be a need for further clarity in the Bill.

The proposed legislation also may fall quickly out-of-touch with both the priorities of Canadians and the state of reproductive and genetic technologies, given the rapid pace of scientific developments in this area. For example, one of the motivations behind banning such practices as the therapeutic cloning of embryos is the human health and safety risks that are posed by this technology in its current state. Further technological advances, however, may eliminate many of these risks, at which time it may be appropriate to de-

[99] Bill C-56, *supra* note 91, at cl. 3.
[100] *Building Families*, *supra* note 54.

criminalize such practices. To do so, however, would require legislative amendments, which involve a complex and time-consuming process. Indeed, the Standing Committee acknowledged that there exists a "rapidly changing scientific and technological environment," and recommended parliamentary review of any legislation within three years.[101] Such a provision was adopted in Bill C-56;[102] however, a lot of significant changes can occur even within three years. This brings to question the appropriateness of using criminal law in trying to control scientific fields as dynamic as biotechnology.

ii) The problems with a criminal law approach:

Just as new scientific developments may eliminate certain risks, other developments can give rise to new social issues or concerns that were unforeseeable just a short while before. This means that the scientific fields at issue will need to be revisited constantly. However, as has been shown, it is impractical to do so with criminal legislation.[103] Indeed, it is quite likely that if and when Bill C-56 finally passes into law, new issues will have arisen that, while requiring attention, had not been anticipated. An additional concern with criminal legislation is that police, who play a prominent role in enforcing criminal law, have little experience with human reproductive and genetic technologies.

What are the alternatives to criminal law? Two of Canada's prominent health law experts, Bartha M. Knoppers and Timothy Caulfield, have suggested the creation of a comprehensive regulatory scheme. This scheme would establish effective control over controversial scientific practices but still be flexible enough to accommodate scientific

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[101] *Id.*
[102] Bill C-56, *supra* note 91, at cl. 70(1).
[103] Bartha M. Knoppers and T. Caulfield, Comment, *Don't make science a crime: Criminal law is too blunt a tool to cope with genetic research, say health-law experts Bartha Maria Knoppers and Timothy Caulfield. We need flexible regulations*, THE GLOBE AND MAIL (20 August 2001), at A13.

developments and changing social priorities.[104] The suggested scheme could perhaps consist of an expanded version of the regulatory regime already contemplated by Bill C-56. In fact, some of the expert witnesses who appeared before the Standing Committee, citing the benefits of regulatory flexibility, recommended the elimination of the prohibited activities category altogether.[105] With a regulatory scheme in place, desired amendments could be achieved more quickly through the usual process for amending regulations, rather than through legislative changes.

Part V. Conclusion

Research on embryonic stem cells has emerged as one of the more controversial areas of medical science. While the medical benefits of the research look promising, the ethical dilemmas of embryo research and destruction remain. Capitalizing on the benefits of stem cell research will require a clarification of the legal status of the embryo and the adoption of clear ethical standards and guidelines.

Canadian jurisprudence currently deems unborn children to be prenatal entities with rights that remain inchoate until birth. It is not clear, however, how the law will treat the in vitro embryo, which has an independent physical existence. The courts have recognized a parliamentary right to legislate on behalf of the embryo in well-defined circumstances. Draft legislation has now been introduced to limit reproductive and genetic technologies.

Any future legislation must remain cognizant of a number of concerns. Applications of stem cell therapies, due to the primitive state of the technology as well as

[104] *Id.*
[105] *Building Families, supra* note 54.

the nature of the biological processes involved, have numerous safety risks. Canadians need to be protected against these. Legislating protections to the embryo can also indirectly affect female reproductive autonomy, a fact that needs to be addressed. Other rights will also need to be balanced, including any right to scientific research, and the rights of disease-afflicted Canadians to benefit from stem cell therapies. Finally, scientific advances in other fields of biotechnology, such as adult stem cell research, may provide similar benefits to embryonic stem cell research in less morally controversial ways. The significance of these advances will need to be recognized.

While Canada's draft legislation goes some way to addressing these issues, certain ambiguities within it suggest that Parliament may not yet have a full understanding or appreciation of this complex technology. Moreover, the use of criminal law may be too rigid a mechanism to apply to this dynamic field. The important ethical, health and social issues that embryonic stem cell research gives rise to make it critical for Canada to establish an effective policy with respect to this technology. With a proper dialogue between scientists, ethicists and jurists, such a policy hopefully will not only be conducive to medical progress, but will also address the legitimate ethical and legal concerns of the Canadian public.