



Bioethics Update

Canada's Proposed Assisted Human Reproduction Act (Bill C-13)

Canadians are awakening to the reality that the use of some technologies assisting human reproduction and their link to genetic and cell research in recent years have serious social and moral implications. Our attitudes towards childbearing and family relationships have changed profoundly. To a far greater extent than before, we have the ability to design our own children. We also face increasing pressure to justify allowing some humans early in their development to be used or destroyed to benefit other humans. The Catholic Church supports medical knowledge and technology that result in human well-being, but is concerned about some developments that disregard human dignity and contribute to a "profound change in the way in which life and relationships between people are considered."¹ Recently a few ethicists have warned of a "posthuman future" in which humans are increasingly de-humanized. Leon Kass has urged that, "for anyone who cares about preserving our humanity, the time has come to pay attention."²

The Canadian government's effort to "pay attention" comes nearly a decade after the report of the Royal Commission on New Reproductive Technologies called for a federal law to regulate the use of these technologies. The proposed *Assisted Human Reproduction Act* (Bill C-13) is now being studied by the Standing Committee on Health, which could recommend changes before a final vote in the House of Commons. The following is an attempt to apply some insights from the Canadian Catholic Bioethics Institute's think tank discussions in June 2002 to a review of this Act.³

Overview of the Act

The Act addresses two issues: how to regulate procedures that help couples with reduced fertility to have children, and how to set boundaries for technologies that use human genes, sex cells, and embryos for research. The Act proposes broad classes of activities that will be prohibited by criminal law, and others that will be subject to licensing and monitoring by an "Assisted Human Reproduction Agency" for compliance to future regulations. The government will write these regulations. Parliament has sixty days to suggest changes but such suggestions will not be binding on the government. The future regulations will cover important ethical matters such as the conditions for destroying human embryos "left over" from assisted reproduction procedures and the sorts

of research that may be licensed to exploit them [clauses 65(1)(c) and (r)], the parts of the human genome that may be combined with genes of other species [clause 65(1)(d)], and even the controlled activities that may be *exempted* from the legislation [clause 65(1)(z)].

The Assisted Human Reproduction Agency will interpret and enforce the regulations, maintain a registry of health information about donors, recipients and children involved in assisted human reproduction procedures, and disclose this information to the government and the public under specific conditions [clauses 18(3) to (7) and 24(2)(b)]. The Agency is to be directed by a Board of 13 people each serving a 3-year term and appointed by the government "to reflect a range of backgrounds and disciplines relevant to the Agency's objectives" [clause 26(2)]. Although the Agency is supposed to operate at arm's length from the government, the Deputy Minister of Health is entitled to participate in Board discussions [clause 27] and the Minister of Health may "issue policy directions to the Agency concerning any of its powers" that will be binding [clause 25(1)].

General Assessment of the Act

Any assessment of Bill C-13 at this point is bound to be incomplete. Much of the legislation's impact will depend on future regulations and the membership and policies of the proposed Agency, which in turn will be shaped by the government without very much input from the public or Parliament. This is cause for concern and a challenge to Canadians to be vigilant.

Britain's Human Fertilisation and Embryology Authority, on which the proposed Canadian Agency appears to be modelled, has faced criticism for being out-of-touch with the public interest on a number of recent decisions. For example, a fertility clinic in the U.K. was given permission to help a couple to conceive and genetically select an embryo whose umbilical cord blood cells could be used to treat the couple's other child with thalassaemia.⁴

Nevertheless Bill C-13 is an important first step in addressing the lack of legislation in Canada governing the use of reproductive technologies and their link to genetic and cell

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research. The Bill does set some important boundaries. For example, clause 5(1)(a) bans human cloning; clause 5(1)(e) prohibits procedures that identify, or increase the likelihood of creating, an embryo of a particular sex (with one exception); clauses 5(1)(f) to (j) make illegal any germ-line modifications, i.e. procedures that add or delete genes in human sperm or eggs. Also prohibited are techniques that combine human sperm, eggs or embryos with non-human cells or embryos (hybrids and chimeras); clause 5(1)(b) bans creating human embryos for any purposes other than reproduction (with one exception); clause 11(1) calls for regulations relating to recombinant genetic research, which inserts parts of human DNA into non-human DNA and vice versa. This sort of research can do much good in studying the genetic basis of diseases, their potential cure through “gene therapy”, and the testing of drugs; however, some oversight is necessary to address ethical and social issues as they arise.

In addition, the Act allows adoption of donated frozen embryos (“embryo transfers”), as an alternative to their destruction, because only the *selling* of human embryos is prohibited in clause 7(2). However, whether this sort of adoption is morally acceptable is still a subject of debate among moral theologians.⁵

Despite these good provisions of the Act, there are nevertheless areas of concern to Catholics and other like-minded Canadians. Aside from sex selection, the Act does not control genetic screening of embryos created by assisted reproduction procedures. Even with respect to sex selection, there is an exception made to allow destruction of human embryos affected or potentially affected by a sex-linked “disorder or disease”, with no definition given as to what constitutes a “disorder”.

Under clause 5(1)(b), human embryos may be created in the laboratory for research and instruction in assisted reproductive procedures. This is significant because, for the first time, a Canadian law has adopted the morally problematic view that a human life can be *created solely to be used for the benefit of others*.

Bill C-13 also leaves open the possibility that, with the consent of parents, research involving embryos “left over” from assisted reproduction procedures may be licensed. This could include the destruction of embryos for stem cells. The Bill does not specify the need for a regulation requiring researchers to demonstrate that there are no alternatives to using human embryos, as an earlier report of the House of Commons’ Standing Committee on Health recommended. Moreover, research using human embryos could be exempted from licensing requirements altogether by a future regulation.

Significant Issues Overlooked

Assisted Human Reproduction: Bill C-13 regulates assisted reproductive procedures, but it does so without attending to the roots of the social and ethical problems encountered in this area. Using a medical analogy, one could say that the proposed Act manages symptoms but fails to address the underlying condition and its prevention. Infertility affects 1 in 8 Canadian couples

who want a child. Factors such as delayed age of childbearing, exposure to environmental toxins, the effects of sexually-transmitted diseases and substance abuse have been linked to this difficulty.⁶ There is need for health promotion and government incentives to better address these causes of reduced fertility and to provide help to couples who want safe and morally acceptable options for having children.

Many Canadians do not consider the intrusions of most types of assisted human reproduction, especially *in-vitro* fertilization, (that is, occurring outside the body), to be morally acceptable. For example, Catholics hold that children should always originate from the “one-flesh” union of an act of inter-personal love-making between spouses. The experience of childlessness is often painful. Nevertheless children are a gift and not a commodity to which one has a right. Using technology and other people to “make” children, however well-intentioned, inevitably creates an imbalance in the relationship between parents and their creation. It is a short slide from producing children to commercializing this activity, which Bill C-13 prohibits.

In addition, the medical and social consequences of many assisted reproductive procedures are increasingly of concern to society: for example, health problems in many children born after *in vitro* fertilization⁷, the possible harmful effects on women of drugs that stimulate the release of more than one egg at a time and of multiple births⁸, and the “bewilderment” of many children who do not know the identity of their donor or surrogate parents.⁹ Although Bill C-13 purports to promote the health and well-being of children born through assisted human reproductive procedures [section 2], it fails sufficiently to protect these children. For example, the Act requires informed consent from prospective parents and donors, but does not recognize the need for counselling that is adequate and apart from the fertility clinic where a conflict of interest is most likely to arise. Nor does Bill C-13 call for particular regulations in section 65 limiting who may have access to these technologies or the number of eggs that may be harvested, fertilizations allowed from a single donor and embryos created and stored. Furthermore the possibility of children finding out about their donor parents is limited under the Act because donors may request the destruction of some types of information and refuse consent for disclosure of their identities [clauses 16(2) and 18(2)].

It is necessary in Canada today to consider the big picture in relation to assisted human reproduction. Canadians need public policies that minimize the environmental and social factors contributing to reduced fertility. In a culture where reproduction is increasingly considered a “right” of an individual, attention needs also to be paid to the welfare of human embryos and children. The government should encourage the study and promotion of alternative means of assisting human reproduction to *in vitro* fertilization, which gives rise to so many ethical and social concerns.

Genetic Screening: The Human Genome Project begun in 1990 has increased scientists' knowledge about the structure of human genes and their functions. This has greatly expanded the range of genes for which embryos created in the laboratory can be screened before being implanted. Bill C-13 does not address the need for regulation in this area. Human embryos created through *in vitro* fertilization can now be screened for disorders like Cystic Fibrosis, many of which cannot be effectively treated. Increasingly embryos can also be screened for thousands of genetic markers that indicate a *possible risk* of developing diseases in later life (like breast cancer) or have been linked to physical or mental *traits* that parents might consider "undesirable". The reverse is also possible: for instance, in the British case mentioned earlier, genetic matching of embryos created by *in vitro* fertilization was undertaken for a specific characteristic that would benefit a sibling.

The prospect of parents designing "perfect babies" according to their own or societal standards is remote because genes are not the only factor determining the characteristics and health of offspring. Nevertheless the practice of screening for *particular* genetic markers does place parents in the position of determining the fate of their children in the embryonic stage, on the basis of information whose meaning and long-term implications can never be known with certainty.¹⁰ This power further distorts the relationship of parents to their children, and multiplies the number of human embryos who could be used to fulfill particular needs or simply discarded. Because of the seriousness of the social and ethical problems that could arise from misuse of information from genetic screening in assisted human reproduction, a national policy is needed that has the sanction of law.

Gene Patenting: Another area of social and ethical concern not tackled in Bill C-13 is the patenting of human genes and life forms. The Agency set up under the legislation will license, and could even exempt from a license, research that inserts a *part* of human DNA into the cells of non-human species, including their reproductive cells. This sort of research often can contribute to human well-being by helping to correct mutations or "errors" in genes or intercepting faulty "messages" sent by genes in human body cells (gene therapy) or producing effective and safe vaccines and drugs. However, the question of patenting what is discovered and produced, including life forms if non-human reproductive cells are involved, is likely to arise. Also the Act leaves open the possibility of making stem cell lines from human embryos not selected to live after *in vitro* fertilization. The question of patenting these stem cell lines containing a set of human genes will inevitably arise. Finally "chimera" in Bill C-13 refers to an entity formed by inserting non-human cells or cells of different individuals into a *human embryo* [section 3]. There is nothing in the Act that would prohibit the grafting of human embryonic *stem cells* (which are not entire embryos) into *non-human embryos and fetuses* to study their development. Grafts could alter the genes in the reproductive cells of these entities

and their offspring. The issue of patenting such life forms is bound to arise.

The *Patent Act* in Canada was not written to deal with these issues, and, in the absence of amendments to the Act, researchers will continue to put pressure on the courts to define what is permissible. There is no official Catholic teaching on patenting genes or complex life forms. Some Catholic ethicists have suggested that genes have intrinsic value, and should not be patented, because they are the biological medium through which intrinsically valuable humans are what they are. Moreover genes are both unique to a person and common to a species, always and at the same time.¹¹ Economic barriers to sharing the benefits of research based on genetic research, especially in situations of great medical need, seem unjust. Others claim that patents can encourage research that otherwise would not be done to improve human health outcomes, but in reality this is difficult to demonstrate. The patenting of complex life forms raises further questions about the relationship of humans to other living beings.

Ethical Framework

The above examples indicate that there are some important social and ethical issues that have been overlooked in Bill C-13. Of course no law in one area can anticipate and address every relevant issue. Whether these further issues are to be dealt with on the level of policies and regulations or by future legislation and court decisions, there ought to be a stable and coherent ethical framework enacted as part of the Act which will guide these considerations.

To its credit, the government followed the recommendation of an earlier report of the Standing Committee on Health to include a declaration of guiding principles in the body of Bill C-13 [section 2]. The principles that are listed, however, are not entirely consistent. Furthermore, various conflicts within the provisions of the Act cannot be resolved by appeal to any of the principles. Thus the principles declared in Bill C-13 do not seem to constitute an adequate framework to guide decision-making. A few illustrations will serve to make this point.

The first principle emphasizes the value of protecting and promoting "human health, safety, dignity and rights" in the use of assisted reproductive technologies and related research. However these human goods can often be in conflict. For example, it is clear that, under the legislation, parents have the *right* to undergo assisted reproduction procedures, as long as they understand that these procedures could pose some health risks to their child and they provide consent. The second principle states that the *health and well-being* of children born from such procedures must be given priority over their use. How will these conflicting goods be resolved concretely?

Furthermore, the principles themselves do not justify why human embryos can be *created* for the purpose of some types of research (relating to assisted reproductive procedures) but not others (e.g. stem cell research). While it may be argued

that what is gained in the former is knowledge that will make assisted reproductive procedures safe, it is not the health of the particular embryo that is being protected. In *any* use of human embryos for research that results in their destruction, they are being treated as mere means to another's end. How will the prohibitions against creating human embryos for stem cell research or indeed even the ban on human cloning, which Bill C-13 rightly considers to be in the public interest, stand up to a court challenge?

Moral and Legal Status of the Human Embryo

The main difficulty with the principles declared in Bill C-13 is that it is ambiguous on the moral and legal status of the human embryo. In Canada where abortions are allowed and *in-vitro* fertilization clinics create embryos that are sometimes discarded, it is a challenge to promote a culture that respects the dignity of human life at its most vulnerable stage of development.

The moral and legal status of human embryos is a divisive issue in society. It is important to be precise, however, about what the issue is, and to understand that, even in a pluralistic society, the insights of biologists, philosophers, political theorists and theologians of various faiths can be integrated to provide a solid argument for recognizing the right of a human embryo not to be used as the mere means to another's end.

Biologists observe that embryos created from human sperm and egg normally develop according to a plan that is distinctively human as long as there is no natural or artificial interference. This dynamic process of development (and later deterioration) begins at fertilization and does not stop until death. From the union of sperm and egg to the adult at death, this organism is *human* genetically and developmentally, and it is a *being* because it directs its own changes through interaction with its environment.

The issue that is divisive is whether such biological human beings have a moral worth that ought to be recognized and therefore legal rights that should be protected. Biologists can rely on data to make estimates about the extent of growth and functioning of body parts in embryonic human beings, but the question of moral worth depends on a further set of data from philosophy and theology.

Many Canadians affirm the dignity of human beings, including those in the embryonic stage of development, on philosophical grounds. This recognition of moral worth is not the result of a logical deduction but of an insight that understands the various biological changes that human beings undergo from conception to natural death to be *connected*. For instance, prior developments in the embryonic human being are necessary for later developments to emerge, and the whole sequence of the growth and functioning of new parts is not haphazard but involves the organism "preparing", as it were, its own future development. Thus the moral worth of human beings cannot be judged in the way that inanimate things, which do not direct their own ends, are judged. *Things* have value according to

their usefulness to external agents. *Human beings* have value as ends in themselves.

From political theory, it can be argued that, to claim that only *some* human beings have intrinsic moral worth is to reduce other human beings, whose moral worth society chooses not to recognize, to the status of things. Lamentably that has been the case whenever governments have chosen to discriminate between two classes of human beings, for example between Jews and non-Jews, slaves and citizens, pre-born and born, embryos that are selected and those that are frozen or discarded.

Finally one can add a theological perspective. Canadians who belong to the Christian, Jewish and Muslim faiths (the majority of Canadians) hold that the moral worth of human beings comes from their relationship to a loving God, in whose image they have been created. This reality does not change from the first moment of a new life to its death. It does not depend on qualities that human beings possess or have the "potential" to acquire. (Genesis 1.26-27) Moreover Catholics and many other Christians also believe that human beings have an intrinsic moral worth because God in the Person of Jesus Christ "became flesh and dwelt among us." (John 1.14)

Professor John Heng, Department of Philosophy and Religious Studies, King's College, University of Western Ontario, email: jheng@uwo.ca. Thanks to Professor Joseph Boyle and Dr. William Sullivan for their input.

Notes

1. John Paul II, *Evangelium vitae* (1995), 4.
2. Leon R. Kass, *Life, Liberty and the Defense of Dignity: The Challenge for Bioethics* (San Francisco: Encounter Books, 2002), 4.
3. Proceedings are scheduled to be published in 2003.
4. BBC (UK), July 18, 2002.
5. John Berkman, "The Morality of Adopting Frozen Embryos in Light of *Donum Vitae*", *Studia Moralia*, 40 (2002): 115-141.
6. "Delayed childbearing", editorial in *British Medical Journal* (Dec. 16, 1995), 311: 1585-6; K.A. Workowski *et al.*, "U.S. Centers for Disease Control and Prevention guidelines for the treatment of sexually transmitted diseases: an opportunity to unify clinical and public health practice", *Annals of Internal Medicine* (Aug. 20, 2002), 137(4): 255-62; P. Kovacic & J.D.Jacintho, "Reproductive toxins: pervasive theme of oxidative stress and electron transfer", *Curr. Med. Chem.* (June 2001), 8(7): 863-92.
7. B. Stromberg *et al.*, "Neurological sequelae in children born after in-vitro fertilisation: a population-based study", *Lancet* (2002), 359 (9305): 461-5.
8. A. Lynch *et al.*, "Preeclampsia in multiple gestation: the role of assisted reproductive technologies", *Obstetrics & Gynecology* (Mar. 1, 2002), 99(3): 445-51.
9. Ellen S. Glazer (1998), "Who speaks for the children?", <http://www.gis.net/~eglazer/children.html>.
10. Anne Summers, "Genetics in Health Care", in *Ethics and Human Genetics*, forthcoming publication of the Canadian Catholic Bioethics Institute.
11. Daniel Sulmasy OFM, "Who Owns the Human Genome?", in *Ethics and Human Genetics*, forthcoming publication of the Canadian Catholic Bioethics Institute.