

Brickbats and Bouquets for the Draft Legislation on Assisted Human Reproduction

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On May 3, 2001, the Canadian Health Minister Allan Rock presented draft legislation on assisted human reproduction to the House of Commons Standing Committee on Health. The legislation contains a set of guiding principles for the research and practice of assisted human reproduction. It bans certain practices, including cloning human beings, the sale and purchase of human embryos, and paying women to act as surrogate mothers. Other activities would be permitted only with a license. The legislation contains provisions on consent requirements for use of donated reproductive material. The Minister of Health would also have the authority to develop regulations on, for example, informed consent; counselling requirements for donors and recipients; safety of laboratories and other facilities; how human sperm, eggs and embryos should be handled; research involving use of human embryos; and the safety of donated sperm.

The Committee was asked to provide a report on the draft legislation by January 2002. Since May, the Standing Committee has been holding ongoing hearings on the proposed legislation.

The following is the text of a presentation to the Committee on May 31, 2001 by Dr. F. Baylis, Departments of Bioethics and Philosophy, Dalhousie University.

Presentation to the Standing Committee On Health¹

My presentation today is in two parts. First, I will outline features of the draft legislation that, in my view, are to be

commended. Second, I will identify aspects of the draft legislation that need to be corrected. My comments in the latter category are illustrative, not comprehensive.

Features of the Draft Legislation to be Retained

At the outset, it is important to highlight aspects of the proposed legislation that are to be applauded. Too often, in our eagerness to provide a critical commentary on a draft proposal, we neglect to mention that which is positive and should be retained. The risk in so doing is that positive features of the original proposal may subsequently be revised for the worse – at least that has been my limited experience in the realm of policy-making. And so, learning from my past mistakes, I am particularly mindful of the need to first tell you what I like about the draft legislation. My strong recommendation is that these features of the proposal not be amended.

The Preamble

The preamble to the draft legislation is exceptionally good. It names a number of important considerations and entrenches core values in the legislation. This will undoubtedly assist law-makers in interpreting and implementing the legislation, and developing coherent regulations. Particularly noteworthy are: (1) recognition of the need to attend to the best interests of children born of Assisted Reproductive Technologies (ARTs); (2) recognition of the disproportionate impact of ARTs on women; (3) the commitment to respect autonomy and, in particular, to promote free and informed consent; and (4) awareness of the problems of commercialization and commodification.

The Prohibited Activities

The following procedures are prohibited in the legislation: human cloning by blastomere separation and somatic cell nuclear transfer (SCNT); germ-line gene transfer; maintaining an embryo *ex utero* beyond 14 days; the creation of embryos for research purposes; the creation of embryos from an embryo or a foetus; transplantation of animal sperm, ovum or embryo into a human; transplantation of human reproductive material into an animal to create a human; and sex-selection. As well, offering or paying for any of these prohibited activities is itself prohibited, as is brokering or paying for surrogacy, and purchasing or bartering gametes or embryos.

Some will argue that these prohibitions will hinder research and innovation. Hopefully, their assessment is correct because it is imperative that we slow research and innovation in these very areas.

I stand firmly with those who maintain that “just because we can, doesn’t mean we should.” Unless and until we are confident that we should proceed with the novel and ethically controversial activities identified, it is imperative that they be prohibited. A moratorium is simply not an effective alternative, presuming that the goal is to ensure that these activities are not undertaken before a critical evaluation can be conducted on the merits of highly questionable practices that threaten core concepts such as identity and justice.

No doubt others will tell you of dire consequences associated with legislating these prohibitions. An oft-alleged consequence is that talented Canadian researchers and health care providers will leave Canada if their practice is constrained. First, I doubt the accuracy of this claim. In my view this is mostly scare-mongering. Canada is a wonderful place to live and work, and many scientists and health care providers are eagerly looking to the federal government for guidance. Might some people emigrate? Possibly, and this brings me to my second point. The possible departure of talented Canadians is not a sufficient reason to modify the proposed prohibitions. Imagine that a talented group of physicists at one time had told Canadian parliamentarians that they needed to be able to develop the atomic bomb or they would leave Canada. Also imagine that Canadians believed atomic warfare to be morally wrong and that the government had chosen to limit such research. Would the “threat” of losing talented physicists have constituted a sound moral argument against national policy that was consistent with the will of the people? Not to put too fine a point on this, consider the current situation with health care and the loss of talented physicians to the US. This in itself is insufficient reason to introduce a two-tiered

health care system and destroy the current system of which Canadians are so proud.

2. Features of the Draft Legislation to be Revised

Consent

The preamble to the draft legislation includes the following statement: “The Parliament of Canada... wishes to promote the principle of free and informed consent as a fundamental condition of the use of human reproductive technologies.” But some questions remain. Perhaps most important among these is, whose consent is required for embryo research?

Section 6(3) provides that donors of an “*in vitro* embryo” (or any part of one) must consent in writing to its use “for the purpose of research or the prevention, diagnosis or treatment of disease, injury or disability” (s. 8(2)). This suggests that licensable controlled activities pursuant to s. 8(2) can proceed with the consent of the embryo donor. This is potentially problematic, however, in those cases where gamete donors have been used. The gamete donors may have donated genetic material expressly for reproductive purposes and not research purposes. How are their wishes to be respected? Further, this interpretation of the legislation is inconsistent with the Overview document,² which portrays the gamete providers as the decision makers: “[D]onors would have to consent in writing to the use of their gametes to assist human reproduction. Their consent would be required for the use of their embryos for purposes both of research and of reproduction.”

A critical question that needs to be addressed in your review of the legislation is: whose consent is required for embryo research, the gamete donor(s) and/or the embryo donor(s)? Your answer to this question must be clearly and consistently reflected in both the revised legislation and the supporting documentation.

Animal-Human Hybrids and Chimeras

The draft legislation on cross-species research prohibits the transplantation of animal sperm, ovum, embryo or foetus into a human being (s. 3(1)(f)). It also prohibits the creation of a human being using human reproductive material that is or was transplanted into an animal (s. 3 (1)(g)). The creation of chimeras is not prohibited, however. Chimeras could be created for research or other purposes under the authority of a license (s. 9(1)). As well, a license could be granted to combine part of the human genome with part of an animal genome (s. 9(2)).

Significantly, not all categories of genetic mixing are clearly captured and delineated in these sections of the draft legislation. At the very least, clear definitions of interspecific hybrids, nuclear-cytoplasmic hybrids and interspecific chimeras are needed.

In genetic terms, an interspecific hybrid occurs when a human ovum is fertilized with a non-human sperm or vice versa. If successful development occurs, the being produced would have 50% of its genes from each of its parents, and its development would be driven by the genes of both species. In nature, true interspecific hybrids rarely develop very far, unless the species are very close. Another sort of animal-human hybrid involves nuclear transfer across species. A non-human nucleus is inserted into a human enucleated ovum or vice versa to create a nuclear-cytoplasmic hybrid. Both types of hybrids are complete hybrids and would be a challenge to species integrity. They should be prohibited.

Another kind of manipulation that involves human-animal genetic mixing (frequently confused with interspecific hybrids) is interspecific chimeras where embryonic cells from two species (e.g., human and chimpanzee) are mixed together at an early stage to make one foetus that is a mixture of the two original genotypes. This manipulation also poses a challenge to species integrity and should be prohibited.

The insertion of a non-human gene into a human or vice versa would not be captured by these proposed prohibitions and could legitimately be classified as a controlled activity.

Excessive Reliance on Regulations

As regards the controlled activities, too much is left to the regulations. While I understand the need for flexibility in this fast-paced area (hence, the general preference for regulations over legislation), there are some issues in the area of assisted human reproduction better dealt with in legislation than regulation. Three examples are provided.

(a) Disclosure requirements for a valid informed consent

In the draft legislation, the disclosure requirements for consent are to be specified in the regulations (s. 40(1)(c)). In my view, given the importance of free and informed consent as outlined in the preamble, the need for national uniform standards of disclosure and the option afforded provinces to not be subject to ss. 8-40 of the draft legislation, there would appear to be no good argument against (at a minimum) codifying the currently well-accepted common law in this area.

(b) Grandfathered activities

Section 43 provides that a person without a license carrying out controlled activities may continue to do so “until such time as may be fixed by the regulations.” Instead of having an indefinite period, a limit should be set. For example, it should be specified in the legislation that a license should be obtained within a year of the regulations coming into force. Otherwise, it is within the realm of possibility that those to whom this section refers could successfully lobby to have permanent grandfathering. This possibility should be clearly precluded in the legislation.

(c) National regulatory body

As currently worded, it is possible to read the draft legislation as not creating any kind of national regulatory body, and yet this was clearly contemplated by the drafters. The Overview document states:

A regulatory body, either within Health Canada or external to it, i.e., at arm’s length, would be responsible for overseeing the implementation of the proposed legislation. (p. 9)

Such a body should be broadly representative of all parties interested in assisted human reproduction, transparent in its process and accountable. It should also be flexible and responsive in order to react in a timely and effective way to new developments in the field. (p. 10)

The creation of a national regulatory body should be entrenched in legislation.

Regulatory Body

On my understanding, in addition to providing general feedback on the proposed legislation, this Committee has specifically been tasked by the Minister of Health to provide recommendations on the proposed national regulatory body. Of particular interest is the Committee’s view on whether this regulatory body should be within or external to Health Canada.

I cannot address this specific issue directly, as I do not have a clear enough understanding of the ramifications of the choice. There may be increased accountability with a committee internal to Health Canada, but possibly also increased conflict of interest. In any case, I am sure there are multiple factors to consider. I can assist you in your appointed task, however, by helping you to appreciate some of the problems with the current research ethics review system which underline the need for national oversight.

In Canada, all research involving humans, human remains, cadavers, tissues, biological fluids, embryos or fetuses must be reviewed by Research Ethics Boards (REBs), and at the present time there is no national oversight body. There are significant problems with this review system and, since 1990, there have been different calls for a national committee to review reproductive and/or genetic technologies and research. Most recently, in March of this year, the Canadian Institutes of Health Research (CIHR) recommended that stem cell research be subject to full ethics review, including review at the national level.

The problems with research ethics review in Canada are manifold and include: (i) the absence of a national education and certification program for REB members to ensure that they are adequately trained for the job; (ii) the absence of a national accreditation program for REBs (perhaps with special competence areas); (iii) the failure of REBs to comply with the Tri-Council Policy Statement for Research Involving Humans; (iv) the inability of REBs (that rely on volunteers and are typically under-staffed and under-funded) to monitor the research they approve; (v) the lack of uniformity across the country as regards to what constitutes ethically acceptable/unacceptable research; and (vi) the lack of legislation, regulations or guidelines governing privately-funded research.

In addition to these problems, there are problems specific to the ethics review of complex research on novel genetically-based technologies. These include: (i) the lack of expertise at the REB level because of the highly specialized nature of the research; and (ii) the potential for conflict of interest on the part of qualified REB members who are likely to be closely affiliated with the researchers whose project is under review.

A national oversight committee is recommended in the belief that it will: (i) assure the Canadian public that the research undertaken is of the highest scientific quality and is ethically acceptable (does not violate widely held social values and norms); (ii) provide a greater degree of accountability than currently exists with self-regulation; (iii) ensure that there is a national standard for research that applies to both private and public sector research; and (iv) ensure greater access to appropriate experts with the background and knowledge to review the research and who are completely at arms-length from the proposals.

For these and no doubt other reasons, a number of other countries around the world are recognizing the benefits of national oversight.

A significant problem with the proposed legislation is that it does not expressly create a national regulatory body. As

drafted, nothing requires the Minister or the Governor in Council to establish a national regulatory body.

Provincial Opt-Out Clause

A further problem with the draft legislation concerns the opt-out clause for the provinces. Section 41(1) creates a provincial opt-out clause for ss. 8-40 of the Act provided the Minister agrees that “there are in force...laws of the provinc[ial] equivalent” to ss. 8-11, 18-21 and 23-32.

There are at least two discrete and serious problems with this. First, if a province establishes equivalence with respect to the regulation of controlled activities, they become exempt from the penalty sections for the prohibited activities (e.g., ss. 34, 36-39). Second, the potential for provincial opting-out seriously undermines the possibility of establishing national standards in this area. And yet, this is precisely what is needed and wanted by Canadians.

Additional Comments for Consideration

In addition to the thematic concerns that I have outlined, there are a number of specific problems that need to be addressed. These are briefly summarized below.

Section 4(4), which provides an exception to the prohibition for payment for surrogacy (s. 4(1)), is ambiguous; it potentially allows a lawyer to broker such arrangements.

Section 4(5) prohibits a person from “counsel[ing] or induc[ing] a female to become a surrogate mother...knowing or having reason to believe that the female person is under eighteen years of age”. However, the overview states that “[i]t would be illegal for a woman under 19 years of age to become a surrogate”. This should be consistent, and some justification should be provided regarding the age limit given the existing common law with respect to mature minors.

Section 5(1) prohibits the purchase, barter or exchange of human gametes, as well as the purchase or sale of human embryos. According to the Overview, however, “[s]perm banks and clinics would continue to sell and purchase human gametes.... The practice does not contravene the prohibition since the donation would have already been made and the donor could not make a profit.” (p. 7) Is this approach sufficiently attentive to the risk of exploitation for commercial ends (see preamble) as people are expected to donate reproductive material to sperm banks and clinics, only to have them sell this material to make a profit?

Section 8(1) provides that a license is required to “alter, manipulate or treat any human reproductive material for the purpose of creating an embryo or facilitating human reproduction.” In contrast, s. 8(2) provides that a license is required to “make use of any *in vitro* embryo or part of one for the purpose of research or the prevention, diagnosis or treatment of a disease, injury or disability.” The latter provision should include “any reproductive material” as opposed to an *in vitro* embryo.

Section 18(2) requires that the donor of human reproductive material be “inform[ed]...of the requirements of this Act respecting the retention, use, disclosure and destruction of the health reporting information or the retention, use, provision to other persons and destruction of the human reproductive material, as the case may be.” Section 19(4) stipulates that a licensee may disclose “health reporting information, except information that would identify or permit the identification of any person, to any individual or organization for scientific research or statistical purposes.” This appears to allow for research use of health information without consent. That is, the Act mandates that the donor is informed about this possibility but fails to require consent to that effect. This position is highly controversial and it is not at all clear that it was intentional.

The exception found in s. 19(4) should also be applied to s. 21(1). That is, the Minister’s use of information under s. 21(1) should exclude “information that would identify or permit the identification of any person.”

Section 22(h), which requires disclosure of “the names and addresses of licensees, [and] the names of individuals performing assisted reproduction procedures,” risks making the clinic staff targets of violence, and is accordingly too broad. Disclosure of identifying information should be limited to the licensees and should not include their employees.

Similarly, s.24(2)(a), which allows an inspector to “examine any thing that is relevant to the administration or enforcement of this Act,” may be interpreted in such a way as to capture patients. Again, this is too broad.

Section 29(1) allows “thing[s] seized under this Act,” including embryos, for instance, to be “disposed of” (i.e., destroyed) after 60 days have elapsed. What if patients do not know their reproductive material has been seized and they would not want it disposed of? Should the Minister have the authority to destroy such material without their knowledge or consent?



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1. Health Canada, *Proposals for Legislation Governing Assisted Human Reproduction* (Ottawa: Health Canada, 2001), online: Health Canada <<http://www.hc-sc.gc.ca/english/reproduction/legislation.pdf>> (date accessed: 5 August 2001).
2. Health Canada, *Proposals for Legislation Governing Assisted Human Reproduction: An Overview* (Ottawa: Health Canada, 2001), online: Health Canada <http://www.hc-sc.gc.ca/english/reproduction/repro_over.pdf> (date accessed: 5 August 2001).