HOUSE OF COMMONS
CANADA

ASSISTED HUMAN REPRODUCTION: BUILDING FAMILIES

Standing Committee on Health

Bonnie Brown, M.P.
Chair

December 2001

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THE STANDING COMMITTEE ON HEALTH

has the honour to present its

SECOND REPORT

In accordance with its mandate under Standing Order 108(2), your Committee has considered the draft legislation on assisted human reproduction tabled in the House of Commons on May 3, 2001. After hearing evidence, the Committee has agreed to report to the House as follows.

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CHAIR'S FOREWORD

In May of this year, the Honourable Allan Rock tabled draft legislation on assisted human reproduction in the House of Commons and invited the Standing Committee on Health to "reflect on this draft legislation and to lead a non-partisan dialogue with Canadians on this very important subject." This report represents the Committee's response to that request.

The Committee has attempted to balance its mandate to conduct a consultation with Canadians with the urgent need for legislation consistent with Canadian values. Attempts to address this need over a period of more than ten years have been carefully studied, expert advisers have been diligently consulted, the structure and responsibilities of international regulatory bodies have been considered, representatives of interested groups have been heard, and a large volume of written submissions have been reviewed.

The Committee is convinced that a sound approach to the regulation of reproductive technologies must treat as its first concern the well-being of the resulting children. The health and safety of adults, particularly women who submit to assisted reproductive procedures, must be effectively safeguarded. The potential benefits of research must always take second place to these priorities.

This said, the Committee is conscious of the potential for some of the new technologies to contribute to the alleviation of human suffering. It has attempted to establish a framework within which related medical research can pursue this goal, while respecting the deep desire communicated to the Committee by many Canadians that human embryos and other "reproductive materials" be accorded the respect and dignity which is their due.

This report results from the collaboration of a dedicated team of researchers, Nancy Miller Chenier, Sonya Norris, Monique Hébert, and François Côté. Our clerk, Gary Sokolyk and the Committee editors, interpreters, console operators and others are also deserving of our thanks.

I would particularly like to thank the members of the Committee from all parties whose hard work was so generously given notwithstanding their many other parliamentary responsibilities. Our report reflects the spirit of principled non-partisanship, which characterized this vital study.

SECTION 1: URGENT NEED FOR LEGISLATION

On 3 May 2001, after tabling *Proposals for Legislation Governing Draft Legislation on Assisted Human Reproduction*, Allan Rock, the Minister of Health, asked the Standing Committee on Health to provide recommendations on the draft legislation and in particular, to advise on options for a possible regulatory body that would govern the implementation of the legislation, monitor developments, and recommend future changes. The Minister emphasized to the Committee that the draft legislation covers two things: assisted human reproduction and related research.

Committee members welcomed the challenge of involvement at this formative stage of draft legislation. We saw an opportunity for open, participatory, and thoughtful work on a subject of wide public concern. After listening to the many committed and articulate witnesses involved in areas of assisted human reproduction, we remain convinced that the proposed legislation is fundamental to shaping our future society.

As a Committee, we see our review of the draft legislation as the beginning of a period of increased parliamentary scrutiny. Through our work, we realized the complexity of the issues and the breadth of the legislation. We know that there is a need for more concrete data collection and information dissemination. We feel that the Minister of Health must also address outstanding concerns about economic implications, federal, provincial and territorial coordination, enforcement details and other particulars relevant to the legislation and its regulations. In our report, we have chosen to address issues of key concern to us and to our many witnesses. We urge the Minister to move quickly to address our recommendations and to introduce comprehensive legislation into Parliament on a priority basis.

The Committee recommends that:

RECOMMENDATION 1:

The Minister of Health introduce legislation on assisted human reproduction and related research as a priority.

On hearing the multiple ethical, social, legal, scientific, medical, and other perspectives on this complex issue, we understood the urgent need to establish clear boundaries around efforts to assist human reproduction and to conduct related research. We became more conscious of the tension arising from the potentially conflicting interests between facilitating reproduction and supporting research. Witnesses told us about the many benefits arising from procedures and practices and the potential for more good to

come from ongoing research. They also pointed to the possibilities for harm to individuals and society if current directions were left unchecked by legislation and regulation.

But, most important, the witnesses reminded us that assisted human reproduction is first and foremost about enabling people to have children. We have kept this idea central to our thinking in this report.

SECTION 2: FRAMEWORK FOR LEGISLATION

Previous consultations on reproductive technologies produced frameworks of guiding principles that were ethical or social in nature. The Health Committee also has adopted a framework to guide its assessment of the proposals for legislation on assisted human reproduction and related research. This framework can be used to ensure a consistent approach and to achieve desirable outcomes.

A. Our Priorities

We have established three priorities to be used in appraising the individual components of the draft legislation. These flow from the Committee's view that the primary goal of assisted human reproduction is to build families. Thus, our review focused on the potential effect of the draft legislation for:

(i) **Children** resulting from the assisted human reproduction procedures

The legislation must protect the physical and emotional health as well as the essential dignity of the children who are the intended and desired result of the procedures.

(ii) **Adults** participating in the assisted reproduction procedures

The legislation must protect the adults undergoing the procedures from potential negative physical, social, and emotional effects.

(iii) **Researchers and physicians** who conduct research leading to and emanating from these procedures

The legislation must oversee the experimental aspects of the assisted human reproduction procedures while allowing selected procedures that might alleviate human suffering.

Overall, our thinking is directed by the feeling that children conceived through assisted human reproduction warrant even greater consideration than the adults seeking to build families or the physicians or researchers seeking new knowledge.

In our framework, children who are physically, emotionally, and spiritually healthy are the anticipated and desired endpoint of the activities and procedures. Of the participating adults, while both men and women can experience adverse emotional and financial consequences, women are subjected to the most invasive, and potentially harmful, physical processes. The researchers and physicians seeking new knowledge and applications from the activities, procedures and processes are to proceed only if the general well-being of the directly affected children and adults is paramount.

B. Our Over-Arching Considerations

But we also heard that the major goal of the legislation is to protect the vulnerable from adverse health effects and from exploitation connected to assisted human reproduction. In addition, we were told that where there is a conflict between the ethically unacceptable and the scientifically possible, the ethical view must prevail. To accomplish this, witnesses suggested that we reflect on several considerations in assessing the legislation. We also feel that if these over-arching considerations are applied to these proposals, it will ensure greater consistency in the final legislation:

(i) Respect for human individuality, dignity and integrity;

(ii) Precautionary approach to protect and promote health;

(iii) Non-commodification and non-commercialization;

(iv) Informed choice; and

(v) Accountability and transparency.

(i) Respect for Human Individuality, Dignity and Integrity

Assisted human reproduction is technologically oriented and physically intrusive. With its calculated and deliberate use of human reproductive material and production of human embryos, it impinges on society's sense of the uniqueness, worthiness, and wholeness associated with being human. It raises concerns about the measure of respect and protection that should be afforded to the people who participate, the children produced, and the reproductive materials and embryos containing the potential to mature into full personhood. The Committee agrees that the association of human reproductive material with the genetic, biochemical, and cellular composition of the human species gives it a particular status. It also concurs that there must be a measure of respect and protection for the embryo that is based on its potential for personhood.

(ii) Precautionary Approach to Protect and Promote Human Health

The draft legislation is based largely on the premise that the health and safety of adults, particularly women, undergoing the procedures and children resulting from them must be protected. The Committee feels that a precautionary approach is needed when any activity raises threats of harm to human health. Even where some cause and effect relationships are not fully established scientifically and uncertainty exists, the Committee feels that the burden of proof should be shifted to those who create the risks. We agree with the witnesses who called for greater attention to prevention of infertility and those who argued that, where evidence of the intended benefits is lacking, procedures, treatments or medications should be provided only as part of carefully controlled research, not as standard medical practice. We would like to see more researchers and medical practitioners provide extensive analysis of alternatives to the potentially harmful activities currently associated with assisted human reproduction.

(iii) Non-commodification and Non-commercialization

It is contrary to our thinking to treat human beings or human material as commodities that can be regarded in terms of their economic value rather than their intrinsic worth. In particular, we feel that children can never be objects to be acquired or exchanged. Women and men need to know that their bodies and their reproductive material are not for sale or barter. The Committee does not support any elements of trading, exchanging, buying or selling of human reproductive materials. We are aware that, in recent years, commodification, and in many respects, commercialization, have occurred in the field of assisted human reproduction. We want to ensure that the legislation will prevent the commodification of children, women's bodies, human reproductive material, and reproduction.

(iv) Informed Choice

The Committee agrees that informed choice can lead to either informed refusal or informed consent. We want individuals participating in assisted human reproduction to be able to choose freely on the basis of full information of risks as well as benefits pertaining to medical, legal, ethical, social, or psychological implications. For the resulting children, they must be able to rely on the involved adults. For participating adults, this can mean having full understanding of short-term as well as long-term ramifications including the consequences for others who may be involved. We want to ensure that consent is given freely for all aspects of assisted human reproduction such as treatment, donation, and research. We also want continual assessment of the consent that is given and an acknowledgement that, for most activities, consent may be withdrawn at any time.

(v) Accountability and Transparency

The Committee feels strongly that a high measure of accountability entails an obligation on the part of individuals and organizations to answer for their actions. Thus, individual adults who undertake to produce children through assisted human reproduction have a responsibility to ensure that the future well-being of those children is considered carefully. But, we feel particularly that those in positions of power such as governments and professional organizations have a responsibility to ensure that their actions in this area are always transparent and focused on the overall good of society.

SECTION 3: THE NEED FOR A STATUTORY DECLARATION

The preamble may set out the intent, purpose and spirit of the legislation. It may also set out the guiding principles that underpin the legislation, as well as the aspirations that motivated the legislators. The preamble, however, is primarily an interpretive tool intended to assist in explaining the legislation's purpose and object. As such, it is considered to carry less weight.

Because the legislation before us deals with such fundamental values as human dignity and integrity, the Committee believes that the guiding principles enunciated in the preamble must be given greater legal significance and effect. They must form an integral part of the enactment by being enshrined in a statutory declaration set out in the body of the legislation.

The Committee recommends that:

RECOMMENDATION 2:

The Preamble be replaced by a Statutory Declaration enacted in the body of the legislation.

After careful consideration of the current Preamble and applying our framework, the Committee recommends that:

RECOMMENDATION 3:

The Statutory Declaration set forth the following guiding principles:

It is hereby recognized and declared that:

(a) assisted human reproduction and related research must be governed by principles and practices that respect human individuality, dignity, and integrity;

(b) the health and well-being of the children born from assisted human reproduction must be given priority in decisions regarding assisted human reproduction;

(c) while all participating persons are affected by assisted human reproduction, women more than men are directly and significantly affected by the application of the technologies;

(d) the integrity of the human genome must be protected;

(e) the principle of free and informed choice as a fundamental condition of the use of assisted human reproduction must be promoted and applied;

(f) human reproductive technologies provide benefits to individuals, families, and society in general;

(g) those benefits can be most effectively secured by taking appropriate measures for the protection and promotion of human health, safety, dignity, and rights in the use of such technologies;

(h) persons with disabilities can lead full and satisfying lives and enrich the lives of those around them; and

(i) the commodification of the reproductive capacities of women and men, and the exploitation of children, women and men for commercial ends must not be allowed.

In addition to the Statutory Declaration, it would be desirable if a Purpose Clause were enacted to clearly identify the following objectives of the legislation. The Committee recommends that:

RECOMMENDATION 4:

The Statutory Declaration be supplemented by a Purpose Clause within the body of the legislation, which would state as follows:

The purpose of this legislation is to provide a national legislative framework for assisted human reproduction and the conduct of research using human reproductive material. It is to ensure in particular that:

(a) the interests of the children born from assisted human reproduction procedures are protected and given paramount consideration;

(b) the interests of the adults participating in assisted human reproduction procedures be protected and their participation is based on informed choice; and

(c) the interests of researchers and physicians are supported to the extent that they do not compromise the interests of the children and adults.

SECTION 4: PROHIBITED AND CONTROLLED ACTIVITIES

Under the legislative proposals, the activities and procedures related to assisted human reproduction and related research are classified under two broad categories:

(i) Prohibited activities that are specifically banned in the legislation itself; and

(ii) Controlled activities that may be carried out only under a licence issued in accordance with the regulations.

If the regulations specify that no licences may be issued for a particular controlled activity, that activity becomes, for all intents and purposes a prohibited activity. The prohibition in this case, however, stems from the regulations rather than the statute.

Both prohibited activities and controlled activities are based on the federal criminal law power. One of the main differences between the two categories is that a prohibited activity could be changed or repealed only through a legislative amendment passed by Parliament. A controlled activity (including any regulatory prohibition that was created through the non-licensing of a particular activity) could in turn be changed or repealed by the usual process for amending the regulations, through public consultation.

Some witnesses recommended the elimination of the prohibited activities category altogether. Citing the benefits of regulatory flexibility, they felt that all activities should come under the controlled activity category, including the more reprehensible activities like reproductive cloning for which licences, arguably, would never be allowed under the regulations.

Although prohibitions could be indirectly implemented under the controlled activities categories by simply making licences unavailable in their case, the Committee believes that a licence-related prohibition of this sort would not carry the same weight or degree of social censure as the statutory prohibition. This is reflected in the penalty clauses in the legislative proposals which prescribe maximum penalties for offences involving a prohibited activity that are roughly twice as severe as those prescribed for controlled activity violations.

We believe that there is considerable justification for retaining the prohibited activities category. An outright statutory ban signals more clearly that certain activities are either unsafe or socially unacceptable. The use of the statutory ban also signals that these activities are of such concern to Canadians that their status as a prohibited activity may not be altered except with the approval of Parliament.

The Committee recommends that:

RECOMMENDATION 5:

The prohibited activities currently set out in the draft legislation be retained and enacted as prohibited activities in the new legislation, subject to the additional modifications reflected in the following recommendations.

SECTION 5: STATUTORY PROHIBITIONS

Using our framework, we remain firmly convinced that the prohibited activities listed in the draft legislation warrant statutory status. In terms of activities that are to be banned due to health and safety considerations the Committee is satisfied that a three-year legislative review, as recommended in a later section, is sufficient means by which to re-evaluate their prohibited status.

(i) Cloning for Reproductive and "Therapeutic" Purposes

The Committee feels strongly that the potential adverse effects, whether physical, psychological or social, for the resulting children are sufficient reason to prohibit reproductive cloning. In addition, "therapeutic cloning" should be banned as it is unsafe and commodifies the embryo.

(ii) Germ-line Genetic Alteration

The Committee heard that germ-line genetic alteration is both unsafe and impractical at this time as well as having unknown consequences for subsequent generations. The Committee acknowledges that the intention of germ-line genetic alteration is to affect patterns of genetically based diseases. However, it agrees with the draft legislation that this should also be banned by statute.

(iii) Maintenance of an Embryo Outside a Woman's Body

The Committee sees serious social harm in eliminating the role of women in reproduction. The role of a woman in carrying and giving birth to a child is indispensable. Moreover, such a process could cause serious harm to any resulting child. The Committee agrees that it should be prohibited.

(iv) Creation of Embryos Solely for Research Purposes

The Committee agrees that embryo creation should be prohibited when the sole purpose of creating the embryo is to provide material for research. However, the prohibition as stated in the draft legislation does not accurately reflect its intent. The Committee is concerned that the current wording would also prohibit research that aims to improve gamete storage and maturation procedures.

Therefore the Committee recommends that:

RECOMMENDATION 6:

Clause 3(1)(*d*) be reworded to reflect more accurately its intention to prohibit the creation of embryos on which research is to be carried out.

(v) Embryo Creation from an Embryo or Fetus

The goal of this prohibition is to protect against the creation of children whose genetic parents never lived as individuals. The Committee finds that the wording of this prohibition is very awkward and unclear as to what activity is to be banned.

The Committee recommends that:

RECOMMENDATION 7:

The prohibition in clause 3(1)(*e*) simply state that gametes cannot be removed from embryos or fetuses for the purpose of creating an embryo.

(vi) Transplantation of Animal Reproductive Material into a Human

The Committee concurs that such activities not only have the potential to produce harm for participating adults but they also violate human dignity. In addition, they clearly are not needed to produce a healthy child.

To be fully consistent, the Committee recommends that:

RECOMMENDATION 8:

An additional prohibition be included that bans the creation and use of all animal/human hybrids for the purpose of reproduction.

(vii) Use of Human Reproductive Material Previously Transplanted into an Animal

On the grounds of human safety and of human dignity, such an activity constitutes a concern for children and for women. The Committee agrees with the draft legislation in prohibiting it.

(viii) Sex Selection Except for Health Reasons

The Committee is in agreement with the concept in the draft legislation that sex selection should be a prohibited practice. We are concerned, however, that the stated prohibition does not include sex selection through genetic pre-implantation diagnosis of embryos. It only addresses such procedures as gamete manipulation and modification of fertilization techniques that would increase the probability of obtaining an embryo of one sex or the other.

Therefore the Committee recommends that:

RECOMMENDATION 9:

Clause 3(1)(*h*) specifically prohibit all sex selection with the noted exception of disorders linked to the sex chromosomes as defined in the regulations.

(ix) Surrogacy

The overall well-being of children is compromised by deliberately producing children through assisted human reproduction, who may be uncertain about their origins. Commercial surrogacy treats children as objects and treats the reproductive capacity of women as an economic activity. Non-commercial (altruistic) surrogacy arrangements can also be socially harmful for the resulting child and place the health of women at risk.

The Committee agrees with the prohibition on surrogacy for commercial gain and also feels that surrogacy for non-commercial reasons should be discouraged but not criminalized.

There should be a prohibition against any form of consideration, incentive or compensation, financial or otherwise, being offered or provided to any party involved, directly or indirectly, in any surrogacy arrangement. This must include those parties who provide professional medical, legal, and psychological services.

Therefore, to minimize the commodification of the surrogate mother and resulting child, the Committee recommends that:

RECOMMENDATION 10:

Clauses 4(4) that excepts legal, medical, and psychological services and 10(*d*) that allows reimbursement of expenses to a surrogate mother be eliminated.

However, in order to protect the health of the surrogate mother and of any resulting child in any surrogacy arrangement, we further recommend that:

RECOMMENDATION 11:

An exception be created for physicians and other health care professionals who provide services necessary for the care of the pregnant woman.

If non-commercial surrogacy is to occur, the well-being of the resulting child and the fully informed choice of the participating surrogate mother should be ensured through several mechanisms. Counselling for all parties must be provided with respect to non-commercial surrogacy. Physicians donating services to facilitate non-commercial surrogacy must take responsibility to ensure that all parties have access to social as well as medical counselling. Individuals who aspire to add a child to their family through surrogacy must be subject to the same scrutiny as individuals who seek to adopt a child.

Thus, the Committee recommends that:

RECOMMENDATION 12:

The provinces and territories be encouraged to provide mandatory counselling to the commissioning couple, surrogate mother and partner through existing publicly funded services available for adoption and to amend relevant family law to recognize the birth mother as the legal mother.

(x) Purchase of Gametes and Embryos

The Committee feels strongly that the commodification and commercialization of human gametes and human embryos can have far-reaching social and emotional effects for any resulting families. But, in addition, such activities are contrary to Canadian practice whereby human organs and tissues are not sold or purchased. The purchase, barter or exchange of human gametes and embryos is contrary to human dignity. The Committee agrees with the prohibition on the sale and purchase of gametes and embryos. We are also opposed to any reimbursement of a donor for any expenses incurred in the course of donating any sperm, ovum or embryo. The Committee further recommends that:

RECOMMENDATION 13:

Clause 10(*a*) that permits reimbursement of a donor for expenses incurred in the course of donating any sperm or ovum be eliminated.

(xi) Use of Reproductive Materials and Embryos without Consent

Without full and informed consent for any controlled activity, participating adults could face unknown long-term harm. Consent must be freely given and be based on full understanding of the implications of providing one's personal reproductive material for use by others. The Committee strongly supports this prohibition on the use of reproductive materials and embryos without consent.

SECTION 6: CONTROLLED ACTIVITIES

In the draft legislation, controlled activities may be carried out only under a licence issued in accordance with the regulations. We look forward to the opportunity to review any proposed regulations when they are laid before the House of Commons. We have already recommended changes against reimbursement of expenses for donations and surrogate mothers. We also want to place some specific limits on embryo research.

The Committee wants to emphasize that the gains to be made in new scientific knowledge and medical applications should proceed only if any benefit for society does no harm to the resulting children and participating adults. We particularly want to stress that, while science has tremendous potential for good, its applications can have the capability for negative effects on the diversity of the human population. We do not want to support any public policy, scientific research or medical practices that seek to use knowledge of hereditary or genetic characteristics to change the intrinsic characteristics of the human population. As stated earlier, the activities permitted by this legislation must recognize the importance of preserving and protecting human individuality and the integrity of the human genome.

(i) Embryo Research: The Current Situation

The Committee heard that embryo research currently could include: research on embryos that already exist as a result of in vitro fertilization (IVF); research that creates embryos as a result of research; and the creation of embryos specifically for research purposes. Generally, research on existing embryos is used to study areas such as fertilization, drug interactions and development. Other research such as perfecting storage techniques for ova could involve the creation of embryos. More recently, stem cell research using embryos as a source has been seen as having potential for the treatment of several ailments and injuries.

We are concerned that there is a lack of clarity about what is currently taking place in Canada in relation to research that uses existing embryos or research that creates embryos. Rationales for research on embryos up to 14 days include efforts to improve infertility treatments such as IVF, increased knowledge of genetic diseases, and improved conception. This type of research work was noted at the time of the Royal Commission on New Reproductive Technologies. Currently, research in the private sector is not required to report to any authority and is able to operate outside of the Canadian Institutes for Health Research guidelines for embryo research. The Committee would like this situation to be corrected.

(ii) Embryo Research: Our Process

In our deliberations over these issues, we applied the framework laid out in the introduction. We had to decide whether disallowing all types of research involving embryos, or restricting it in some way, would adversely affect the health and well-being of the children born of assisted human reproduction, or of the women seeking the technologies. Similarly the Committee had to consider how the condition of the embryos intended for but not used in IVF procedures fit within our other considerations.

On the issue of precautionary measures to protect and promote health, we heard about the potential health advantages that accrue from embryo research. On non-commodification, we heard that there is a potential for commodification and commercialization of women in producing the necessary eggs and embryos that can be traded and exchanged as a source of reproductive material. On informed choice, we were told that women who produced the eggs were seldom fully informed about the need to give consent for additional embryos to be used for research. Some witnesses expressed concerns that the embryo has no part in any consent process. On respect for human individuality, dignity and integrity, we were told that any research on embryos must value their status as having potential for full human personhood. On accountability, we heard that any activity in this area must be transparent and open to public scrutiny.

(iii) Embryo Research: Our Views

We agree with the draft legislation that embryo research should be a controlled activity. It should, however, be strictly regulated and limited to using only embryos created but not used for IVF subject to the consent of their donors.

We recognize that the research and medical communities have a responsibility to properly validate fertility techniques. This research does in some instances require the use of existing embryos and can result in the creation of an embryo in other instances. Such research may be necessary to ensure the health of any resulting children as well as the health of the women being treated.

We heard that while embryonic stem cell research presents some possibilities, other sources such as umbilical cord blood and adult source stem cells are more available, more easily obtainable, and less ethically contentious. Some witnesses argued that research on stem cells using sources other than embryos might be sufficient to attain the stem cell potential. Others pointed out that, although use of adult stem cells is the preference for most researchers, the use of embryonic stem cells at this time might provide the information needed to properly manipulate adult stem cells.

The Committee was struck by testimony that, in the past year, there have been tremendous gains in adult stem research in humans. We also heard that, after many years of embryo stem cell research with animal models, the results have not provided the expected advances. Therefore, we want to encourage research funding in the area of adult stem cells.

We are concerned that embryonic stem cell research commodifies the embryo. It involves research that uses embryos to obtain further research material. We believe that licences for the conduct of all research on embryos should be issued only after a clear demonstration that non-embryonic sources would not achieve the sought after research outcomes.

Therefore, the Committee recommends that:

RECOMMENDATION 14:

Research using embryos be a controlled activity requiring a licence. Even if all other regulatory criteria are met, no licence may be issued unless the applicant clearly demonstrates that no other category of biological material could be used for the purposes of the proposed research.

SECTION 7: THE REGULATIONS

Clause 40 of the draft legislation sets out the matters for which regulations could be made under the legislation. Notably, regulations could be made designating classes of controlled activities for which licences could be issued or withheld. Regulations could also be made to determine the conduct of any class of controlled activity, as well as the terms and conditions under which licences might be issued. These provisions are key because they authorize the development of standards that will regulate the manner in which controlled activities must be carried out.

(i) Regulations in Relation to Selected Matters

Evidence presented to the Committee suggests that the health of women involved in assisted human reproduction is not always paramount. Ovaries may be over-stimulated through excessive fertility drug therapy. Eggs may be harvested from women too

immature to appreciate the full implications of their involvement. Too many in vitro embryos may be produced and too many of them may be transferred into the womb.

The Committee is particularly concerned about the excess number of embryos that may be produced and stored, allegedly for reproductive purposes. We appreciate that, until egg-storage techniques are perfected, an excess number of embryos may have to be produced. However, we expect this practice to cease once the storage technology has been validated. At that time, it will be possible to limit the number of embryos produced to those actually used for implantation.

In keeping with our framework to protect children and participating adults, the Committee feels that it is essential that specific requirements and restrictions be prescribed in the regulations to guard against abuses and exploitation.

The Committee recommends that:

RECOMMENDATION 15:

Regulated standards be developed in relation to the following matters:

- **(a) The maximum number of eggs that may be harvested and fertilized;**
- **(b) The maximum number of embryos that may be produced, stored, and transferred for in vitro fertilization procedures, although a prohibition on the production and storage of excess embryos should be prescribed once egg-storage techniques have been perfected and validated;**
- **(c) The maximum number of times a patient should be offered a given procedure;**
- **(d) The counselling that must be provided to donors and recipients of treatment;**
- **(e) The maximum number of children that may be produced from a single gamete donor;**
- **(f) Eligibility requirements for donors and recipients; and**
- **(g) The known pre-existing heritable genetic diseases or conditions in relation to which pre-implantation genetic diagnosis would be allowed.**

(ii) The Exemption in Clause 40(1)(*m*)

Several witnesses questioned the propriety of allowing regulations to be developed under clause 40(1)(*m*) of the draft legislation. This clause allows regulations to be made

that would essentially exempt a class or classes of controlled activity from the application of the legislation or regulations.

The Committee joins the witnesses in believing that subordinate legislation, namely the regulations, should not be able to override the provisions of the statute. If there is a need to create exemptions, these should be enacted through legislative amendments subject to full parliamentary scrutiny.

The Committee recommends that:

RECOMMENDATION 16:

Clause 40(1)(*m*), which allows regulations to be made to exempt a class or classes of controlled activities from the application of the legislation or regulations, be eliminated.

(iii) The Exemption in Clause 43

Clause 43 would exempt from the licensing requirements any person engaged in a controlled activity commenced before the cut-off date (the date on which the controlled activity clauses come into force) until such time as was prescribed by the regulations.

The Committee notes that this vaguely worded clause is capable of at least two different interpretations. The first is that, on the cut-off date, the requisite regulations would not be ready. Consequently, any pre-existing activities carried out lawfully could not be licensed on the cut-off date. They would thus become controlled activities carried out unlawfully, unless they were exempted under the regulations.

The second interpretation is that the requisite regulations would be in place on the cut-off date, thus allowing licences to be issued immediately for that particular activity. However, a given party or parties would be exempt under the regulations from complying with the licensing requirements, possibly because they needed more time to adjust to the regulated standards.

Whichever interpretation applies, we find this clause to be objectionable. It is too open-ended and could lead to abuses. It could also lead to a flurry of activities being undertaken just before the cut-off date in order to defer compliance with the regulated standards for as long as possible.

The Committee appreciates that a transitional period might be needed to develop the requisite regulations or to enable some parties to make the necessary adjustments in order to comply with the regulated standards. The exemption, however, should be of a reasonably short duration. We recommend a maximum period of one year. One year should be sufficient for the relevant action to be taken.

The Committee recommends that:

RECOMMENDATION 17:

Clause 43 be modified to provide a maximum one-year expiry date for the licensing exemption.

(iv) The Governor in Council's Regulation-making Power

The Committee is also concerned about the broad and largely unfettered regulation-making power of the Governor in Council. We believe that some form of direct parliamentary oversight is needed, along the lines of section 42.1 of the federal *Tobacco Act. (see Appendix A)*

The *Tobacco Act* section requires that regulations proposed under that Act be laid before the House of Commons for possible study by the appropriate House committee — presumed to be the Health Committee. If the House concurs with the committee's report, the Governor in Council is limited to making regulations in the form that was concurred in, including any changes that were recommended. Conversely, if the House disagrees with the committee's report, the Governor in Council may proceed to promulgate the regulations, as originally proposed.

Given that assisted human reproduction and related research is such a highly sensitive and controversial area, we strongly feel that a parliamentary safeguard of this nature is necessary. Elected representatives should have the opportunity to shape essential regulations to ensure that they reflect the best interest of Canadians.

The Committee recommends that:

RECOMMENDATION 18:

Provisions similar to section 42.1 of the federal *Tobacco Act* be included in the new Act to require that all proposed regulations be laid before the House of Commons for approval or modification within 30 sitting days. Provision should also be made requiring the proposed regulations to be referred specifically to the House of Commons Standing Committee on Health.

SECTION 8: HEALTH INFORMATION

The collection and maintenance of registries aim to facilitate surveillance in the area of assisted human reproduction. In the draft legislation, health reporting information is defined as information respecting the:

(a) identity, personal characteristics, genetic information and medical history of:

(i) donors of human reproductive material including sperm, eggs and embryos;

(ii) persons who have undergone assisted reproduction procedures including infertility drugs, assisted insemination, and in vitro fertilization;

(iii) persons who were conceived by means of such procedures;

(b) custody of donated human reproductive materials and any uses that are made of them.

(i) Personal Health Information Registry

The Committee heard that the information collected through the personal health information registry proposed in clause 21(2) of the draft legislation is intended to serve several purposes:

(i) Assessment of short and long-term health outcomes for the children resulting from the procedures;

(ii) Assessment of health effects for the women who undergo the procedures;

(iii) Ongoing information on assisted human reproduction services, drugs and procedures including the outcomes and success rates;

(iv) Access by genetic offspring from sperm, egg or embryo donation to non-identifying donor information;

(v) Provision of research data for understanding the physical and emotional outcomes on persons involved with or resulting from assisted human reproduction processes.

We agree with the establishment of the proposed personal health information registry in clause 21(2), but would like to see it given more prominence at the beginning of the section currently called *Privacy and Information*. We want this information to be collected on a national basis. We feel that this registry can be a positive contribution to our desire to ensure respect for human individuality, dignity and integrity, precautionary measures to protect and promote health, non-commodification, informed choice and accountability and transparency.

We were surprised to learn that Canadians do not yet have ready access to data about assisted human reproduction. Although we were told that medical practitioners have been trying for ten years to develop a voluntary registry, we received neither concrete evidence of a registry nor specific data from a registry. We heard that few sperm banks in Canada keep detailed information about donors and the uses of the donated sperm and we heard nothing about egg or embryo donations.

The Committee wants more than voluntary efforts by the medical professionals. We want mandatory reporting, collection and analysis of data. We want consistent and clear facts on the: clinics offering all or some procedures related to assisted human reproduction; general practitioners offering drugs and assisted insemination; sperm, egg or embryo banks and donors; recipients of assisted insemination, egg donation or embryo donation; etc. Without this information, we have no conclusive evidence for supporting the further development of assisted human reproduction.

(ii) Open System for Donation

In particular, the Committee was told that registries with donor information are important to offspring resulting from donor treatment procedures; descendents of offspring; couples who had a child through donation procedure; donors who provided sperm, eggs, or embryos; relatives of the people; and genetic siblings of offspring resulting from procedures.

We were particularly moved by the arguments for an open donation system that would not treat children as commodities to be negotiated among participating adults such as parents, donors, and physicians. We agree that the children who result from gamete and embryo donation should receive equivalent respect to those who are adopted. Like adoption, we want a donation system that is regulated, non-commercial, and transparent. We aim for a system whereby donation records are securely controlled but accessible to those who need relevant information. We also believe that children who are born from surrogacy arrangements should have access to full information.

In moving to an open system that eliminates secrecy, the Committee would like to see a strategy that combines legislation and education, focusing particularly on physicians and others who facilitate the process of donation. We want to ensure that before any donation takes place, the prospective donor is fully informed of the implications of assisted human reproduction, especially of having an offspring. We believe that only donors who consent to have identifying information released to offspring should be accepted. We feel that, where there is a conflict between the privacy rights of a donor and the rights of a resulting child to know its heritage, the rights of the child should prevail. We need a system of responsible donation and greater public awareness. We want to end the current system of anonymous donation.

As a Committee, we recommend that:

RECOMMENDATION 19:

(a) Consent to the release of identifying information be mandatory before accepting an individual as a sperm, egg, or embryo donor;

(b) All donor offspring (or legal guardians) have access to their regularly updated medical histories;

(c) The number of babies born through the same donor be limited;

(d) The number of donations from the same donor be limited;

(e) Connections between genetic siblings are to be facilitated to avoid possibilities of sexual relations or marriage; and

(f) Medical and personal records be maintained;

(g) Mandatory counselling be provided for donors before a choice to donate is made and before an offspring establishes a link with a donor;

(h) No legal responsibilities respecting offspring, financial or otherwise, should arise out of a donation.

The Committee heard that several provinces (Newfoundland, Nova Scotia, and Quebec) and one territory (Yukon) have already enacted laws that specifically or implicitly exclude donors as the legal parent of a child, thereby eliminating them as a possible source of financial support for the offspring.

To encourage this type of legislation in other provinces and territories, the Committee recommends that:

RECOMMENDATION 20:

The federal Minister of Justice, in collaboration with provincial and territorial counterparts, seek to develop uniform legislation across the country establishing the legal status of donors in relation to offspring.

SECTION 9: EQUIVALENCY AND ENFORCEMENT AGREEMENTS

Clause 41 of the draft legislation authorizes equivalency agreements to be signed with the provinces and territories. Such agreements may be entered into if a province or territory has enacted laws that are equivalent to selected clauses and corresponding regulations, namely: clauses 8 to 11 (controlled activities), clauses 18 to 21 (health reporting information) and clauses 23 to 32 (inspection and enforcement). Once in place, an equivalency agreement suspends the application of clauses 8 to 40 of the federal

legislation. Instead, the “equivalent” measures enacted at the provincial or territorial level apply.

The Committee heard widespread unease about clause 41. Some witnesses were concerned that the provinces and territories would not be required to establish a public information registry because clause 22 is not among the selected clauses for which equivalent measures would have to be enacted. Others were worried that equivalency agreements would not have to incorporate equivalent penalty provisions to those set out in the federal legislation. Still others were apprehensive that equivalency agreements would undermine the establishment of a strong, national regulatory regime for assisted human reproduction and related research.

The Committee shares these concerns. *Equivalent* measures are clearly not *identical* measures. There is room for interpretation and therefore the potential for different systems to be enacted from one jurisdiction to the next. A patchwork might result. In our opinion, it would be in the best interest of the resulting children, as well as the men and women participating in assisted human reproduction, if a single regulatory regime encompassing one set of standards and one set of penalties, was in effect across the country, with no exceptions.

We recognize, however, that assisted human reproduction and related research is an area of shared responsibility. The provinces and territories may also want to take action. Equivalency agreements would enable them to do so. Even though the Committee has serious reservations about equivalency agreements, we accept that these agreements may be a necessary tool in the advancement of cooperative federalism.

In addition to equivalency agreements, it would be possible for the Minister, under clause 33, to sign enforcement agreements with provincial/territorial governments, law enforcement agencies and non-governmental organizations.

The Committee also has misgivings about this type of agreement. We are particularly concerned that such agreements might be signed with non-governmental organizations. In our opinion, the law enforcement powers of the state should not be delegated to non-governmental bodies.

Given the specialized nature of the inspections that would have to be carried out, as well as the high degree of technical expertise that would be required, it would be preferable, in our opinion, if a single, specialized inspection body were put in place to inspect and enforce the legislation. A single inspection body would best ensure that the legislation was being applied evenly across the country. We question whether consistency could be ensured if more than one inspection body was involved.

Both enforcement and equivalency agreements are of concern to us. Although we are not prepared to recommend that they be precluded, we agree with witnesses that a number of safeguards must be put in place to ensure accountability and transparency.

The Committee therefore recommends that:

RECOMMENDATION 21:

Enforcement agreements not be allowed to be entered into with a non-governmental organization.

The Committee further recommends that:

RECOMMENDATION 22:

Both equivalency and enforcement agreements be subject to the following safeguards:

- **(a) The Minister must be accountable to Parliament for all equivalency and enforcement agreements;**
- **(b) The public must be actively consulted on the draft agreements before they are finalized;**
- **(c) The draft agreements, together with a summary of the comments made by the public, must be tabled in the House of Commons before they are finalized to give elected representatives the opportunity to make recommendations in relation to them;**
- **(d) The text of all finalized agreements must be included in the public information registry established under the Act;**
- **(e) All agreements be subject to termination or revocation upon reasonable notice being given by either party;**
- **(f) The Minister must be empowered to intervene under a savings clause that would enable him or her to take any action deemed necessary for the administration and enforcement of the Act;**
- **(g) All agreements be subject to a maximum five-year sunset clause, with the possibility of renewal for further maximum five-year periods in appropriate cases; and**
- **(h) As a condition precedent to the signing of an agreement, the other government must agree to comply with the same reporting requirements that apply at the federal level. The other government must also agree to transmit the related data to the regulatory body for inclusion in the federal personal health information registry and the public information registry.**

SECTION 10: REGULATORY BODY

According to the draft legislation, the Minister of Health, aided by his Department, would be responsible for implementing the legislation. Given the many moral, ethical and social questions surrounding human embryo research and infertility treatment, most witnesses felt that an arm's length agency would be more appropriate. Some witnesses also felt that an outside agency would be better able to provide timely responses in such a rapidly changing technological field.

While there was broad consensus for the creation of a regulatory body outside the Department, the Committee heard differing views on the regulatory body's structure and mandate. There was also disagreement on whether the regulatory body should report directly to Parliament or whether it should report to Parliament through the Minister of Health. We endorse the creation of an outside agency to manage and oversee the operation of the Act. Such an agency should be a semi-independent body, directed by a Board that reports directly to the Minister of Health, and with mechanisms that ensure accountability to Parliament.

The Committee recommends that:

RECOMMENDATION 23:

A regulatory body be created outside the Department of Health to manage and oversee the operation of the Act. The regulatory body should be a semi-independent agency, directed by a Board that reports directly to the Minister of Health, and with mechanisms that ensure accountability to Parliament.

In our opinion, requiring the agency to report to the Minister is more in keeping with the principle of ministerial accountability. The Minister's involvement is also desirable in terms of intergovernmental relations given that the provinces and territories share constitutional authority to take action in this area.

In devising a regulatory framework for assisted human reproduction, we were asked to consider a "checks and balances" approach. Under this approach, the Minister would be responsible for establishing general policies and standards relating to the safety and efficacy of reproductive and genetic technologies allowed in Canada. The Minister would also be responsible for auditing and assessing the effectiveness of the inspection and enforcement activities of the regulatory body to ensure compliance with health and safety standards. The Minister, however, would not participate in the day-to-day operations of the agency.

The Committee supports this approach as it provides a workable compromise between ministerial accountability, on the one hand, and an autonomous, arm's length agency, on the other.

The Committee recommends that:

RECOMMENDATION 24:

The Minister under the legislation be responsible for:

(a) reproductive and genetic technology policies for the Government of Canada;

(b) the overall direction of the regulatory body;

(c) the negotiation of equivalency agreements and enforcement agreements; and

(d) the assessment of the regulatory body's effectiveness.

The role of the regulatory body, in turn, should consist of monitoring relevant domestic and international developments in order to make recommendations to the Minister about changes required to the legislation, regulations, and policies. It should be responsible for issuing, renewing, amending, suspending or revoking licences to qualified applicants regarding approved treatments and research. It should ensure compliance with the Act, either through its own "in-house" inspection staff or through some other entity deemed acceptable as a substitute under an enforcement agreement.

In addition, the regulatory body should be responsible for maintaining the personal health information registry, as well as the public information registry. Notably, it should keep track of the children born of assisted human reproduction and, to the extent possible, update the information collected on donors and offspring. In addition, in order to ensure that sound science is applied, the regulatory body should report on the outcomes of the treatments that were provided and the research that was carried out.

The regulatory body should also assume a strong information and communications role. In this regard, it should engage in ongoing consultations with interested parties. It should also provide the individuals involved in assisted human reproduction with complete information to enable informed choices.

In addition to its day-to-day operations, the regulatory body should be accountable to Parliament and the public through a combination of mechanisms including the following:

(i) Annual report to Parliament;

(ii) Audit by the Office of the Auditor General of Canada;

(iii) Strategic plan every three years for approval by Parliament as well as the Minister;

(iv) Public hearings on licensing matters and specific issues of concern;

(v) Reporting of activities in the public information registry;

(vi) Ministerial review of the effectiveness of the regulatory body; and

(vii) Scrutiny by the House of Commons and the Standing Committee on Health of proposed regulations before implementation by the regulatory body.

In order to ensure that the regulatory body carries out its functions in a manner that is faithful, and gives effect, to the core values of the legislation, the Committee strongly believes that the principles enshrined in the Statutory Declaration should be explicitly set out in the regulatory body's mandate. The regulatory body should also be required to develop a Code of Ethics based on these principles that would inform Canadians about the way in which it proposes to exercise its powers.

The Committee recommends that:

RECOMMENDATION 25:

The regulatory body be given a statutory base. Its functions should include:

(a) monitoring Canadian and international developments in order to make recommendations to the Minister about changes that should be made to the legislation, regulations, and policies;

(b) issuing, amending, renewing, suspending or revoking licences for qualified applicants with respect to approved treatments and research;

(c) ensuring compliance with the Act through inspection and enforcement;

(d) maintaining the public information registry, as well as the personal health information registry, including information on the number of children born from assisted human reproduction and updates on offspring and donor information;

(e) reporting to the public on the outcomes of the treatments provided and the research carried out;

(f) engaging in regular, ongoing consultations with interested parties;

(g) providing complete information to enable Canadians to make informed choices.

The Committee also recommends that:

RECOMMENDATION 26:

The principles enshrined in the Statutory Declaration be explicitly set out in the regulatory body's mandate and the regulatory body should be required to develop a Code of Ethics based on these principles. The regulatory body must also table an annual report in Parliament and prepare a strategic plan every three years for the approval of the Minister and Parliament.

With respect to the composition of the regulatory body, we recognize that there are two distinct regulatory areas suggested in the draft legislation; on the one hand, assisted reproduction treatments and on the other, research involving embryos, eggs, and sperm. We acknowledge that the expertise required to issue a licence respecting assisted human reproduction is quite different from that required to license embryonic research unrelated to the treatment of infertility. Although this could eventually lead to the creation of two distinct bodies to regulate these two materially different fields of assisted human reproduction and research involving human subjects and human tissue, we want no further delays in relation to the enactment of this much-needed legislative framework. We want legislation tabled immediately to establish appropriate boundaries around ongoing activities. In the short term, we believe that our proposed regulatory board can deal with the separate fields.

After careful consideration of the various options presented to us, the Committee largely supports a regulatory body governed by a Board of about nine members who are chosen for their wisdom, judgment, and ability to comprehend the multiple dimensions of assisted human reproduction and related research. This Board composed of broad thinkers with diverse life experiences should be supported by multiple panels or advisory committees representative of persons drawn from a variety of academic disciplines and community perspectives.

To maintain the Board arm's length status, none of its members should be drawn from government or represent any specific interests. In particular, members should not be in any financial conflict of interest. Since women are affected more directly by the reproductive therapies than men, the Committee believes that a majority of the Board should consist of women.

After consultation with provincial and territorial governments, stakeholders, and the House of Commons Health Committee, Board members should be appointed by the Governor in Council. They should serve for a three year renewable term and the initial appointments must be staggered to ensure rotation and gradual replacement of the knowledge base.

The Committee recommends that:

RECOMMENDATION 27:

(a) The Board consist of about nine members to be appointed by the Governor in Council, after consultation with provincial and territorial governments, stakeholders, and the House of Commons Health Committee;

(b) Board members be chosen for their wisdom, judgment, and ability to comprehend the multiple dimensions of assisted human reproduction and related research;

(c) Board members not represent or have any ties with specific interests nor have a financial conflict of interest;

(d) There be no government representation on the Board;

(e) Women comprise at least half of the Board's membership;

(f) Board members serve for staggered terms of three years, which could be renewed twice.

A Secretariat, headed by a Chief Executive Officer and staffed by individuals with expertise in such areas as medical and health policy, regulatory affairs, etc. should be established to assist the Board in achieving its policy and administrative objectives. In addition, the Board should be authorized to create expert panels or advisory committees to advise it and to study special issues and developments. Notably, these panels or advisory committees should be established to provide advice and make recommendations to the Board on the two broad regulated areas, namely, reproductive therapy and research.

The Committee recommends that:

RECOMMENDATION 28:

A Secretariat, headed by a Chief Executive Officer and staffed by individuals with expertise or experience in a variety of relevant fields, be established in the legislation to assist the Board in its policy and administrative objectives.

The Board be authorized to establish expert panels or advisory committees to advise the Board and to study special issues and developments.

The panels include persons with perspectives of those with disabilities, those who are infertile, those who are members of racial minorities, those from the faith communities as well as those with a broad range of expertise, including reproductive medicine, health research, ethics, social sciences, and law.

One of the Board's more immediate tasks will be its licensing function. In our opinion, the licensing hearings should be public. Some hearings will obviously be more routine than others, but we believe that it is important to give the public an opportunity to be heard.

The Committee also believes that the Board should have the authority to hold public hearings on specific issues of concern. By providing a public forum for debate on possibly contentious subjects, the Board will enable Canadians to participate more fully in the formulation of policy. The Board will also benefit from the public debate and will be in a better position to make recommendations to the Minister.

The Committee recommends that:

RECOMMENDATION 29:

The licensing hearings be held in public.

The Board be authorized to hold public hearings on specific issues of concern.

We feel that the actions of the regulatory body, as well as those of the Minister, should be as transparent as possible. The public information registry proposed in clause 22 of the draft legislation is a step in the right direction in requiring information prescribed by regulations such as licences issued, applied for, and renewed; decisions on licensing and enforcement; aggregated outcomes of procedures performed by licencees, and so on. However, to keep the public more fully informed, we believe that all of the Board's activities should be reported in the public information registry, except for those explicitly exempted in the legislation.

The Committee recommends that:

RECOMMENDATION 30:

All of the Board's activities be reported in the public information registry unless specifically excluded in the legislation.

Finally, many witnesses emphasized the need to provide adequate funding to the regulatory body to enable it to do the job at hand. The Committee agrees. We want the regulatory body to be given a separate, adequate budget to cover its activities. We do not want the process of regulating assisted human reproduction and related research to be influenced by cost-recovery considerations. We believe, therefore, that the regulatory body should not be made subject to the current federal cost-recovery policy.

The Committee recommends that:

RECOMMENDATION 31:

The federal government, under separate appropriations voted by Parliament, adequately fund the regulatory body.

The regulatory body not be subject to the federal government's cost recovery policy.

SECTION 11: PARLIAMENTARY REVIEW CLAUSE

Clause 42 in the proposed legislation calls for a five-year parliamentary review of the legislation. The Committee believes this proposed five-year term is too long.

Once the legislation is adopted by Parliament, regulations essential to its application will have to be developed. The regulatory body will also have to be set up and be ready to go. It may therefore take months before the legislation can be proclaimed in force. In the meantime, the technology employed in assisted human reproduction and related research may evolve at such a rapid pace that the new legislation will require updating.

Because of the rapidly changing scientific and technological environment, we feel that a parliamentary review within three years would be more appropriate. The subject matter of this legislation is highly sensitive and controversial. Parliament must carry out an earlier, more timely review to ensure that the legislation is still in tune with the changing times and technologies.

The Committee recommends that:

RECOMMENDATION 32:

The new Act require a parliamentary review of the legislation within three years of its proclamation date.

SECTION 12: ADDITIONAL CONCERNS

(i) Prevention

The Committee heard that precautionary measures must be taken to reduce infertility. In our view, preventing some of the risk factors contributing to infertility would be more appropriate than developing new medical interventions to bypass the infertility that may result from exposure, to sexually transmitted diseases, occupational and environmental exposures or even postponement of pregnancy. We feel that a comprehensive national program focused on sexual and reproductive health is

imperative. We are aware that Health Canada has made tentative steps to develop a strategy over the last decade but feel that it needs more resources and commitment.

The Committee recommends that:

RECOMMENDATION 33:

The Minister of Health bring focus and resources to a sexual and reproductive health program with a particular emphasis on data collection, research, information dissemination, and policy development related to prevention of infertility.

The program include horizontal coordination with relevant federal departments such as Human Resources Development Canada on issues related to delayed childbearing and occupational health; Environment Canada on environmental threats to reproductive health; Canadian Institutes for Health Research on research into risk factors for and prevention of infertility.

The program continue the ongoing collaboration with provincial and territorial counterparts.

(ii) Definitions and Terminology

The Committee would like to see a significant improvement in the accuracy and clarification of certain definitions and terminology in the draft legislation. Although we have neither the particular expertise nor the time for extensive consultation, we are reassured that Health Canada has noted the problems that were brought to our attention and is working to improve the relevant sections. For consistency and clarity, we believe that all the definitions should be together at the beginning of the legislation. In addition, we find the term “human reproductive material” offensive in its inclusion of embryo. We also have problems with the definitions provided for gene, genome, embryo, and embryo donor. As well, we note that the term gamete should be defined in the legislation. Moreover, we heard that there appears to be no reason for defining “woman.”

(iii) Patenting Human Material

The Committee is seriously concerned about the patentability of human material. We are deeply disturbed that the *Patent Act* does not specifically disallow patenting with respect to human genes, DNA sequences, and cell lines. Treating human biological components as patentable property is repugnant to many of us. It entails their commodification and paves the way for their commercialization. Given the importance that this Committee attaches to the respect of human dignity and integrity, we urge that patents be denied in relation to human material. There should be particular emphasis on the ethical and social consequences of patenting human material as well as on the

implications for the development and availability of related therapies and corresponding costs to health care delivery in this country.

Therefore, the Committee recommends that:

RECOMMENDATION 34:

The *Patent Act* be amended to prohibit patenting of humans as well as any human materials.

(iv) Application to the Crown

The extent to which the federal, provincial, and territorial governments engage in any of the activities covered by the draft legislation is unclear. However, as major financial contributors to research in this area, we want to ensure that they are bound by this legislation. We believe that, to the extent of their involvement, whether direct or indirect, all the governments within Canada should be subject to the same standards and controls as other Canadians operating in the field. A clause expressly binding the Crown must therefore be included in the legislation.

The Committee recommends that:

RECOMMENDATION 35:

The legislation include a clause to provide that the Act is binding on her Majesty in right of Canada or of a province or territory.

(v) Essentials of Informed Choice

The Committee recognizes that informed choice must involve the right to consent and the right to refuse. We agree that informed choice is an ongoing process that must be open to change as required by personal circumstances. We heard that, while written and informed consent is a basic principle of the proposal, it is not defined or given substance. We suggest several ways to accomplish a more substantive legislative framework for informed choice.

The Committee recommends that:

RECOMMENDATION 36:

The legislation include a clear definition of informed choice. The definition and subsequent regulations should include, but not be limited to, the following components:

(a) Mandatory independent counselling for all assisted human reproduction;

(b) **The provision of such counselling be made a condition of any licence;**

(c) **Consent be obtained at all stages of all processes; and**

(d) **Consent may be withdrawn at any time, except as regards the retention and disclosure of medical records and personal identifying information where an offspring is involved.**

LIST OF RECOMMENDATIONS

RECOMMENDATION 1:

The Minister of Health introduce legislation on assisted human reproduction and related research as a priority.

RECOMMENDATION 2:

The Preamble be replaced by a Statutory Declaration enacted in the body of the legislation.

RECOMMENDATION 3:

The Statutory Declaration set forth the following guiding principles:

It is hereby recognized and declared that:

(a) assisted human reproduction and related research must be governed by principles and practices that respect human individuality, dignity, and integrity;

(b) the health and well-being of the children born from assisted human reproduction must be given priority in decisions regarding assisted human reproduction;

(c) while all participating persons are affected by assisted human reproduction, women more than men are directly and significantly affected by the application of the technologies;

(d) the integrity of the human genome must be protected;

(e) the principle of free and informed choice as a fundamental condition of the use of assisted human reproduction must be promoted and applied;

(f) human reproductive technologies provide benefits to individuals, families, and society in general;

(g) those benefits can be most effectively secured by taking appropriate measures for the protection and promotion of human health, safety, dignity, and rights in the use of such technologies;

(h) persons with disabilities can lead full and satisfying lives and enrich the lives of those around them; and

(i) the commodification of the reproductive capacities of women and men, and the exploitation of children, women and men for commercial ends must not be allowed.

RECOMMENDATION 4:

The Statutory Declaration be supplemented by a Purpose Clause within the body of the legislation, which would state as follows:

> **The purpose of this legislation is to provide a national legislative framework for assisted human reproduction and the conduct of research using human reproductive material. It is to ensure in particular that:**
>
> **(a) the interests of the children born from assisted human reproduction procedures are protected and given paramount consideration;**
>
> **(b) the interests of the adults participating in assisted human reproduction procedures be protected and their participation is based on informed choice; and**
>
> **(c) the interests of researchers and physicians are supported to the extent that they do not compromise the interests of the children and adults.**

RECOMMENDATION 5:

The prohibited activities currently set out in the draft legislation be retained and enacted as prohibited activities in the new legislation, subject to the additional modifications reflected in the following recommendations.

RECOMMENDATION 6:

Clause 3(1)(*d*) be reworded to reflect more accurately its intention to prohibit the creation of embryos on which research is to be carried out.

RECOMMENDATION 7:

The prohibition in clause 3(1)(*e*) simply state that gametes cannot be removed from embryos or fetuses for the purpose of creating an embryo.

RECOMMENDATION 8:

An additional prohibition be included that bans the creation and use of all animal/human hybrids for the purpose of reproduction.

RECOMMENDATION 9:

Clause 3(1)(*h*) specifically prohibit all sex selection with the noted exception of disorders linked to the sex chromosomes as defined in the regulations.

RECOMMENDATION 10:

Clauses 4(4) that excepts legal, medical, and psychological services and 10(*d*) that allows reimbursement of expenses to a surrogate mother be eliminated.

RECOMMENDATION 11:

An exception be created for physicians and other health care professionals who provide services necessary for the care of the pregnant woman.

RECOMMENDATION 12:

The provinces and territories be encouraged to provide mandatory counselling to the commissioning couple, surrogate mother and partner through existing publicly funded services available for adoption and to amend relevant family law to recognize the birth mother as the legal mother.

RECOMMENDATION 13:

Clause 10(*a*) that permits reimbursement of a donor for expenses incurred in the course of donating any sperm or ovum be eliminated.

RECOMMENDATION 14:

Research using embryos be a controlled activity requiring a licence. Even if all other regulatory criteria are met, no licence may be issued unless the applicant clearly demonstrates that no other category of biological material could be used for the purposes of the proposed research.

RECOMMENDATION 15:

Regulated standards be developed in relation to the following matters:

(a) The maximum number of eggs that may be harvested and fertilized;

(b) **The maximum number of embryos that may be produced, stored, and transferred for in vitro fertilization procedures, although a prohibition on the production and storage of excess embryos should be prescribed once egg-storage techniques have been perfected and validated;**

(c) **The maximum number of times a patient should be offered a given procedure;**

(d) **The counselling that must be provided to donors and recipients of treatment;**

(e) **The maximum number of children that may be produced from a single gamete donor;**

(f) **Eligibility requirements for donors and recipients; and**

(g) **The known pre-existing heritable genetic diseases or conditions in relation to which pre-implantation genetic diagnosis would be allowed.**

RECOMMENDATION 16:

Clause 40(1)(*m*), which allows regulations to be made to exempt a class or classes of controlled activities from the application of the legislation or regulations, be eliminated.

RECOMMENDATION 17:

Clause 43 be modified to provide a maximum one-year expiry date for the licensing exemption.

RECOMMENDATION 18:

Provisions similar to section 42.1 of the federal *Tobacco Act* be included in the new Act to require that all proposed regulations be laid before the House of Commons for approval or modification within 30 sitting days. Provision should also be made requiring the proposed regulations to be referred specifically to the House of Commons Standing Committee on Health.

RECOMMENDATION 19:

(a) **Consent to the release of identifying information be mandatory before accepting an individual as a sperm, egg, or embryo donor;**

(b) **All donor offspring (or legal guardians) have access to their regularly updated medical histories;**

(c) The number of babies born through the same donor be limited;

(d) The number of donations from the same donor be limited;

(e) Connections between genetic siblings are to be facilitated to avoid possibilities of sexual relations or marriage; and

(f) Medical and personal records be maintained;

(g) Mandatory counselling be provided for donors before a choice to donate is made and before an offspring establishes a link with a donor;

(h) No legal responsibilities respecting offspring, financial or otherwise, should arise out of a donation.

RECOMMENDATION 20:

The federal Minister of Justice, in collaboration with provincial and territorial counterparts, seek to develop uniform legislation across the country establishing the legal status of donors in relation to offspring.

RECOMMENDATION 21:

Enforcement agreements not be allowed to be entered into with a non-governmental organization.

RECOMMENDATION 22:

Both equivalency and enforcement agreements be subject to the following safeguards:

(a) The Minister must be accountable to Parliament for all equivalency and enforcement agreements;

(b) The public must be actively consulted on the draft agreements before they are finalized;

(c) The draft agreements, together with a summary of the comments made by the public, must be tabled in the House of Commons before they are finalized to give elected representatives the opportunity to make recommendations in relation to them;

(d) The text of all finalized agreements must be included in the public information registry established under the Act;

(e) All agreements be subject to termination or revocation upon reasonable notice being given by either party;

(f) **The Minister must be empowered to intervene under a savings clause that would enable him or her to take any action deemed necessary for the administration and enforcement of the Act;**

(g) **All agreements be subject to a maximum five-year sunset clause, with the possibility of renewal for further maximum five-year periods in appropriate cases; and**

(h) **As a condition precedent to the signing of an agreement, the other government must agree to comply with the same reporting requirements that apply at the federal level. The other government must also agree to transmit the related data to the regulatory body for inclusion in the federal personal health information registry and the public information registry.**

RECOMMENDATION 23:

A regulatory body be created outside the Department of Health to manage and oversee the operation of the Act. The regulatory body should be a semi-independent agency, directed by a Board that reports directly to the Minister of Health, and with mechanisms that ensure accountability to Parliament.

RECOMMENDATION 24:

The Minister under the legislation be responsible for:

(a) **reproductive and genetic technology policies for the Government of Canada;**

(b) **the overall direction of the regulatory body;**

(c) **the negotiation of equivalency agreements and enforcement agreements; and**

(d) **the assessment of the regulatory body's effectiveness.**

RECOMMENDATION 25:

The regulatory body be given a statutory base. Its functions should include:

(a) **monitoring Canadian and international developments in order to make recommendations to the Minister about changes that should be made to the legislation, regulations, and policies;**

(b) **issuing, amending, renewing, suspending or revoking licences for qualified applicants with respect to approved treatments and research;**

(c) ensuring compliance with the Act through inspection and enforcement;

(d) maintaining the public information registry, as well as the personal health information registry, including information on the number of children born from assisted human reproduction and updates on offspring and donor information;

(e) reporting to the public on the outcomes of the treatments provided and the research carried out;

(f) engaging in regular, ongoing consultations with interested parties;

(g) providing complete information to enable Canadians to make informed choices.

RECOMMENDATION 26:

The principles enshrined in the Statutory Declaration be explicitly set out in the regulatory body's mandate and the regulatory body should be required to develop a Code of Ethics based on these principles. The regulatory body must also table an annual report in Parliament and prepare a strategic plan every three years for the approval of the Minister and Parliament.

RECOMMENDATION 27:

(a) The Board consist of about nine members to be appointed by the Governor in Council, after consultation with provincial and territorial governments, stakeholders, and the House of Commons Health Committee;

(b) Board members be chosen for their wisdom, judgment, and ability to comprehend the multiple dimensions of assisted human reproduction and related research;

(c) Board members not represent or have any ties with specific interests nor have a financial conflict of interest;

(d) There be no government representation on the Board;

(e) Women comprise at least half of the Board's membership;

(f) Board members serve for staggered terms of three years, which could be renewed twice.

RECOMMENDATION 28:

A Secretariat, headed by a Chief Executive Officer and staffed by individuals with expertise or experience in a variety of relevant fields, be

established in the legislation to assist the Board in its policy and administrative objectives.

The Board be authorized to establish expert panels or advisory committees to advise the Board and to study special issues and developments.

The panels include persons with perspectives of those with disabilities, those who are infertile, those who are members of racial minorities, those from the faith communities as well as those with a broad range of expertise, including reproductive medicine, health research, ethics, social sciences, and law.

RECOMMENDATION 29:

The licensing hearings be held in public.

The Board be authorized to hold public hearings on specific issues of concern.

RECOMMENDATION 30:

All of the Board's activities be reported in the public information registry unless specifically excluded in the legislation.

RECOMMENDATION 31:

The federal government, under separate appropriations voted by Parliament, adequately fund the regulatory body.

The regulatory body not be subject to the federal government's cost recovery policy.

RECOMMENDATION 32:

The new Act require a parliamentary review of the legislation within three years of its proclamation date.

RECOMMENDATION 33:

The Minister of Health bring focus and resources to a sexual and reproductive health program with a particular emphasis on data collection, research, information dissemination, and policy development related to prevention of infertility.

The program include horizontal coordination with relevant federal departments such as Human Resources Development Canada on issues related to delayed childbearing and occupational health; Environment

Canada on environmental threats to reproductive health; Canadian Institutes for Health Research on research into risk factors for and prevention of infertility.

The program continue the ongoing collaboration with provincial and territorial counterparts.

RECOMMENDATION 34:

The *Patent Act* be amended to prohibit patenting of humans as well as any human materials.

RECOMMENDATION 35:

The legislation include a clause to provide that the Act is binding on her Majesty in right of Canada or of a province or territory.

RECOMMENDATION 36:

The legislation include a clear definition of informed choice. The definition and subsequent regulations should include, but not be limited to, the following components:

- **(a) Mandatory independent counselling for all assisted human reproduction;**
- **(b) The provision of such counselling be made a condition of any licence;**
- **(c) Consent be obtained at all stages of all processes; and**
- **(d) Consent may be withdrawn at any time, except as regards the retention and disclosure of medical records and personal identifying information where an offspring is involved.**

APPENDIX A

TOBACCO ACT

(Statutes of Canada, 1997, c. 13)

PART V.1: LAYING OF PROPOSED REGULATIONS

42.1(1) Laying of proposed regulations

42.1(1) The Governor in Council may not make a regulation under section 7, 14, 17, 33 or 42 unless the Minister has first laid the proposed regulation before the House of Commons.

42.1(2) Report by committee

(2) A proposed regulation that is laid before the House of Commons is deemed to be automatically referred to the appropriate committee of the House, as determined by the rules of the House, and the committee may conduct inquiries or public hearings with respect to the proposed regulation and report its findings to the House.

42.1(3) Making of regulations

(3) The Governor in Council may make a regulation under section 7, 14, 17, 33 or 42 only if

(a) the House of Commons has not concurred in any report from a committee respecting the proposed regulation within the thirty sitting days following the day on which the proposed regulation was laid before the House, in which case the regulation may only be made in the form laid; or

(b) the House of Commons has concurred in a report from a committee approving the proposed regulation or an amended version of it, in which case the Governor in Council may only make the regulation in the form concurred in.

42.1(4) Definition of "sitting day"

(4) For the purpose of this section, "sitting day" means a day on which the House of Commons sits.

APPENDIX B
LIST OF WITNESSES

Associations and Individuals	Date	Meeting
Health Canada	03/05/2001	13
Allan Rock, Minister		
Health Canada	10/05/2001	15
Rhonda Ferderber, Director, Special Projects Division, Policy, Planning and Priorities Directorate		
Francine Manseau, Senior Policy Analyst, Health Policy and Communications Branch		
Ian Shugart, Assistant Deputy Minister		
Justice Canada		
Glenn Rivard, Counsel, Legal Services		
Canadian Fertility and Andrology Society	17/05/2001	16
Roger Gosden, Research Director, Department of Obstetrics and Gynaecology, McGill University		
Arthur Leader, M.D., Chair of the Committee Government Relations		
Marie-Claude Léveillé, Director, Clinical Laboratory		
Health Canada Advisory Committee on the Interim Moratorium on Reproductive Technologies	29/05/2001	17
Madeline Boscoe, Executive Coordinator, The Canadian Women's Health Network		
Jeffrey Nisker, Professor of Obstetrics and Gynaecology, Coordinator of Bioethics		
Dalhousie University, Dalhousie Medical School	31/05/2001	18
Françoise Baylis, Associate Professor, Department of Bioethics		
McGill University, Centre for Medicine, Ethics and Law		
Margaret Somerville, Acting Director		
University of Alberta, John Dossetor Bioethics Centre		
Laura Shanner, Associate Professor, Population Health		

Associations and Individuals	Date	Meeting
Royal Commission on Reproductive and Genetic Technologies (1989-1993)	05/06/2001	19
Patricia Baird, Chair of the Royal Commission; Professor and Chair of the Department of Medical Genetics		
Canadian Council of Muslim Women	07/06/2001	20
Farhat Rehman, President, Ottawa Chapter		
Catholic Organization for Life and Family		
Bridget Campion, Assistant Professor of Moral Theology, St-Augustine's Seminary, Toronto		
Jennifer Leddy, Co-Director		
Temple Anshe Sholom, Hamilton		
Irwin Zeplowitz		
Tengye Ling Tibetan Buddhist Temple, Toronto		
Ven. Tenzin Kalsang, Spiritual Director		
The Evangelical Fellowship of Canada		
Bruce Clemenger, Director, Centre for Faith and Public Life		
Health Canada	18/09/2001	22
Rhonda Ferderber, Director, Special Projects Division, Policy, Planning and Priorities Directorate		
Lise Lavoie, Senior Policy Analyst, Special Projects Division		
Francine Manseau, Senior Policy Analyst, Health Policy and Communications Branch		
Ian Shugart, Assistant Deputy Minister		
Justice Canada		
Glenn Rivard, Counsel, Legal Services		
Canadian Multi-disciplinary Assisted Reproduction Coalition	25/09/2001	23
Sherry Levitan, Lawyer		
Joanne Wright, Canadian Surrogacy Options		

Associations and Individuals	Date	Meeting
Health Canada Advisory Committee on the Interim Moratorium on Reproductive Technologies	25/09/2001	23
Phyllis Creighton, Member		
University of Calgary		
Juliet Guichon, Instructor in Bioethics		
Health Canada	26/09/2001	24
Rhonda Ferderber, Director, Special Projects Division, Policy, Planning and Priorities Directorate		
Francine Manseau, Senior Policy Analyst, Health Policy and Communications Branch		
Justice Canada		
Glenn Rivard, Counsel, Legal Services		
Canadian Institutes of Health Research	27/09/2001	25
Thérèse Leroux, Director of Ethics		
Muscular Dystrophy Association of Canada		
Claredon Robicheau, President, Southwest Nova Scotia Chapter		
Yves Savoie, National Executive Director		
Ottawa Health Research Institute		
Michael Rudnicki, Canada Research Chair in Molecular Genetics		
Ronald Worton, Chief Executive Officer		
Parkinson Society Canada		
Mary Jardine, National Executive Director		
David Simmonds, Chair		
Health Canada	04/10/2001	28
Rhonda Ferderber, Director, Special Projects Division, Policy, Planning and Priorities Directorate		
Francine Manseau, Senior Policy Analyst, Health Policy and Communications Branch		

Associations and Individuals	Date	Meeting
Justice Canada	04/10/2001	28
Judy Hunter, Counsel		
Canadian Council on Health Services Accreditation	16/10/2001	29
Paula Greco, Manager, Research and Development		
Gilles Lanteigne, Assistant Executive Director		
Health Canada — Health Products and Food Branch Inspectorate		
Étienne Ouimette, Blood, Tissues and Organs Compliance Coordinator		
Royal Canadian Mounted Police — Society for the Policing of Cyberspace		
Earl Moulton, Chief Superintendent and President of the Society		
Health Canada — Population and Public Health Branch	17/10/2001	30
Robert McMurtry, Assistant Deputy Minister		
Ron St. John, A/Executive Director		
Advanced Cell Technology (Boston, MA)	18/10/2001	31
Jose Cibelli, Vice-President, Research		
University of Alberta — Health Law Institute		
Timothy Caulfield, Professor		
University of Toronto — Mount Sinai Hospital — Samuel Lunenfeld Research Institute		
Janet Rossant, Principal Researcher		
Canadian Fertility and Andrology Society	23/10/2001	32
Arthur Leader, M.D., Chair of the Committee Government Relations		
Jacquetta Trasler, M.D., Ph.D., President		
Canadian Medical Association	23/10/2001	32
Henry Haddad, M.D., President		

Associations and Individuals	Date	Meeting
Canadian Nurses Association		
Janet Storch, Ph.D., Ethics Scholar in Residence		
College of Family Physicians of Canada		
Richard MacLachlan, M.D., Chair of the Committee on Ethics		
Federation of Medical Licensing Authorities of Canada		
Donald Chadsey, M.D., Acting Registrar, Executive Director		
Society of Obstetricians and Gynecologists of Canada		
André Lalonde, M.D., Executive Vice-President		
McGill University	24/10/2001	33
Patrick Healy, Associate Professor		
Queens University		
Alison Harvison Young, Dean		
University of Toronto		
Bernard Dickens, Professor in Health Law and Policy, Chair in Biomedical Ethics		
Canadian Institute for Health Information	25/10/2001	35
John Millar, Vice-President		
Joan Rock, Privacy Secretariat		
Coalition for an Open Model in Assisted Reproduction		
Rona Achilles		
Catherine Clute		
New Reproductive Alternatives Society		
Shirley Pratten, Founding Member		
Olivia Pratten		
As an Individual	25/10/2001	35
Barry Stevens		

Associations and Individuals	Date	Meeting
Canadian Institutes of Health Research	31/10/2001	37
Alan Bernstein, PhD, FRSC, President		
Health Canada	06/11/2001	38
Michael Bryden, Senior Planning Advisor		
Rhonda Ferderber, Director, Special Projects Division, Policy, Planning and Priorities Directorate		
Justice Canada		
Glenn Rivard, Counsel, Legal Services		
Office of the Auditor General of Canada		
Alan Gilmore, Principal		
Michael McLaughlin, Deputy Auditor General		
University of Victoria		
Michael Prince, Lansdowne Professor of Social Policy		
Dalhousie University	07/11/2001	39
Jocelyn Downie, Director, Health Law Institute, and Assistant Professor		
Royal Commission on Reproductive and Genetic Technologies (1989-1993)		
Suzanne Scorsone, PhD		
University of Montreal		
Bartha Maria Knoppers, Professor		
Canadian Council of Professional Engineers	08/11/2001	40
Marie Lemay, Chief Executive Officer		
John Runciman, PhD, Associate Professor		
Infertility Awareness Association of Canada, Inc.		
Norman Barwin, M.D., C.M., FSOGC, FRCOG, FACOG, Director, Gynaecology and Infertility Clinic		
London Health Sciences Centre	08/11/2001	40
Jean Haase, Social Worker		

Associations and Individuals	Date	Meeting
National Council of Women of Canada		
Ruth Brown, National Health Convener, Past President		
McMaster and Dalhousie Universities	20/11/2001	41
John Collins, MD, FACOG, FRCOG, FRCPSC, Professor Emeritus (McMaster) and Adjunct Professor (Dalhousie)		
McMaster University Medical Centre		
Valerie Fines, Social Worker		
The Infertility Connection (Edmonton, Alberta)		
Irene Ryll		
The Infertility Network (Toronto, Ontario)		
Diane Allen, Executive Director		
"Université du Québec à Montréal"	21/11/2001	42
Louise Vandelac, PhD, Full Professor		
Royal Commission on Reproductive and Genetic Technologies (1989-1993)		
Maureen McTeer, Former Commissioner		
University of Manitoba		
Gordon Giesbrecht, PhD, Professor		
University of Ottawa	22/11/2001	43
Martha Jackman, Professor		
As an Individual		
Gerald Chipeur, Lawyer		
British Columbia Civil Liberties Association	26/11/2001	44
Micheal Vonn, Member		

Associations and Individuals	Date	Meeting
Campaign Life Coalition John Shea, MD, FRCP, Consultant		
Canadian Bar Association Brent F. Windwick, Chair		
Canadian Conference of Catholic Bishops Ron Mercier, S.J., Dean Terence Prendergast, Archbishop of Halifax		
Catholic Health Association of Canada Mary Lou Cranston, cnd, STD, Director		
Juvenile Diabetes Research Foundation of Canada Lawrence Soler, Director of Government Relations		
Lesbian Mothers Association Mona Greenbaum, Coordinator		
REAL Women of Canada Gwendolyn Landolt, National Vice-President		
The Canadian Women's Health Network Abby Lippman, Professor	27/11/2001	45
The Human Fertilization and Embryology Authority (London, U.K.) Maureen Dalziel, M.D., Chief Executive Officer		
Indiana State University David Prentice, PhD, Professor of Life Sciences	28/11/2001	46
Indiana University Centre for Bioethics Eric M. Meslin, PhD, Director		
University of Canterbury (New Zealand) Ken Daniels, Associate Professor	28/11/2001	46

Associations and Individuals	Date	Meeting
Canadian Association for Community Living	29/11/2001	47
Audrey Cole, Former Board Member, Family Member		
Canadian Environmental Law Association		
Paul Muldoon, Executive Director		
Council of Canadians with Disabilities		
Kathy Marshall, Secretary, National Coordinator and Projects Supervisor		
Pembina Institute		
Mark Winfield, Special Adviser		

APPENDIX C
LIST OF BRIEFS

Advanced Cell Technology (Boston, MA)

Patricia Baird

Françoise Baylis

British Columbia Civil Liberties Association

Micheal Burgess

Alex Cameron

Campaign Life Coalition

Canadian Association for Community Living

Canadian Bar Association

Canadian Conference of Catholic Bishops

Canadian Council of Muslim Women

Canadian Council of Professional Engineers

Canadian Council on Health Services Accreditation

Canadian Environmental Law Association

Canadian Fertility and Andrology Society

Canadian Institute for Health Information

Canadian Institutes of Health Research

Canadian Medical Association

Canadian Multi-disciplinary Assisted Reproduction Coalition

Canadian Nurses Association

Catholic Health Association of Canada

Catholic Organization for Life and Family

Timothy Caulfield

Gerald Chipeur

Coalition for an Open Model in Assisted Reproduction

“Collège des médecins du Québec”

College of Family Physicians of Canada

John Collins

William Chase Conell

Council of Canadians with Disabilities

Phyllis Creighton

Ken Daniels

Linda De Merchant

Bernard Dickens

Jocelyn Downie

Federation of Medical Licensing Authorities of Canada

Valerie Fines

Focus on the Family

Gordon Giesbrecht

Juliet Guichon

Jean Haase

Steve Hands

Health Canada — Health Products and Food Branch Inspectorate

Health Canada Advisory Committee on the Interim Moratorium on Reproductive Technologies

Infertility Awareness Association of Canada, Inc.

Juvenile Diabetes Research Foundation of Canada

David Kaplan

Bartha Maria Knoppers

Lesbian Mothers Association

Maureen McTeer

Eric Meslin

Muscular Dystrophy Association of Canada

National Council of Women of Canada

New Reproductive Alternatives Society

Office of the Auditor General of Canada

Ottawa Health Research Institute

Parkinson Society Canada

Pembina Institute

David Prentice

Michael Prince

REAL Women of Canada

Rick Hansen Institute

Janet Rossant

Royal Canadian Mounted Police — Society for the Policing of Cyberspace

Suzanne Scorsone

Laura Shanner

Keith Shields

Society of Obstetricians and Gynecologists of Canada

Margaret Somerville

Barry Stevens

The Canadian Women's Health Network

The Evangelical Fellowship of Canada

The Infertility Connection (Edmonton, Alberta)

The Infertility Network (Toronto, Ontario)

Gilles Vachon

Anne Wood

Irwin Zeplowitz

APPENDIX D
LETTERS RECEIVED ON THE SUBJECT OF STEM CELL RESEARCH

Date Received MM/DD/YYYY	Sender	
	First Name	Last Name
11/26/2001	Judy	Aalders
12/03/2001	Debbie	Acton
10/18/2001	Dora	Adrian
10/09/2001	Lynda	Adrian
10/17/2001	D.	Ainsworth
09/28/2001	Marilyn	Akre
10/11/2001	Alice	Albers
09/28/2001	Audrey	Allen
11/14/2001	E.J.	Antoniw
10/09/2001	Sam and Colette	Aragones
10/09/2001	Nancy	Armstrong
10/09/2001	Susan	Arnold
11/01/2001	Barb	Arsenault
12/03/2001	Mary	Atkins
10/11/2001	Karen	Aughtry
11/20/2001	Cam	Baergen
11/27/2001	Natasha	Bandstra
10/05/2001	Dave	Banks
10/11/2001	Marlene	Barritt
10/18/2001	Kenneth and Lois	Barron
10/18/2001	Josephine	Barron
10/23/2001	Shelley	Baumbrough
10/23/2001	Leroy	Bauming
10/23/2001	Marie	Bauming
10/11/2001	Pauline	Beange
09/25/2001	Norma	Becker
10/09/2001	Bastian and Ada	Belder
10/15/2001	Patricia E.	Bell
10/11/2001	John D.	Bender
10/22/2001	Linda and Grant	Bennett
10/15/2001	Scott S.	Benson
10/15/2001	Helen	Bergen

Date Received MM/DD/YYYY	Sender	
	First Name	Last Name
11/29/2001	Elsie	Bevan
10/11/2001	Trudy	Beyak
10/18/2001	Albert	Biel
11/05/2001	Darlene	Birt
10/11/2001	Cathy and Jim	Boothby
09/25/2001	Graham	Borch
10/09/2001	Betty	Boyd
12/04/2001	Richard C.	Braam
11/20/2001	Karen	Bradshaw
10/09/2001	C. and Gloria	Bradshaw
10/30/2001	Isaac	Braun
10/22/2001	Lois	Bridge
10/19/2001	Mildred	Brockie
12/04/2001	Marlene	Brown
10/09/2001	Mark	Brown
10/11/2001	Leora J.	Brown
11/05/2001	Wade	Bryant
11/07/2001	Carolyn	Bryant
10/11/2001	Fred and Rachel	Bryant
10/09/2001	Kathleen	Bucher
10/12/2001	Mary, Rita and Helen	Burnie
11/20/2001	Ted and Evelyn	Bush
12/03/2001	Bob	Cappelle
10/10/2001	Diane and Gordon	Catania
10/23/2001	Deborah	Cavan
10/16/2001	Lucille	Chisholm
11/28/2001	Mary and St. Ellsworth	Clair
11/29/2001	Ana	Clarridge
11/21/2001	Faye	Climenhaga
10/11/2001	Henri J.H.	Cloudt
10/09/2001	Nona M.	Collier
11/20/2001	Chase	Conell
10/11/2001	Ruth	Cooper
12/03/2001	John H.	Cridland
12/03/2001	Jack	Cridland
10/17/2001	D.	Cross
11/27/2001	Lorraine	Crow
10/11/2001	Judith	Cutts

Date Received MM/DD/YYYY	Sender	
	First Name	Last Name
10/23/2001	Herb and Sonia	Daichendt
12/04/2001	Allan and Marie	Dalberg
11/21/2001	Glenda	Davidson
11/15/2001	Murray and Joyce	Davies
10/18/2001	Joan	Davies
12/06/2001	Sylvia	Davison
10/22/2001	Jennifer	de Blieck
10/11/2001	Bert	De Gier
10/11/2001	Rev. J.	De Vries
11/26/2001	Sylvia	DeBoer
11/05/2001	Mary	Debus
10/17/2001	Judy and Chris	den Hertog
10/17/2001	Judy and Chris	den Hertog
10/09/2001	D.J.	Devereaux
11/20/2001	Lorelei	Diakow
10/29/2001	Christy	Dickie
10/29/2001	Clara	Dittrich
10/12/2001	Florence and Ray	Dodson
09/28/2001	Greg	Doerksen
10/09/2001	Michelle	Downer
10/11/2001	Elaine	Downing
10/09/2001	Sally	Dunbar
11/26/2001	Cathy	Dupuis
10/11/2001	Diane	Dyck
10/11/2001	Dan	Dyck
09/28/2001	Marilyn	Dykstra
10/23/2001	Otto and Magda	Eckhardt
10/05/2001	Dan and Karen	Effa
10/17/2001	Église Évangélique Libre Chambly	
10/16/2001	Gene	Elliott
10/16/2001	Elizabeth	Endis
10/25/2001	Gloria	Epp
10/11/2001	Jocelyn	Erhardt
11/29/2001	Erna	Ewert
10/29/2001	Dan and Laurie	Faber
12/03/2001	Anna	Feddema
10/25/2001	Rienie	Feenstra
10/11/2001	Patty and Dennis	Fenrich

Date Received MM/DD/YYYY	Sender	
	First Name	Last Name
10/11/2001	Joy	Fera
10/17/2001	Elizabeth	Forbes
10/23/2001	Irene and Ian	Forsyth
10/11/2001	Edith	Foster
10/09/2001	Denise	Franke
10/15/2001	Jim	Frey
10/18/2001	Mimi	Friesen
10/05/2001	Merlyn	Friesen
10/09/2001	Martin and Elma	Friesen
10/09/2001	Menno and Lizabeth	Friesen
10/09/2001	Hanna	Friesen
10/11/2001	Arden	Friesen
10/11/2001	Bernard	Friesen
10/11/2001	Helen	Friesen
10/11/2001	Michelle	Friesen
10/11/2001	Ruth	Frith
11/28/2001	Hubert and Corrie M.	Fullgraf
11/22/2001	Subhas C.	Ganguli, MD
10/11/2001	Claire	Garant
10/05/2001	Mary	Garason
11/22/2001	Marion E.	Gardiner
11/20/2001	Irene	Gawel
10/09/2001	Sister Lucille	Gendron
10/22/2001	Debbie	Gentleman
10/18/2001	George and Mary	Gerbrandt
10/24/2001	Nathalie	Gibbons
11/27/2001	Nathalie	Gibbons
11/29/2001	James J.	Gilbert, F.R.C.S.
09/28/2001	Maxine	Girard
10/11/2001	Elaine	Goehring
12/03/2001	Heather	Grannis
10/30/2001	Janet	Grant
11/20/2001	Kevin	Groat
10/11/2001	Guido	Groeliker
10/12/2001	Grace	Groen
11/06/2001	Sharon	Gryba
11/02/2001	Marie	Guenter
10/16/2001	Cheryl	Gummerson
10/05/2001	Supin	Hachey

Date Received MM/DD/YYYY	Sender	
	First Name	Last Name
12/03/2001	Arnold B. H.	Hagen
12/04/2001	David T.	Haley
12/04/2001	Carol B.	Haley
11/07/2001	Barbara	Hann
10/11/2001	Jackie and Tim	Harden
09/28/2001	Candice	Harder
10/24/2001	Debbie D.	Hardy
10/11/2001	John	Harrison
10/17/2001	Marion R.	Harvey
10/16/2001	Marion	Harvey et al.
09/25/2001	Alain	Hashimoto
10/25/2001	Jeffrey L.	Hastings
09/28/2001	Bernice and Keith	Hawes
10/30/2001	Catherine	Hayes
10/11/2001	G. Edward	Hazen
09/25/2001	Roger	Heath
10/17/2001	Connie	Heckenliable
10/09/2001	Phyllis	Heidebrecht
11/20/2001	Mary	Heidmiller
11/06/2001	Sophie	Hein
09/25/2001	Phyllis	Heppner
10/09/2001	Phyllis	Heppner
09/28/2001	Vaerie	Hicke
10/19/2001	Pam	Highgate
10/15/2001	Mary	Hildebrand
10/09/2001	Dr. Jerry	Hildebrand
10/09/2001	Linda	Hill
10/23/2001	Marilyn	Hiscox
10/09/2001	Ben and Mary	Hoeppner
10/09/2001	Allison	Holt
10/09/2001	Arlene	Holte
11/30/2001	Irene	Hoogkamp
10/17/2001	Michael	Horie, Ph.D.
10/09/2001	Susan	Hotson
10/11/2001	Bill and Kathrine	Hunt
10/11/2001	E.S.	Hunter
10/16/2001	Sylvia	Huziak

Date Received MM/DD/YYYY	Sender	
	First Name	Last Name
10/30/2001	Diana	Ing
10/22/2001	Ross and Gail	Jackson
10/09/2001	Yvonne	Jamault
10/11/2001	Archie	Jantzen
11/21/2001	Ronald J.	Jarvis M.D.
10/09/2001	John and Frances	Jeninga
10/11/2001	J.	Johnson
10/11/2001	T.	Johnston
10/24/2001	Sion	Jones
10/11/2001	John and Diane	Jonker
12/03/2001	Leo Y. K.	Jung
10/12/2001	Anna	Jushkevich
10/17/2001	Gertrude	Kamerman
10/11/2001	Sharon	Kasdorf
10/16/2001	Jessica	Keizer and family
10/16/2001	Priscilla	Kember
10/25/2001	Norah	Kennedy
10/05/2001	R.	Kennedy
10/17/2001	Dr. M.C.	Keresztesi, M.D., Dip. Obs., C.C.F.P.
10/09/2001	Johnny	King
10/18/2001	J & G	Klassen
10/09/2001	Erma	Klassen
10/09/2001	Teresa	Kleywegt
10/09/2001	Sarah	Kleywegt
10/09/2001	G.	Kleywegt
09/28/2001	Irislee	Koch
10/09/2001	Jule	Koch
11/21/2001	Linda	Korgemets
11/07/2001	Loretta	Krentz
10/09/2001	Gary and Gaétane	Kroeker
10/11/2001	Elizabeth	Kroeker
10/11/2001	Katherine	Krueger
10/05/2001	Kevin	Lageer
10/15/2001	Raina and Jim	Lahti et al.
10/11/2001	Lola	Lane
10/29/2001	Wendy	Langdale

Date Received MM/DD/YYYY	Sender	
	First Name	Last Name
10/11/2001	Marius	Lapierre
10/18/2001	Diane	Leask
11/29/2001	Simon and Brenda	Leblanc
11/05/2001	Linda and Stan	Lemstra
10/11/2001	Debbie and Gary	Leon
10/29/2001	Melody	Lewis
10/11/2001	Jacob and Lillian	Leyenaar
11/20/2001	Gwen	Little
10/09/2001	Patricia	Luke
09/28/2001	Pamela	Lundstrom, BAC, HE
11/05/2001	Margaret	Lutz
11/13/2001	C.	Luyt
10/11/2001	Gary, Mildred et al.	Lybeck
10/25/2001	Rev. H.A.	MacDonald
10/29/2001	Joan	MacDonald
10/11/2001	Michael	MacDonald
11/06/2001	Suzanne	MacDonell
11/07/2001	Betty	Madsen
10/11/2001	Doris	Mahoney
10/11/2001	Karen	Maier
11/21/2001	Lucia	Mak, BSc Pharmacy
10/11/2001	Lucie	Marchand
11/30/2001	Rosemary	Marentette
10/11/2001	Andrey	Marr
10/19/2001	Pat and Judy	Martens
10/17/2001	Dawn and Gordon	Martin
12/03/2001	Bill	McKay
10/11/2001	Renee	McKee
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10/30/2001	Kay	McLean
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10/11/2001	Sharon	Meier MacDonald
10/18/2001	Sister Pauline	Menard
11/06/2001	Pat	Meraw
10/11/2001	Isabel	Mercado

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10/09/2001	Elaine	Merritt
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10/12/2001	D.	Miller
10/11/2001	KJVT	Miquelon
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10/11/2001	Rod	Moffitt
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10/11/2001	Richard	Mueller
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10/09/2001	Mr. and Mrs.	Nakagawa
11/07/2001	Diane	Neemeu
10/09/2001	Raema	Nelson
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10/18/2001	Elsa	Niebuhr
10/09/2001	Ronald and Toni	Nygren
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10/15/2001	Jeannette	Olney
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10/05/2001	Ruth A.	Orr
10/11/2001	Ruth A.	Orr
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10/18/2001	Jeff	P.
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10/19/2001	Margaret	Patton
10/29/2001	Loren and Catherine	Pearson
10/05/2001	Wendy	Perkonig

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10/05/2001	T. & R.	Peterson
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11/20/2001	Jeremy	Phillips
10/19/2001	Clifford David	Phillips
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10/09/2001	Edie	Pitchko
10/09/2001	Linda	Plett
10/11/2001	Mr. and Mrs.Bill	Plooy
10/23/2001	William	Poetker
10/16/2001	Diana	Poetker
09/28/2001	William and Barbara	Pooles
09/28/2001	Kate	Pops
10/29/2001	Vermica	Price
11/21/2001	Cathie	Proulx
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10/23/2001	Grace	Reist
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10/15/2001	G.	Riediger
10/11/2001	Angela	Roberts
10/12/2001	Bryan and Colleen	Roller
10/09/2001	Bob and Lesley	Ross
11/01/2001	Corrine	Roste
10/05/2001	Fiona	Roth
10/11/2001	Ivy J.	Rowson
09/28/2001	Cheryl	Rowswell

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10/25/2001	Ria	Rystra
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11/20/2001	Pam	Sattler
11/20/2001	Shane	Sauer
12/04/2001	Henriette	Savage
10/25/2001	Jouke and Margaret	Schaafsma
10/09/2001	Lynn	Schaman
10/22/2001	Douglas L.	Schantz, M.D., FRCPC, FACP
10/16/2001	B.	Schenderling
10/18/2001	Randy	Schenderling
10/30/2001	Mary	Schlamp
11/06/2001	Blake	Schroeder
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10/11/2001	Noreen	Schulte
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10/16/2001	Bob	Scruton
10/11/2001	Lynette	Sedun
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09/28/2001	Ingrid	Shantz
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10/09/2001	Neil	Siemens
10/10/2001	Shireen V.	Singer
11/05/2001	Jennifer	Sipkens
10/18/2001	Arnold	Siroen
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10/16/2001	Agatha M.	Smith
10/11/2001	Jayne	Smith
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09/27/2001	Jerry	Soderman
11/07/2001	David W.	Spence
10/18/2001	Mary	Sproul
11/07/2001	Bea M.	Stark
09/28/2001	Danny	Stebeck

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10/09/2001	J.A.	Stephens
11/16/2001	Donnalene M.	Steven
12/03/2001	Shawn	Stewart
10/09/2001	Brenda	Stibbs
11/23/2001	Debi	Stodolka
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10/11/2001	Fran	Strandholt
10/15/2001	Marilyn	Stuart
10/10/2001	Shawna	Sturk
10/11/2001	Lois	Sutcliffe
10/29/2001	Fawne S.	Teele
10/29/2001	A.	Thibodeau
10/11/2001	Del and Lynda	Thiessen
10/18/2001	Carole	Thompson
09/28/2001	Goeff and Joey	Tipping
10/09/2001	Elaine	Toews
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10/11/2001	Jen	Travers
10/25/2001	Paul A.	Trawick
10/05/2001	Marie	Trimboli
10/05/2001	Pastor Marcus	Tso
10/29/2001	Aaron and Louise	Tully
10/09/2001	G.	Tupper
10/11/2001	Sandra	Turner
10/11/2001	Rhandi L.	Tyssen
09/28/2001	Melany	Unrau
10/18/2001	Timothy and Diane	Vais
10/05/2001	Hendrik	van der Breggen
11/20/2001	Jennifer	Van Dyken
10/29/2001	Corrine	Van Housen
10/11/2001	Warren and Carole	Van Nice
10/11/2001	Christina	Van Schaik
11/20/2001	Stephen	Vander Klippe
10/29/2001	E.	Vanderlinden
10/11/2001	Jerry and Jeannette	Vandervalk

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10/10/2001	Yolanda	Vanderweed
10/18/2001	John and Jeannette	Vanderweff
10/11/2001	Marie	Vautour
10/11/2001	Andrea	Velthuizen
10/17/2001	Henry and Margaret	Verschuur
11/20/2001	Yvonne	Vickruck
10/09/2001	Don	Warren
10/23/2001	Anita and Bryan	Wassenaar
10/11/2001	Lynn	Wassenaar
10/29/2001	Sonja	Watt
09/28/2001	Dwayne	Weatherall
10/09/2001	Renee	Wedel
10/09/2001	Helen and Rod	Wensley
10/12/2001	T.	Westerhof
10/16/2001	Shirley	Westerhuis
11/02/2001	John and Wilhelmina	Westerink
10/11/2001	Jack	Westerink
10/29/2001	Sister Zetta G.	Whelly
10/19/2001	Hilda	Wiebe
10/09/2001	Christina	Wiebe
10/11/2001	John and Mary	Wiebe
09/28/2001	Steve, Marge, Brendon, Brett and Simeon	Wiebe
10/16/2001	Cynthia	Wielgoz
10/10/2001	Vic and Esther	Wiens
10/25/2001	R.L.	Williamson
10/09/2001	Mary A.	Williamson
10/09/2001	Mike and Cathy	Wind
11/20/2001	Dianne	Wood
11/21/2001	Paul Michael	Wood
10/16/2001	Pat	Woode
10/10/2001	Robert A.	Wormald
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10/23/2001	Sylvia	Wukasch
12/03/2001	Ralph and Linda	Wyatt
10/15/2001	Mary	Yamashita
10/25/2001	Alcide	Yelle

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11/29/2001	Paul John	Yong, M.D.
10/11/2001	Donald N.	Young
10/16/2001	Greg and Tammy	Yzerman
09/28/2001	Sandy	Zalit
10/09/2001	Sandy	Zalit
11/06/2001	Neely and Randy	Zawadsky
10/09/2001	Barbara S.	Zimmer
12/03/2001	Andrew	Zyp

REQUEST FOR GOVERNMENT RESPONSE

Pursuant to Standing Order 109, the Committee requests that the Government table a comprehensive response to this report.

A copy of the relevant Minutes of Proceedings of the Standing Committee on Health is tabled.

Respectfully submitted,

Bonnie Brown, M.P.
Chair

REGULATING ASSISTED HUMAN REPRODUCTION AND RELATED RESEARCH

Canadian Alliance Minority Report

Issued by Preston Manning, M.P.;
Diane Ablonczy, M.P.;
Rob Merrifield, M.P.;
James Lunney, M.P.

The Canadian Alliance members of the Standing Committee on Health wish to commend the Chair, Bonnie Brown, M.P., and our fellow Committee members for their diligence and non-partisan approach in scrutinizing the draft bill on Assisted Human Reproduction and Related Research. We have participated fully in the preparation of the Majority Report and concur in many of its recommendations, particularly those pertaining to the statutory declaration of purpose, the activities to be prohibited by statute, and the provisions establishing the Regulatory Body.

The purpose of this Minority Report is to highlight subjects on which we would place a **stronger emphasis** and on which we recommend an **alternative approach** for consideration by the Minister of Health.

1. Urgency

It has been more than ten years since the Royal Commission on New Reproductive Technologies began to study this issue. It has been five years since the government's last attempt to legislate on this subject (Bill C-47 died on the Order Paper). It has taken eight months for the Health Committee to report on the government's current draft bill, and it will probably take another six months before draft legislation actually becomes law. Meanwhile, scientific and clinical advancements respecting assisted human reproduction and genetic science are proceeding by leaps and bounds.

Patricia Baird, the former Chair of the Royal Commission stated to the committee: "We've been discussing and consulting widely on these topics in Canada for over a decade, and I think the overriding need now is to put in place a system to deal with reproductive technology." (June 5, 2001)

If the government is prepared to bring forward the prohibition sections of the re-drafted bill in January 2002, we would be supportive of such a procedure. In any event, we urge the government to give the highest priority to fast-tracking legislation based on this report.

Recommendation: That the Minister of Health bring forward a re-drafted bill on Assisted Human Reproduction and Related Research before March 31, 2002.

2. Respect for Human Life

We concur with the Majority Report that an "over-arching consideration" in framing this legislation must be "respect for human individuality, dignity, and integrity." But we believe that this description of an over-arching consideration should be strengthened by using the phrase "respect for human life."

Bartha Knoppers (Adjunct Professor, Faculty of Law, University of Montreal) testified to the committee as follows: "I am surprised that nowhere in the Preamble do we find an allusion, not to the issue of knowing when life starts or when we become a human being, but to the ethical principle of respect for human life. I am surprised that it is not in the Preamble, which serves as a statement of underlying principles." (November 7, 2001)

The committee responded in part to Professor Knoppers' concern by recommending that an over-arching consideration in framing the legislation should be "respect for human individuality, dignity, and integrity." But we believe that the description of this over-arching consideration would be stronger and more accurate if it insisted on "respect for human life."

This, for example, would require respect and protection for the human embryo not simply because of its potential but because of the fact that it is human life.

Recommendation: That the final legislation clearly recognize the human embryo as human life and that the Statutory Declaration include the phrase "respect for human life."

3. Conflicts between Ethics and Science

A great deal of attention has been given to the possible conflicts between what science may desire to stretch the frontiers of knowledge and what society in general may consider "ethically acceptable." It should be acknowledged, however, that scientific research and advancement can also mitigate certain ethical concerns. For example, embryonic stem cell research raises a major ethical concern in that the embryo must be destroyed in order to obtain the stem cells. Recent scientific advances with respect to adult stem cells, however, provide an alternative which is more ethically acceptable.

Nevertheless, there will always be situations where what is scientifically possible and what is ethically acceptable conflict. In such situations, we concur with the Minister

when he told the committee, “There must be a higher notion than science alone … that can guide scientific research and endeavour. Simply because we can do something, does not mean that we should do it.” (May 3, 2001)

We also concur with Professor Jocelyn Downie (Director, Health Law Institute, and Assistant Professor, Dalhousie University) when she said, “Establishing a clear set of standards about ethics in science with respect to assisted human reproductive activities ensures that practitioners and researchers can know what is expected of them in relation to these activities. Similarly, establishing a clear set of standards ensures that recipients of such activities and the general public can be assured that only ethically acceptable activities are permitted and that they are conducted in a scientifically sound and ethically acceptable manner.” (November 7, 2001)

Recommendation: That the mandate and code of practice of the Regulatory Body to be established by the legislation include a directive to the effect that where there is a conflict between ethical acceptability and scientific possibility, the ethically acceptable course of action shall prevail.

4. Regulation of Embryonic Stem Cell Research

The Majority Report expresses strong support for stem cell research utilizing non-embryonic sources and expresses concern that embryonic stem cell research “commodifies the embryo.” While we share this concern, we feel that the greater problem with embryonic stem cell research is that it involves the planned destruction of the embryo which is contrary to the ethical commitment to respect human individuality, dignity, integrity, and life. While we welcome the sentiment behind the Majority Report recommendation that no licence for research using embryos should be issued “unless the applicant clearly demonstrates that no other category of biological material could be used for the purposes of the proposed research,” we consider this proviso unclear and unenforceable.

The committee heard compelling scientific evidence (Lippman, Prentice, Giesbrecht) about the advances in adult stem cell research, including the fact that they are easily accessible, are not subject to tissue rejection, and pose minimal ethical concerns. Adult stem cell research has shown remarkable advances in the past year and holds great promise for the future.

Recommendation: That the final legislation provide for a three-year prohibition on embryonic stem cell research, and that the government strongly encourage its granting agencies and the scientific community to place the emphasis on adult (post-natal) stem cell research.

5. Respect for Provincial Jurisdiction

We are concerned that the draft legislation contemplated by the Minister may well infringe seriously on provincial jurisdiction in several key areas. These include the provision and regulation of health care services related to assisted human reproduction, the establishment and operation of health information systems, and provisions dealing with privacy and access to health care information. We are concerned that attempted federal regulation of assisted human reproduction facilities may raise constitutional challenges.

The Canadian Alliance members wish to ensure that provincial jurisdiction with respect to health care is respected. The regulation of assisted human reproduction services and related research involves **both** the federal and provincial jurisdictions. This is why we urged the federal Minister of Health over a year ago to convene a federal-provincial conference for the purposes of developing a Federal-Provincial Agreement on Assisted Human Reproduction and Related Research to provide the basis for joint action and cooperation by both levels of government across jurisdictional lines. We still believe that such an agreement will ultimately be necessary, particularly to ensure that the Regulatory Body established under this statute will have sufficient authority to carry out its assigned purposes.

> **Recommendation: That the federal Minister of Health initiate discussions aimed at creating a Federal-Provincial Agreement for the Provision of Assisted Human Reproduction Services and the Regulation of Related Research in Canada.**

6. Privacy and Access to Information

The development and maintenance of a health reporting information system and a personal health information registry in the area of assisted human reproduction as envisioned by the draft bill is another area where federal-provincial cooperation is required. Many witnesses at the committee hearings complained about the inadequacies and deficiencies of the current patchwork system.

> **Recommendation: That the federal government work with the provincial and territorial governments and other stakeholders to create a national, comprehensive, coordinated personal health information registry in the area of assisted human reproduction.**

Also, the original provisions of the draft bill pertaining to privacy and access to information (Sections 18-22) attached a higher weight to the privacy rights of donors of human reproductive materials than to the “access to information” rights of children produced through assisted human reproduction technologies.

While a number of the recommendations of the Majority Report shift this balance more in the direction of the affected children, we would also make the following recommendation:

Recommendation: That the final legislation contain a clear statement to the effect that where the privacy rights of the donors of human reproductive materials conflict with the rights of children to know their genetic and social heritage, that the rights of the children shall prevail.

7. Regulatory Body

The Canadian Alliance members are strongly supportive of recommendations of the Majority Report that the Regulatory Body established to carry out the provisions of the act should be external to the Department of Health, preserve the principle of ministerial accountability, and be subject to special provisions to ensure strong links with Parliament and the public.

The Majority Report also recommends that the Regulatory Body be authorized to establish expert panels and advisory committees to ensure input from a variety of perspectives and interests. These provisions should be strengthened by adding a section giving specific legal "standing" to such interests and perspectives which would guarantee them a "voice" before the Regulatory Body.

Recommendation: That, without limiting the capacity of the Regulatory Body to receive input from whoever it wants, the final legislation create "statutory standing" before the Regulatory Body for key stakeholders including the users of assisted human reproductive technologies; children born with the assistance of AHR technologies; people with disabilities; the scientific and medical communities; the faith communities; professional ethicists and representatives of research ethics boards; private sector providers of services and private research firms; taxpayers and their representatives; and the provincial and territorial governments.

We also note that the one part of the draft bill which received the least commentary by witnesses and the least scrutiny by the committee is the part dealing with Inspection and Enforcement.

Recommendation: That Parliament give special scrutiny to these sections in the final legislation, with particular attention to ensuring the effectiveness of the inspection and enforcement provisions.

8. The Economics of Assisted Human Reproduction and the Cost of Regulation

The Health Committee received very little input describing the assisted human reproduction service sector in economic terms or the role of the private sector. The committee received no input whatsoever on the potential costs of regulating this activity and related research. Given the fact that Canada is heading into a recession, and that the growth of federal revenues is now contracting, it is imperative that Parliament be given a better picture of these important aspects of the subject.

Recommendation: That Health Canada be directed to provide the Health Committee and the Finance Committee with a clear description of the economics of the assisted human reproduction sector, the present and anticipated future role of the private sector, and an estimated cost of establishing and operating the regulatory regime proposed by this report. This analysis should include an assessment of the potential impact on the cost of health care of the anticipated expansion of assisted human reproduction services and the adoption of therapies based on genetic research.

9. Affirmation of Support for Research and Development

Because of the regulatory nature of the draft legislation, many of the provisions of the Majority Report and this Minority Report of necessity deal with prohibitions of activity and the establishment of limits and conditions on scientific research relevant to assisted human reproduction and the alleviation of human suffering.

While recognizing the necessity for these prohibitions and constraints, the Canadian Alliance members wish to affirm their support for the work of scientists and medical practitioners in this area and their dedication to the amelioration of human suffering associated with human infertility and genetically transmitted diseases.

We specifically wish to thank the associations and witnesses representing those suffering from infertility and genetically transmitted diseases for sharing their hopes and fears with us.

Recommendation: That research and development designed to ethically advance scientific and medical progress in assisted human reproduction and related research be strongly supported by the federal government and the public in the years ahead.

10. Free Vote

Recommendation: That, because of the moral and ethical dimensions of legislation dealing with assisted human reproduction and related research, all parties permit a free vote on this legislation at all stages.

BLOC QUÉBÉCOIS DISSENTING OPINION

Report on Assisted Reproductive Technologies
Standing Committee on Health

There can be few more sensitive subjects for the lawmaker than assisted reproductive technologies, an issue where many great questions converge. Ethics, law, sociology, medicine and philosophy each sheds its own light on an area of knowledge where the evolution is rapid and change constant: genetic engineering.

Despite the strikingly multidisciplinary nature of genetic engineering, we feel the need, like our fellow members of the Committee, to reaffirm forcefully that the dignity and integrity of the human genome and of the human individuals who emerge from it are at the heart of our concerns.

As Members of Parliament, we support the broad directions taken by this report, and we regard as essential for further development the broad consensus established in it: the dignity of the human being, non-commercialization of human reproductive material, informed choice, responsibility and transparency, removal of the veil of anonymity from donors of genetic material, and protection of the child. However, there are several points we wish to raise.

By choosing to ban certain activities, the federal government has made its entrance onto the field of medically assisted reproduction via the criminal law. It should be made clear that large sectors of the field of medically assisted reproduction are matters of provincial responsibility. These include the delivery of health-care services (including the establishment of fertility clinics), the status of offspring (which involves family, and thus civil, law), and of course the counselling to be provided to surrogate mothers and to donors of genetic material. It consequently seems obvious to us:

1. That there can be no “Canadian” policy in this regard without solid coordination among the provinces and an unambiguous recognition that this is an area of shared jurisdiction;

2. That no regulatory body can be fully effective without provincial representatives on its Board of Directors;

3. That any legislation or regulation regarding medically assisted reproduction must be drafted with the most absolute respect for family law and for the existence of health and social services networks, both of which are areas of provincial jurisdiction.

In this regard, we believe that the report is unfairly negative about the signing of equivalency and enforcement agreements, pursuant to clause 41 of the draft legislation.

In our opinion, it would be desirable and wise to stipulate that if one or more provinces passed a law or made regulations compatible with the objectives put forward by the federal government, the federal government should withdraw completely and leave the province(s) concerned with full responsibility and authority for this activity.

With regard to the regulatory body, the Committee studied a number of models: the Pest Management Regulatory Agency (PMRA), the Patent Medicine Prices Review Board (PMPRB), the Canadian Food Inspection Agency (CFIA), the Canadian Nuclear Safety Commission (CNSC), the Canadian Radio-Television and Telecommunications Commission (CRTC) and Canadian Blood Services.

We in the Bloc Québécois want to see a regulatory body established that has the following characteristics:

1. It would be independent of Health Canada;

2. Its Board of Directors would include representatives of all stakeholders;

3. It would be fully independent while accountable to Parliament for its general direction.

We affirm without hesitation that recommendations 20, 21 and 22 of the report would entail too great a devolution of powers to the Federal Minister of Health, without at the same time guaranteeing sufficient independence for the future regulatory body's Board of Directors.

Lastly, we were disappointed that the government and the official opposition refused to include in the Preamble to the draft legislation, or Statutory Declaration, a genuine non-discrimination clause under which no citizen could be deprived of recourse to medically assisted reproduction because of race, national or ethnic origin, colour, religion, sex, age, mental or physical deficiency, matrimonial status, social condition or sexual orientation, thus complying with the principles that are in fact set out in the draft legislation.

Pauline Picard, MP
Drummond

Réal Ménard, MP
Hochelaga—Maisonneuve

NEW DEMOCRATIC PARTY DISSENTING OPINION

Standing Committee on Health Report on Assisted Reproductive Technologies

The past two decades have seen a virtual quantum leap in our knowledge of genetics and reproductive technology. The frontier of the possible has shifted dramatically. During the Health Committee's review of the government's draft proposal on assisted reproductive technology, we heard testimony to the value of this new technology in treating infertility, to the promise of developments such as stem cell research for overcoming serious health problems and to the potential risks posed by this technology to citizens in an unregulated environment.

The Health Committee has been assisted by many witnesses during our examination of this wide-ranging topic, witnesses who have shared both their expert opinions and personal experiences. These are complex issues and emotional ones for many and we greatly appreciate the contribution these witnesses have made to our deliberations.

The Committee has made a number of very significant recommendations in its report toward regulating reproductive technologies. The prohibition of human cloning, strict controls on embryonic stem cell research, an end to donor anonymity, a ban on commercial surrogacy and the need for a quasi-independent regulatory body, for example, are proposals supported by New Democrats. There are other areas, however, such as women's health protection, infertility prevention and the impact on persons with disabilities where we feel the Committee has failed to strike the right balance.

Urgent Action Needed

Clearly, there is a need for urgent government action. Canada stands almost alone among industrialized nations without a legal framework to deal with these new scientific developments.

The Baird Royal Commission laid the foundation for legislation in its 1993 report. It made 293 recommendations in that report based on four years of consultations with an estimated 15,000 Canadians through interviews, surveys and focus groups. The Liberal government waited until 1996 to introduce legislation. However, that legislation, Bill C-47, died on the Order Paper with the 1997 election and was never re-introduced. We are now entering 2002 with only a draft document, not even a bill.

In the interim, scientific discovery and industrial development in this area have proceeded apace outside of any regulatory framework. Socially positive and negative impacts cohabit a legal limbo and Canadians are left without necessary health protections. A virtual zoo full of cloned species, patented higher life forms, manipulable human stem cells, internet surrogacy and embryonic screening are all now part of our

daily lives. Unobstructed by regulation and with public health insurance helping to pay some of the costs, biotechnology corporations have turned Canada into a giant laboratory to research and develop their products and services with Canadians as the guinea pigs.

Recommendation: We urge the Health Minister to table an actual bill immediately upon the resumption of House of Commons business in January and to draft regulations as quickly as possible with a view to passing the legislative package into law before the end of the Spring sitting. During the interim, we urge the government to enforce its voluntary moratorium on such practices as germ-line alteration, human embryo cloning and the buying and selling of eggs, sperm and embryos and to use existing laws, in areas such as drug safety, to protect women's health.

End Commercialization

The benefits of appropriately regulated technology should be available to all Canadians through our public health system. However, the lack of active government intervention over the past decades has left control of this field firmly in the grip of multinational biotechnology corporations.

All Canadians should benefit equally from improvements to infertility treatment. This is far from the case now where public coverage of infertility conditions is practically non-existent and private insurance often excludes fertility drugs or imposes severe limits on reimbursement. National leadership is required to validate infertility as a medical condition and to ensure that all women have access to safe, science-based and effective treatment.

Recommendation: We call on the federal government to initiate measures—in conjunction with provincial and territorial governments where appropriate—to bring reproductive technology within the public/non-profit sector. We urge the federal government to encourage and support efforts like that of the Manitoba government to reclaim for-profit services for public health care, particularly in relation to reproductive technology.

Knowledge of the genetic building blocks of life forms part of our common human legacy and the public good. It should not be forfeited to the private preserve of giant life science and drug corporations. However, that has been the effect of the government's over-zealous support for patent protection and its placing of intellectual property rights over the public interest. The Canadian Patent Office is already beset with patent claims on various genetically manipulated human cells.

Recommendation: We call on the government to change the Patent Act to prohibit the patenting of human genetic material and to preempt applications currently before the Canadian Patent Office for patents on genetically

engineered human stem cells. We also urge the federal government to play a leading role internationally, in line with the UNESCO 1997 Declaration on the Human Genome and Human Rights, to keep international trade agreements from overriding the health interests of Canadians. This is an important pro-active step toward shaping international trade law to prevent Canada from being obligated to grant patents on human genes in the future.

Women's Health: A Priority

The rights and health of women must be the first consideration in regulating reproductive technologies. Our approach to reproductive technology must be grounded solidly in the concept of women's reproductive freedom. This requires the federal government to ensure that reproductive technologies are proven to be safe before being permitted, that the risks and benefits of any treatment for women are fully disclosed, that the evaluation of reproductive health services include women's experiences and that the funds needed to achieve these objectives are made available.

Currently, women are often not informed about the links between some fertility drugs and cancers or about the real success/failure rates of fertility clinics. Canada's drug approval process is failing women if unsafe drugs are allowed to remain on the market.

Recommendation: We urge the government to review, on a precautionary rather than risk assessment basis, the safety of fertility drugs currently being marketed in Canada and to promptly remove any drugs of questionable safety. We further recommend that the proposed regulatory body for reproductive technologies establish formal mechanisms to ensure direct input from the Women's Bureau at Health Canada. It is also incumbent on the government to ensure funding for the participation of the women's health community in reproductive technology decisions and we recommend that this funding be a mandated budget item.

We support a precautionary approach to women's health in which the onus is on providers and researchers to prove a procedure's safety before it is approved for use.

Recommendation: We call for the precautionary principle to be explicitly set out in the legislation as a prerequisite for the approval of all standards and procedures.

A priority on women's health requires a focus on the causes of infertility. Neglecting the causes of infertility means that women are being subjected to intrusive and risky procedures to treat problems that might very well have been preventable. Sexually transmitted diseases, environmental toxins, workplace hazards and delayed child bearing for economic reasons are well-known contributors to infertility, yet the Committee Report relegates these to "additional concerns".

Recommendation: Prevention must be seen as a central aspect of any policy on reproductive technologies and a key part of the work of any newly established regulatory authority.

Genetics: Who Charts the Future?

Reproductive technology has given us new tools to predict and manipulate our genetic futures. There are negative as well as positive implications. Advocates for persons with disabilities have raised concerns that genetic testing for the purpose of eliminating disabilities is a form of eugenic cleansing that will effectively lead to the bio-medical elimination of diversity. There are further concerns that these questions are being decided by private corporations beyond public control.

Genetic-based discrimination is also an issue. Without regulation, we already see: pre-natal testing taking place without a full knowledge of what is or is not treatable; routine screening of newborns without parental consent; no prohibition of "home" genetic tests; employer demands for genetic testing; and life insurance companies demanding genetic test results as part of customer screening. Since 1993, 30 gene therapy experiments have been approved without any policy framework or national genetics strategy. Without regulation, there are serious safety concerns for persons engaged as subjects in genetic experimentation.

Like organ transplantation, genetics transcends federal-provincial jurisdictional boundaries. It requires a national vision and federal leadership—especially given the extent of commercial activity in the area.

Recommendation: We call on the federal government to move quickly to develop a national strategy on genetics based on respect for human dignity and diversity. We must enshrine specific legal rights, including the right to genetic privacy and informed consent and the right to freedom from all forms of genetics-based discrimination. And we must ensure that persons with disabilities and their organizations are involved in all discussions in this area.

New reproductive and genetic technology must not be used to further marginalize people with disabilities. Policies and legislation must reflect the fundamental principle that every person is unique and by way of their gifts and assets contributes to their own well-being and to the well-being of society as a whole.

Safety is Paramount

Above all, the area of reproductive and genetic technologies needs a strong regulator. The Committee recommendations for a regulatory framework are a step in this direction.

The proposal for a quasi-independent regulatory body is an acknowledgement of the frequently voiced call for independence, transparency, accessibility, accountability and diversity. However, the central requirement for active, not passive regulation in this area remains a key concern, whether the regulatory authority is housed within government or an external agency. A precautionary approach takes more than the establishment of a new structure. It requires a commitment from government to support active oversight and a halt in its pursuit of the passive risk-management model. If we have learned anything from the tainted blood tragedy, it is that when safety is not foremost, Canadians pay with their health and their lives. The recommendations of Justice Krever for this country's blood system are equally applicable to reproductive and genetic technologies. Accordingly, it is imperative that a national safety system include the capacity, the resources and the mandate to actively identify the risks that threaten the safety of those involved, conduct frequent inspections of fertility clinics, strictly enforce all regulatory requirements, communicate promptly and constantly review the scientific and medical literature.

As Justice Krever stated, a regulatory authority must not assume a passive or responsive role, or rely on a philosophy of voluntary compliance to protect the health of Canadians. The regulations governing this area must be strictly enforced and the actions taken by those involved to comply with the regulatory directives must be closely monitored.

When taken as a whole, the government's performance to date casts serious doubt on its intention to arm a regulatory agency with the mandate needed, backed by the tools and resources needed. The strength of political will is the determining test for any regulatory effort. It signals those charged with enforcement and it signals those engaged in regulated activity. The strongest possible commitment to the ongoing regulation of reproductive technology must be evident in the mandate of the regulatory body and the urgency with which the government acts to bring in legislation.

DISSENTING OPINION

André Bachand, MP for Richmond—Arthabaska
Progressive Conservative Party Critic

I want to begin by thanking the members of the Committee and its Chair for good work well done. The support and professionalism of the Clerk and the research team are also very commendable.

The high quality of the report reflects the high quality of the witnesses. However, certain points do need be raised.

Prohibited activities

The activities prohibited by the draft legislation, which fall under the Criminal Code, should immediately be the subject of a separate law, which could be brought in by the Minister of Justice. In addition, we want research on embryonic stem cells to be included among the prohibited activities.

Donors (sperm, eggs and embryos)

The report says that "only donors who consent to have identifying information released to offspring should be accepted" (page 34 [?]) Recommendation 18 [19?] would put an end to all anonymity for donors.

We agree that a full medical and background history should be on file. We have however extremely strong reservations about doing away with anonymity. What will the consequences be for the number of donors? In our opinion, while donors should be required to disclose their medical history, their right to personal anonymity should be their own choice.

Equivalency agreements

The question of shared responsibility is one that concerns us greatly. In our opinion, the provinces and territories should **have** to be involved. We do not at all share the hesitation raised in paragraph 1.91, on page 36.

The topics discussed in this report are too important, and should be the subject of in-depth consultations that could lead to a federal-provincial-territorial conference.

We hope that the report will produce concrete results. Other discussion will take place, but it is high time that this country adopted statutory and regulatory tools to govern this area of activity. Science is once again running ahead of legislation.

MINUTES OF PROCEEDINGS

Monday, December 10, 2001
(*Meeting No. 52*)

The Standing Committee on Health met in camera at 12:41 p.m. this day, in Room 536, Wellington Building, the Chair, Bonnie Brown, presiding.

Members of the Committee present: Bonnie Brown, André Bachand, Colleen Beaumier, Jeannot Castonguay, Brenda Chamberlain, Stan Dromisky, Réal Ménard, Rob Merrifield, Hélène Scherrer, Judy Sgro, Yolande Thibeault, Judy Wasylycia-Leis.

Acting Member present: Preston Manning for Diane Ablonczy.

Associate Member present: Preston Manning.

In attendance: From the Library of Parliament: Nancy Miller Chenier, Sonya Norris, François Côté and Monique Hébert, research officers.

The Committee resumed consideration of a draft report on the proposal on Assisted Human Reproduction. (*See Minutes of Proceedings dated Thursday, May 3, 2001, Meeting No. 13*.)

It was agreed — That the Chair be authorized to make such typographical and editorial changes as may be necessary without changing the substance of the Report.

It was agreed — That, pursuant to Standing Order 109, the Committee request the Government to table a comprehensive response to the report within 150 days.

It was agreed — That the draft report, as amended, on the Committee's study of the draft proposal on Assisted Human Reproduction pursuant to Standing Order 108(2), be adopted as the Committee's Second Report, and that the Chair present the said report to the House.

At 1:22 p.m., the Committee adjourned to the call of the Chair.

Gary S. Sokolyk
Clerk of the Committee