

**BILL C-6: ASSISTED HUMAN REPRODUCTION ACT**

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## LEGISLATIVE HISTORY OF BILL C-6

### HOUSE OF COMMONS

Bill Stage	Date
First Reading:	11 February 2004
Second Reading:	11 February 2004
Committee Report:	11 February 2004
Report Stage:	11 February 2004
Third Reading:	11 February 2004

### SENATE

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Statutes of Canada 2004, c.2

N.B. Any substantive changes in this Legislative Summary which have been made since the preceding issue are indicated in **bold print**.

Legislative history by Peter Niemczak

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BILL C-6: ASSISTED HUMAN REPRODUCTION ACT\*

BACKGROUND

Bill C-6, An Act respecting assisted human reproduction and related research, was introduced in the House of Commons and deemed to have passed all stages on 11 February 2004.<sup>(1)</sup> Based on the federal criminal law power, it would prohibit certain activities and would regulate others with respect to assisted human reproduction and related research. The Government has stated that this comprehensive legislation will protect the health and safety of Canadians using assisted human reproduction (AHR), will prohibit unacceptable practices, and will regulate AHR activities and related research.

Since 1989, when the Royal Commission on New Reproductive Technologies was created by the federal government, Canada has been attempting to define the proper legislative and regulatory controls to govern AHR. In 1993, the Royal Commission produced its report entitled *Proceed with Care*, recommending immediate regulation to protect the interests of all Canadians. In 1995, the Minister of Health announced an interim voluntary moratorium on several activities of concern, such as human cloning and paying surrogate mothers. Bill C-47, the proposed Human Reproductive and Genetic Technologies Act that was introduced in Parliament in 1996, would have prohibited specified activities, but it would not have set out a clear mechanism for regulating other activities that could be carried out under prescribed conditions. The bill later died on the *Order Paper* at the call of the 1997 federal election. Similar proposed legislation (Bill C-56) was introduced in the 1<sup>st</sup> session of the 37<sup>th</sup> Parliament; it, too, died on the *Order Paper*.

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\* Notice: For clarity of exposition, the legislative proposals set out in the bill described in this Legislative Summary are stated as if they had already been adopted or were in force. It is important to note, however, that bills may be amended during their consideration by the House of Commons and Senate, and have no force or effect unless and until they are passed by both Houses of Parliament, receive Royal Assent, and come into force.

(1) By a motion adopted on 10 February 2004, the House of Commons provided for the reintroduction in the 3<sup>rd</sup> session of government bills that had not received royal assent during the previous session and that died on the *Order Paper* when Parliament was prorogued on 12 November 2003. The bills could be reinstated at the same legislative stage that they had reached when the 2<sup>nd</sup> session was prorogued. Bill C-6 is the reinstated version of Bill C-13, which died on the *Order Paper*.

On 3 May 2001, the Minister of Health invited the House of Commons Standing Committee on Health to conduct a full review of the Government of Canada's *Proposals for Legislation Governing Assisted Human Reproduction*. In December 2001, the Health Committee tabled its report and, among its multiple recommendations, requested that legislation be introduced on a priority basis. Bill C-13, An Act respecting assisted human reproduction, was introduced in the 2<sup>nd</sup> session of the 37<sup>th</sup> Parliament, but died on the *Order Paper* when that session was prorogued.

Like its predecessor (Bill C-13), Bill C-6, the proposed Assisted Human Reproduction Act (short title), incorporates many but not all of the Health Committee's recommendations. One significant change recommended by the Committee and reflected in the proposed Act is the establishment of a regulatory body to license, monitor and enforce the Act. The Act would also prohibit a range of activities deemed by many Canadians to run contrary to human dignity or societal values, while permitting certain other activities to be carried out, subject to governmental regulation and oversight.

## DESCRIPTION AND ANALYSIS

### A. Declaration of Principles (Clause 2)

Clause 2 outlines seven principles that apply in the regulation of the proposed Assisted Human Reproduction Act, namely:

- the health and well-being of children born through AHR technologies must take priority when making decisions respecting the use of AHR technologies;
- the benefits of AHR technologies and related research for individuals, for families and for society in general can be most effectively secured when appropriate measures are taken for protecting and promoting human health, safety, dignity and rights;
- while AHR technologies affect all persons, women, more than men, are directly and significantly affected by their application and the health and well-being of women must be protected in the application of these technologies;
- the principle of free and informed consent is to be promoted and applied as a fundamental condition of the use of AHR technologies;
- persons who seek to undergo AHR procedures must not be discriminated against, including on the basis of sexual orientation or marital status;

- the health and ethical concerns raised by trade in the reproductive capacities of women and men and the exploitation of children, women and men for commercial ends justify their prohibition; and
- human individuality and diversity, and the integrity of the human genome, are to be preserved and protected.

Because they are enshrined in a “statutory declaration” as opposed to a preamble, these principles have greater legal force than if they were set out in a preamble.

#### B. Interpretation and Application (Clauses 3 and 4)

Clause 3 sets out most of the definitions applicable to this bill. It includes crucial terms such as “donor,” “embryo,” “foetus” and “*in vitro* embryo,” and sets out several scientific terms such as “chimera,” “genome,” “human clone” and “hybrid.” These precise definitions are important to a fuller understanding of many clauses later in the bill, particularly in reference to the “prohibited” and “controlled” activities.

Clause 4 makes the legislation apply to both the federal and the provincial Crown.

#### C. Prohibited and Controlled Activities (Clauses 5 to 13)

The bill creates two broad categories of activities:

- “prohibited activities,” which must *not* be carried out under any circumstances; and
- “controlled activities,” which may be carried out but only in accordance with the legislation and the regulations.

##### 1. Prohibited Activities

Clause 5 sets out most of the activities that are prohibited outright under the new legislation. The remaining prohibitions (i.e., those surrounding surrogacy, the purchase and sale of human gametes and embryos, the use of human material without the requisite consent, and the acquisition of gametes from minors) are contained in clauses 6 to 9.

Clause 5 prohibits the following activities:

- reproductive and therapeutic human cloning (clause 5(1)(a));
- creating *in vitro* embryos for any purpose other than creating a human being or improving or providing instruction in AHR procedures (clause 5(1)(b));

- creating an embryo from the cell or part of a cell of an embryo or foetus for the purpose of creating a human being, or transplanting an embryo so created into a human being (clause 5(1)(c));
- maintaining an embryo for more than 14 days outside the body of a female person, minus any time during which its development is suspended (clause 5(1)(d));
- sex selection, except for preventing, diagnosing or treating sex-linked disorders or disease (clause 5(1)(e));
- germ-line genetic alteration, i.e., altering the genome of a cell of a human being or *in vitro* embryo such that the alteration is capable of being transmitted to descendants (clause 5(1)(f));
- transplanting a sperm, ovum, embryo or foetus of a non-human into a human being (clause 5(1)(g));
- using any human reproductive material or *in vitro* embryo previously in a non-human for the purpose of creating a human being (clause 5(1)(h));
- creating a chimera<sup>(2)</sup> or transplanting a chimera into either a human being or a non-human life form (clause 5(1)(i)); and
- creating hybrids<sup>(3)</sup> for the purpose of reproduction or transplanting a hybrid into either a human being or a non-human life form (clause 5(1)(j)).

Clause 5(2) and (3) prohibits anyone from offering to do or advertising the doing of any of the foregoing prohibited activities, or paying, or offering to pay, someone else to do so.

Clause 6(1) prohibits commercial surrogacy by making it an offence to pay, offer to pay or advertise to pay “consideration” to a female to be a surrogate. Clause 6(2) prohibits intermediaries from accepting any consideration for arranging, offering, or advertising for arranging surrogacy. Clause 6(3) prohibits any person from paying for, offering to pay for, or advertising the payment for an intermediary to arrange for a surrogacy. Clause 6(4) prohibits any person from counselling or inducing a female believed to be under 21 years of age to

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(2) The word “chimera” is defined in clause 2 as an embryo into which a cell of any non-human life form has been introduced or an embryo consisting of cells of more than one embryo, foetus or human being.

(3) The word “hybrid” is defined in clause 2 as: a) a human ovum that has been fertilized by a sperm of a non-human life form; b) an ovum of a non-human life form that has been fertilized by a human sperm; c) a human ovum into which the nucleus of a cell of a non-human life form has been introduced; d) an ovum of a non-human life form into which the nucleus of a human cell has been introduced; or e) a human ovum or an ovum of a non-human life form that otherwise contains haploid sets of chromosomes from both a human being and a non-human life form.

become a surrogate. It would also be an offence for anyone to perform any medical procedure to assist such a person to become a surrogate. Clause 6(5) provides that this section (i.e., clause 6) does not affect the validity under provincial law of any surrogacy agreement.

Clause 7(1) prohibits the purchase, offer to purchase or advertising for the purchase of sperm and ova. Clause 7(2), in turn, prohibits not only the purchase, offer to purchase or advertising for the purchase of *in vitro* embryos, but also their sale, offer for sale and advertising for sale. Clause 7(3) further expands the prohibition to include the purchase, offer to purchase or advertising for the purchase of any human cell or gene for the purpose of creating a human being. Finally, clause 7(4) defines “purchase” and “sell” as including exchanges for property or services.

Clause 8 deals with the requirement for written consent in using human reproductive material or *in vitro* embryos. The regulations would specify the form and nature of the consent required. Specifically, clause 8(1) prohibits the use of human reproductive material for the purpose of creating an embryo without the donor’s written consent. Clause 8(2) prohibits the posthumous removal of human reproductive material for the purpose of creating an embryo without the deceased’s previous written consent, and clause 8(3) prohibits the use of *in vitro* embryos for any purpose, without the donor’s written consent.

Finally, clause 9 prohibits obtaining or using any sperm or ova from a donor under 18 years of age, except for the purpose of preserving them or for the purpose of creating a human being to be raised by the donor.

## 2. Controlled Activities

Clauses 10 to 12 make it an offence for anyone to carry out a “controlled activity” unless the activity is carried out in accordance with the regulations and a licence. The controlled activities are:

- the alteration, manipulation or treatment of any human reproductive material for the purpose of creating an embryo (clause 10(1));
- the alteration, manipulation, treatment or making use of an *in vitro* embryo (clause 10(2));
- the acquisition, storage, transfer, destruction, import or export of sperm or ova (or part thereof) for the purpose of creating an embryo, or of an *in vitro* embryo for any purpose (clause 10(3));



- the combination of any part or proportion of the human genome specified in the regulations with any part of the genome of a species specified in the regulations (clause 11); and
- the reimbursement of expenditures incurred a) by the donors of sperm or ova, b) in relation to the maintenance or transport of *in vitro* embryos, or c) by surrogate mothers in relation to the surrogacy. A receipt would be required in relation to these expenditures (clause 12(1) and (2)). Surrogate mothers, however, could not be reimbursed for loss of work-related income unless a) a qualified medical practitioner certified in writing that their continuing to work might pose a risk to their health; and b) the reimbursement was made in accordance with the regulations and a licence (clause 12(3)).

In addition, clause 13 makes it an offence for licensees to carry out a controlled activity in premises that are not licensed for that purpose.

#### D. Privacy and Access to Information (Clauses 14 to 19)

These clauses pertain mainly to the collection of health reporting information and its maintenance in a personal health information registry. The health reporting information, defined in clause 2, concerns the identity, personal characteristics, genetic information and medical history of three groups of people – donors of human reproductive material and *in vitro* embryos, persons who have undergone assisted reproduction procedures, and persons who were conceived by means of those procedures. It also relates to information on the custody of donated human reproductive materials and *in vitro* embryos and the uses made of them.

Clauses 14 to 16 outline the requirements for licensees with respect to the health reporting information. Under clause 14(1), licensees are required to collect the health reporting information specified in the regulations before accepting a donation or performing a controlled activity. Clause 14(2)(a) requires the licensee to inform all relevant persons in writing of the requirements respecting the retention, use, provision and destruction of human reproductive material or *in vitro* embryos and the retention, use, disclosure and destruction of health reporting information before accepting a donation or accepting health reporting information. Clause 14(2)(b) and (c) requires licensees to make counselling services available to the relevant persons to the extent required by the regulations, to ensure that such persons receive the services and to obtain the latter's written consent regarding the handling of reproductive material and embryos, as well as the handling of health reporting information. In accordance with the regulations, licensees are also required to provide the relevant persons with information that

the Agency makes available to the public under clause 19(i) in relation to aggregated outcomes of assisted reproduction procedures performed by licensees (clause 14(2)(d)).

Clauses 15 and 16 set out the circumstances under which health reporting information must be or may be disclosed and includes a requirement in clause 15(3) to notify the Agency of all embryo transfers between licensees, in accordance with the regulations. Clause 16 also sets out the circumstances under which health reporting information must be or may be destroyed.

Clause 17 requires the Assisted Human Reproduction Agency of Canada, established by clause 21, to maintain a personal health registry containing the health reporting information.

Under clause 18(1), the Agency may use health reporting information, as well as other information relating to controlled activities, for the purposes of the administration and enforcement of the Act or for the identification of health and safety risks, potential and actual abuses of human rights, or ethical issues associated with AHR technologies. Clauses 18(2) to (8), in turn, set out the circumstances under which the Agency may or must disclose the health reporting information under its control, and the conditions of disclosure. As a rule, the health reporting information relating to a donor must be kept confidential unless the donor consents in writing to the disclosure (clause 18(2)). This rule, however, is subject to specified exemptions. For example:

- the Agency must, upon request, disclose to persons undergoing an AHR procedure or persons conceived by such means or their descendants, any “non-identifying” information relating to a donor unless the donor consents in writing to have his or her identity disclosed (clause 18(3));
- the Agency must disclose information on the nature of the relationship between any two individuals who believe that they are genetically related as a result of AHR and who apply in writing to the Agency to obtain the information (clause 18(4));
- the Agency must disclose health reporting information for the purpose of legal proceedings or to the extent required under federal and provincial health and safety laws specified in the regulations (clause 18(5));
- the Agency may disclose donor-identifying information to a physician where there is a health or safety risk to the person who underwent an AHR procedure or who was conceived by such means, or who is a descendant of the latter (clause 18(7)); and
- the Agency may disclose “non-identifying” information for scientific research or statistical purposes (clause 18(8)).

Clause 19 sets out the type of information that the Agency is required to make available for inspection by the public. Such information would be specified in the regulations and could include information relating to: the Act; the Agency; policy directions issued by the Minister; activities related to licences; aggregated outcomes of assisted reproduction procedures; measures to prevent, reduce or mitigate threats to human health or safety from controlled activities; enforcement agreements; equivalency agreements; and reports and documents monitoring and evaluating applicable developments. The details and the manner of making the information available for inspection by the public would also be prescribed in the regulations.

#### E. Responsibility of the Minister (Clause 20)

The Minister is responsible for federal policy respecting assisted human reproduction and any other matter relating to the subject-matter of the Act. He or she is also responsible for the Agency.

#### F. Assisted Human Reproduction Agency of Canada (Clauses 21 to 39)

Clause 21 establishes the Agency (Assisted Human Reproduction Agency of Canada) as a body corporate, subject to the *Official Languages Act*, with a head office at a place in Canada to be designated by the Governor in Council. The objectives of the Agency, outlined in clause 22, are:

- to protect and promote the health and safety, and the human dignity and human rights, of Canadians; and
- to foster the application of ethical principles.

The Agency is required by clause 23 to exercise its powers in a manner consistent with the principles set out in the statutory declaration in clause 2.

Clause 24(1) lays out the powers that the Agency may exercise. These are as follows:

- powers in relation to licences;
- advising the Minister;
- monitoring and evaluating developments in Canada and internationally;

- consulting persons and organizations;
- collecting, analyzing and managing health reporting information;
- providing information to the public and to the professions respecting assisted human reproduction and other matters covered by the Act and regulations, and respecting risk factors associated with infertility;
- designating inspectors and analysts; and
- doing anything reasonably necessary or incidental to achieving the Agency's objectives.

Under clause 24(2), at the Minister's request, the Agency is also required to provide: advice on issues pertaining to assisted human reproduction; non-identifying health reporting information; and general administration and management information about the Agency. Under clause 25, the Minister is authorized to issue policy directives to the Agency concerning the exercise of any of its powers, and the Agency is required to give effect to them. Such policy directives, however, could not affect a matter already before the Agency and relating to a particular person.

Clauses 26 to 32 focus on appointment criteria, terms of office, composition, remuneration, and responsibilities of the board of directors of the Agency. Thus, the board of directors may consist of no more than 13 members, including a Chairperson and the President of the Agency. Members must reflect a range of relevant backgrounds and disciplines. Except for the Chair and the President, members are appointed on a part-time basis for terms not exceeding three years (clause 26). The board of directors is required to meet at least twice a year (clause 27). The federal Deputy Minister of Health (or designated alternate) and equivalent or designated alternates from the provinces and territories are entitled to attend such meetings and speak to any matter under consideration (clause 28).

Clause 30 makes the board of directors responsible for the overall management of the Agency, including: provision of advice to the Minister; approval of goals and operational policies; approval of the budget; and evaluation of performance. Clause 32 sets out which powers (of the board or of the Agency) may be delegated to the Agency's President or to one of its committees, and those that may not be delegated.

Under clause 33, the board of directors may establish advisory panels, composed of board members or outside members, to examine, report on and make recommendations with respect to any issue referred to the panels by the board.

Both the Chairperson of the board of directors and the President of the Agency are to be appointed by the Governor in Council; the Chairperson for a term of not more than three years and the President for a term of not more than five years. Both are eligible for reappointment (clauses 34 and 36).

#### G. Administration (Clauses 40 to 44)

Clause 40(1) gives the responsibility for issuing licences for controlled activities to the Agency. This power must be exercised in accordance with the regulations. The Agency, however, is precluded from issuing a licence for research on *in vitro* embryos unless it is satisfied that the use of such embryos is necessary for the purpose of the proposed research (clause 40(2)). It is also precluded from issuing a licence for embryonic stem cell research unless it receives the written consent of the original gamete providers and the embryo provider in accordance with the *Human Pluripotent Stem Cell Research Guidelines* released by the Canadian Institutes of Health Research in March 2002, as specified in the regulations (clause 40(3.2)). Clause 40(3) covers the issuance of licences for clinical trials, while clause 40(4) specifies that each licence must designate an individual who is responsible under the Act. Clause 40(5) allows for licences to be issued to the owner or operator of premises used to carry out a controlled activity by another licensed person. Finally, clause 40(6) authorizes terms and conditions to be attached to licences, either at the time of issuance or at any time thereafter, while clause 40(7) disallows cost recovery in the issuance of licences.

Clauses 41 and 42 allow for the amendment, renewal, suspension and revocation of licences, in accordance with the regulations. Clause 43 states that the Agency, in exercising its licensing powers, may take into account any information or observations offered by any person, and may seek expert advice. The Agency must disclose such information and observations on request unless disclosure would pose a risk to anyone's health or safety. However, identifying information concerning donors, persons conceived through AHR or clients of AHR may not be disclosed, except to an applicant or licensee if deemed necessary to support an application. Persons offering information in good faith to the Agency for licensing decisions have immunity against civil and criminal proceedings related to the information given.

Clause 44(1) gives the Agency the power to take necessary measures to prevent, reduce or mitigate any threat to human health or safety resulting from, or expected to result from, a controlled activity. In so doing, the Agency may allow an inspector to take over management of the premises in question, and costs incurred by the inspector become the responsibility of the licensee (clauses 44(2) and (3)). Under clause 44(4), no person acting under this section may be held personally liable for those actions, unless carried out in bad faith.

#### H. Inspection and Enforcement (Clauses 45 to 59)

Clause 45 provides definitions of “information” and “material,” which apply to this part of the Bill (inspection and enforcement) as well as to the regulatory powers set out in clause 65.

Clause 46 empowers the Agency to appoint inspectors for the purpose of enforcing the Act. Inspectors must be appointed from among persons who are employed by the federal, provincial or territorial<sup>(4)</sup> governments or who have the qualifications specified in the regulations.

Clause 47 outlines the various powers of inspectors. Clause 48 deals with warrants for a dwelling-house; clause 49, with obstruction, false statements and interference with inspectors; clause 50, with seizure, storage and removal of material or information. Under clause 51(1), an application may be made within 60 days for the restoration of seized material or information, and restoration may be ordered either immediately or later by a provincial court judge in accordance with the criteria set out in clause 51(2) and (3). Clause 52 specifies when seized material or information is forfeited to the Crown, and states that the Agency is responsible for directing the manner of its disposal. In this connection, clause 54 requires the Agency to make reasonable efforts to preserve any viable sperm, ovum or *in vitro* embryo that is seized. Their disposal may take place only:

- with the consent of the donor in the case of human reproductive material, or, in any other case, the consent of the responsible person, as defined in the regulations; or
- in the manner specified in the regulations, if the Agency is unable to identify or contact the donor or responsible person.

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(4) The bill does not explicitly refer to the territories or the territorial governments. However, the latter are implicitly included by virtue of section 35(1) of the federal *Interpretation Act*, which provides that in every federal enactment, a reference to “province” includes the three territories.

If the donor or responsible person does not provide consent, clause 54(3) permits the Agency to return the material to the donor or responsible person or to dispose of it in the manner specified in the regulations.

Clauses 55 to 57 deal with the designation and role of analysts, and the use of any analyst's certificate in criminal proceedings.

Under clause 58, the Agency may enter into agreements with any department or agency of the federal government, a provincial or territorial government or with any law enforcement agency for the purpose of enforcing the Act. Under clause 59, the Agency is authorized to provide assistance in the investigation and prosecution of offences under the Act.

#### I. Offences (Clauses 60 to 64)

Under clause 60, a contravention of sections 5 to 9 (prohibited activities) is punishable on conviction on indictment by a maximum fine of \$500,000 or imprisonment for up to ten years, or both. On summary conviction, a maximum fine of \$250,000 may be imposed, or imprisonment for up to four years, or both.

Pursuant to clause 61, all other contraventions under the Act or regulations are punishable on conviction on indictment by a maximum fine of \$250,000 or imprisonment for up to five years, or both. On summary conviction, the punishment is a maximum fine of \$100,000 or imprisonment for up to two years, or both.

Clause 62 gives a sentencing court additional powers to order the forfeiture and disposition of material or information related to the offence. Also, on application of the Attorney General of Canada, the sentencing court may order the offender not to engage in any activity that might lead to the commission of an offence under the Act.

Consent by the Attorney General of Canada is a prerequisite to any prosecution under the Act (clause 63).

Under clause 64, the Agency may notify "any interested authority," such as a professional licensing or disciplinary body established under a federal, provincial or territorial law, of the identity of a person charged with an offence under the Act or who may have acted in breach of any professional code of conduct.

## J. Regulations (Clauses 65 to 67)

Clause 65 sets out the Governor in Council's regulatory powers. Regulations may be made in relation to 26 different matters, most of which supplement specific provisions of the Act. Notably, regulations may be made:

- defining who is a “donor” in relation to an *in vitro* embryo (clause 65(1)(a));
- governing the consent to be given for the use of human reproductive material or of an *in vitro* embryo, or for the purpose of removing human reproductive material intended to be used for the purposes of clause 8 (i.e., using human reproductive material to create an embryo or using an *in vitro* embryo for any purpose) (clause 65(1)(b));
- designating controlled activities or classes of controlled activities for which licences may be issued under clauses 10 and 11 (i.e., altering, manipulating or treating any human reproductive material for the purpose of creating an embryo; altering, manipulating, treating or making use of an *in vitro* embryo; storing, transferring, importing, etc., an *in vitro* embryo for any purpose, or human sperm or ova for the purpose of creating an embryo; or combining any part of the human genome with any part of the genome of another species) (clause 65(1)(c));
- specifying the reasonable expenditures that may be reimbursed under clause 12(1) to sperm and egg donors (clause 65(1)(e));
- respecting lost income that may be reimbursed to surrogate mothers under clause 12(3) (clause 65(1)(e.1));
- respecting the number of children that may be created from the gametes of a single donor through AHR procedures (clause 65(1)(g));
- respecting the terms and conditions of licences (clause 65(1)(h));
- respecting the issuance of licences for clinical trials of a controlled activity under clause 40(3), the conduct of such trials and related consent issues (clause 65(1)(i));
- respecting the issuance, amendment, renewal, suspension, restoration, and revocation of licences (clause 65(1)(k));
- respecting the collection, use and disclosure of health reporting information (clause 65(1)(o));
- respecting the counselling services to be received under clause 14(2)(b) in relation to the donation of human reproductive material or an *in vitro* embryo or the provision of health reporting information (clause 65(1)(p));



- specifying the notice that must be given to the Agency when an *in vitro* embryo is transferred from one licensee to another (clause 65(1)(s.1));
- respecting the destruction of health reporting information, human reproductive material or *in vitro* embryos under clause 16(2) or (3) (clause 65(1)(t));
- specifying the information to be made available for inspection by the public under clause 19 and the manner of its availability for inspection (clause 65(1)(v));
- prescribing the manner in which the Agency must dispose of human reproductive material, an *in vitro* embryo or a foetus (or any part thereof) under clause 54(2) or (3) (clause 65(1)(z));
- fixing an expiry date for the “grandfathered” controlled activities that could be carried out without a licence under clause 71 (clause 65(1)(aa)); and
- specifying the controlled activities or classes of controlled activities that may be exempted from the provisions of the Act, and prescribing related terms and conditions (clause 65(1)(bb)).

Clause 65(2) to (4) allows the regulations to incorporate any document by reference, including any amendments made to it from time to time; however, such incorporation by reference does not necessarily make a document a regulation within the meaning of the *Statutory Instruments Act*. Also, such documents, when available in both official languages, must have all subsequent amendments available in both languages before they are incorporated.

Clause 66 pertains to the parliamentary scrutiny of regulations. Subject to the exceptions set out in clause 67, clause 66 requires the Minister to lay proposed regulations before both Houses of Parliament. Such regulations must be referred to the appropriate committee of each House, which, in the case of the House of Commons, must be the Standing Committee on Health (or appropriate successor committee). Once they have been laid before Parliament, the proposed regulations may not be passed before one of the following deadlines has expired:

- 30 sitting days after being laid before Parliament;
- 160 calendar days after being laid before Parliament; or
- the day after which the committee of each House has reported its findings.

The Minister must take into account any committee report submitted. If the regulations do not incorporate a recommendation made by the committee of either House, the Minister must lay

before that House a statement of the reasons for not incorporating it. Any proposed regulation laid before Parliament need not be laid before Parliament again, whether it has been altered or not.

Clause 67, however, allows regulations not to be laid before Parliament if the Minister is of the opinion either that the change to an existing regulation is immaterial or insubstantial, or that the regulation must be made immediately to protect the health or safety of any person. In such cases, the Minister must lay an explanatory statement before each House.

#### K. Equivalency Agreements (Clauses 68 and 69)

Clauses 68 and 69 allow the provinces and territories to pass their own legislation and regulations related to assisted human reproduction as long as they are equivalent to the specified parts of this Act. Equivalency agreements, however, may not be entered into in relation to the prohibited activities under clauses 5 to 9 (as opposed to the controlled activities under clauses 10 to 13).

Specifically, clause 68 permits the Governor in Council to declare the non-application of certain sections of the Act in a province or territory if the Minister and the provincial or territorial government agree in writing that equivalent laws are in force in that jurisdiction. Such agreements will apply for five years or less and may be renewed. The Agency, however, may still take measures to prevent, reduce or mitigate any threats to human health or safety resulting from a controlled activity. Furthermore, even if such agreements are in place, persons carrying out an activity that is a controlled activity under the federal Act must comply with specified health reporting information requirements under the federal legislation. Finally, under clause 69, either party may terminate such an agreement upon giving six months written notice.

#### L. Parliamentary Review (Clause 70)

Clause 70 calls for a parliamentary review of the Act by any committee of the House or Senate, or both, established or designated for that purpose. The review must be carried out within three years of the coming into force of clause 21 (establishment of the Agency) and the ensuing report must be tabled within one year, or such other period that may be authorized.

M. Transitional Provision (Clause 71)

Clause 71 exempts from the licensing requirements any person who undertakes a controlled activity at least once during the period of one year preceding the coming into force of the provisions respecting controlled activities under clauses 10 to 13. Such “grandfathered” activities may be continued until such time as may be fixed by the regulations.

N. Consequential Amendments (Clauses 72 to 77)

These clauses require changes to several existing federal statutes as a consequence of the passage and coming into force of this legislation.

O. Coming into Force (Clause 78)

Clause 78 states that the Act comes into force on a day or days to be fixed by order of the Governor in Council.

COMMENTARY

The federal government has presented Canadians with a comprehensive piece of legislation that contains prohibitions and regulatory controls over assisted human reproduction activities and related research. As the chronology below outlines, this legislation has been a goal of the federal government for the last decade.

When presenting Bill C-56 (a predecessor to Bill C-6) in the 1<sup>st</sup> session of the 37<sup>th</sup> Parliament, the Minister of Health thanked the House of Commons Standing Committee on Health for its part in consulting with Canadians and for conducting a full review of earlier draft legislation. In a prepared response to the question of how this legislation differs from the recommendations made by the Standing Committee, it was noted that “the bulk and spirit” of the recommendations had been accepted.<sup>(5)</sup> The response went on to say: “It was only for the most compelling reasons – such as Charter considerations, important governance concerns, operational realities and concerns that the availability of AHR services not be compromised – that some of the Standing Committee’s recommendations were not incorporated.”

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(5) Health Canada, News Release, “Backgrounder Information: Proposed Act Respecting Assisted Human Reproduction – Frequently Asked Questions,” 9 May 2002.

In the days following the introduction of Bill C-56, media reports were mixed. One commented favourably on the effort of the government to balance “along the line separating the relentless advance of science from the inherent dignity of human life.”<sup>(6)</sup> Another noted that while the ethics of using “spare” *in vitro* embryos for stem-cell research was a hot topic, the debate had also “drawn welcome attention to the fertility problems of thousands of Canadians.”<sup>(7)</sup> Yet another argued that, by continuing to permit anonymous donations, the legislation compounded the mistake made by many provincial adoption laws and left resulting children to feel “the same acute lack of connectedness” as adopted children.<sup>(8)</sup>

Following its reinstatement as Bill C-13 (the predecessor to Bill C-6) in the fall of 2002, the bill continued to garner mixed reviews. Members of the medical and research community reiterated their concern that the bill would “criminalize” certain activities by enacting absolute prohibitions in relation to them. In their opinion, assisted human reproduction technologies and related research should be dealt with under the “controlled activities” category and made subject to regulatory controls, rather than being banned outright.

Other commentators argued that the bill should be limited to prohibitions only. Such was the position of the Bloc Québécois, whose Health critic introduced a motion in the House of Commons on 22 November 2002 to divide the bill in two and proceed only with those aspects of the legislation that were needed to support the prohibitions. In seeking the severance, the critic contended that the federal government lacked the constitutional jurisdiction to “control,” as opposed to “prohibit,” selected AHR activities. The former responsibility, he asserted, was a matter of provincial jurisdiction.

On balance, most witnesses appearing before the House of Commons Standing Committee on Health expressed general support for the bill and its classification of activities into two distinct categories, although there was disagreement on whether particular activities should constitute a prohibited or a controlled activity. Cloning is a case in point. Many witnesses felt that cloning for “therapeutic purposes” (i.e., aimed at the treatment of disease or medical conditions) should not be a prohibited activity under clause 5(1)(a), but should instead be a controlled activity under clause 10, to be carried out with a licence and in accordance with the

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(6) James Travers, “Tiptoeing on Stem Cells,” *The Chronicle-Herald* (Halifax), 17 May 2002.

(7) Charlie Fidelman, “Fertile Ground for Debate: Stem-cell Bill Draws Attention to Fecundity Decline,” *Montreal Gazette*, 11 May 2002.

(8) “Editorial,” *Calgary Herald*, 13 May 2002.

regulations. Cloning for “therapeutic purposes” should not be confused with cloning for “reproductive purposes.” The latter is aimed at replicating oneself essentially for the sake of it, with no underlying therapeutic purpose. No one advocated that cloning for “reproductive purposes” should be allowed.

There was also considerable debate on whether research on so-called “excess” *in vitro* embryos should be allowed. Clause 5(1)(b) prohibits the “creation” of *in vitro* embryos for any purpose other than creating a human being or improving or providing instruction in AHR procedures, but it does not prohibit their subsequent “use,” whether for research or other purposes. Such uses would come under the controlled activity category in clause 10(2) and would thus require a licence and compliance with the regulations.

Many witnesses, notably from the faith communities, strenuously opposed allowing research to be carried out on *in vitro* embryos. To do so, in their opinion, would be to treat such embryos as a commodity and would, in all events, result in the taking of a human life. Other witnesses, however, expressed strong support for allowing research on *in vitro* embryos no longer required for *in vitro* fertilization (IVF) because of their potential for alleviating human suffering and disease.

In its 2001 report *Assisted Human Reproduction: Building Families*, the House of Commons Standing Committee on Health had also expressed concern about the use of embryos for research purposes. However, recognizing their potential for medical breakthroughs, particularly in the area of stem cell research, the Committee recommended that research on embryos be allowed as a controlled activity, but only as a measure of last resort. Specifically, it recommended that:

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 14)

In response to the Committee’s recommendation, provision was made in clause 40(2) to permit the licensing of research on *in vitro* embryos only if the Agency was satisfied that their use was necessary for the purpose of the proposed research. Concerns were expressed about the perceived weak wording of the clause and amendments were proposed to change it. The amendments, however, were either defeated, not moved or withdrawn. In the end, the controversial clause was reported back to the House of Commons without amendment.

At Report Stage, however, the House of Commons adopted an amendment that places a further restriction on the issuance of licences involving research on embryos. It added new clause 40(3.2), which precludes the Agency from issuing a licence for embryonic stem cell research unless it receives the written consent of the original gamete providers and the embryo provider in accordance with the *Human Pluripotent Stem Cell Research Guidelines* released by the Canadian Institutes of Health Research in March 2002, as specified in the regulations. This new restriction, it should be noted, applies only to “stem cell research” on embryos. It is different from the restriction in clause 40(2), which applies to “all” research involving embryos.

Donor anonymity was a further area of concern under the bill. Although the bill generally allows health reporting information obtained from donors to be disclosed to persons undergoing an AHR treatment and to any offspring that might result, it does not, as a rule, allow “identifying” information on such donors to be disclosed under clauses 15 and 18, unless the donors consent in writing to the disclosure.

In its 2001 report, the Committee recommended an open system where donations could be accepted only from donors who were willing to have their identity disclosed (Recommendation 19). A number of witnesses who appeared before the Committee on the bill made a compelling case for an open system, based on the best interests of the child and the child’s need to know. There was no consensus on the issue, however, and the several amendments that were proposed to require disclosure of identifying information were defeated. The issue of donor anonymity, however, continued to be a sore point or concern for many MPs. On 1 April 2003, the Health critic for the Canadian Alliance party introduced a motion that the bill not be given third reading but that it be referred back to the Standing Committee on Health for the purpose of reconsidering clause 18 to allow children born through donor eggs and sperm to know the identity of their biological parents. This motion was defeated by a vote of the House of Commons on 29 April 2003.

A further recommendation made by the Committee in its 2001 report that was not fully implemented in the bill and that also proved to be controversial was in relation to the payment of donors and surrogates for services rendered.

Concerned about the commercialization and commodification of human gametes and human embryos, the Committee, in its 2001 report, flatly opposed any form of payment to donors and surrogates (Recommendations 10 and 13). The bill, in turn, although prohibiting various payments to donors, surrogates and intermediaries under clauses 6 and 7, would allow donors and surrogates to be reimbursed for their expenditures (clause 12), if backed up by a receipt and if done in accordance with the regulations and a licence. The government proposed

an amendment that would have relaxed the rule by permitting surrogates to be reimbursed for their “expenses” without having to provide a receipt, whereas more restrictive amendments were proposed by other Committee members. Although none of these amendments were passed in Committee, the House of Commons adopted an amendment at Report Stage, adding new clause 12(3). This new clause makes clear, on the one hand, that a surrogate mother’s loss of work-related income during her pregnancy is a reimbursable expenditure. On the other hand, it precludes reimbursement of such an expenditure unless a) a qualified medical practitioner certifies in writing that continuing to work might pose a risk to the surrogate mother’s health; and b) the reimbursement is made in accordance with the regulations and a licence (new clause 12(3)).

In the end, a total of 30 amendments were made to the bill in Committee, out of the 170 that were submitted (but not necessarily moved). Seventeen additional amendments were made by the House of Commons at Report Stage.

Although some commentators will argue that the bill remains flawed and must be improved, others will no doubt argue that, despite its shortcomings, the legislation is long overdue and should be passed as soon as possible. Indeed, the adoption of legislation on AHR and related research has been urged for over ten years. Some might argue that there is now even greater urgency to the passage of AHR legislation given recent claims by scientists of successfully creating a human clone.

#### BRIEF CHRONOLOGY OF RELATED FEDERAL GOVERNMENT ACTIONS

- 1989 - The Royal Commission on New Reproductive Technologies was established.
- 1993 - The Royal Commission made 293 recommendations, the majority requiring action by the federal government.
- 1993-1996 - A Federal/Provincial/Territorial Working Group on Reproductive and Genetic Technologies (RGT) was established with Health Canada support to advise the Deputy Ministers of Health.
- 1995 - A voluntary moratorium on specific RGTs was announced by the Minister of Health.
- 1996 - The Advisory Committee on Reproductive and Genetic Technologies was established by the Minister of Health to advise Health Canada on moratorium compliance and other developments.

- 1996 - Regulations for the processing and distribution of semen for assisted conception were implemented by Health Canada.
- 1996 - Bill C-47, the proposed Human Reproductive and Genetic Technologies Act, was introduced by the Minister of Health to prohibit specified reproductive and genetic practices.
- 1996 - A discussion paper entitled *New Reproductive and Genetic Technologies: Setting Boundaries, Enhancing Health* was released by Health Canada, proposing a regulatory framework for national standards on permissible practices.
- 1997 - Bill C-47 died on the Parliament of Canada *Order Paper* at the call of the 1997 federal election.
- 1998 - The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* was produced by the Medical Research Council, Natural Sciences and Engineering Research Council, and Social Sciences and Humanities Research Council.
- 1999 - An overview paper on reproductive and genetic technologies was prepared by Health Canada to further the discussion on the proposed approach and management of a regulatory framework.
- 2000 - Health Canada released a discussion paper that outlined options for potential legislation, including both prohibited and regulated practices.
- 2001 - The Government of Canada's *Proposals for Legislation Governing Assisted Human Reproduction* were presented for study to the House of Commons Standing Committee on Health. The Committee issued its report in December 2001.
- 2002 - The Canadian Institutes of Health Research (CIHR) issued guidelines governing CIHR-funded embryonic stem-cell research.