Unlike many other countries, Canada currently has no substantial legislative controls on the spectrum of reproductive technologies used to assist in human conception and to manipulate human genetic material for reproductive purposes.

Despite the four years and almost $28 million that led to the 1993 report of Canada’s Royal Commission on New Reproductive Technologies (RCNRT), there are no well-defined boundaries around the use of reproductive and genetic technologies. (1) Entitled Proceed with Care, the RCNRT report recommended immediate regulation to protect the interests of all Canadians. Many other countries had already reached similar conclusions, and had moved to regulate the practices that had grown rapidly since the birth of the first “test-tube” baby in the late 1970s.

**Canada’s Actions**

Since the 1993 RCNRT report, the federal government has taken several actions, but few have had any regulatory outcome. For example:

- 1993-1999 – Federal/Provincial/Territorial Working Group on Reproductive and Genetic Technologies (RGTs) established to advise the Deputy Ministers of Health.

- 1995 – Interim moratorium on specific RGTs announced; this voluntary moratorium applied to germ-line genetic alteration; human embryo cloning; buying and selling of eggs, sperm and embryos; egg donation in exchange for in vitro fertilization services; retrieval of eggs from cadavers and fetuses for donation, fertilization or research, etc.

- 1996 – Advisory Committee on Reproductive and Genetic Technologies established to advise Health Canada on moratorium compliance and other developments.

- 1996 – Regulations implemented for the processing and distribution of semen for assisted conception.

- 1996-1997 – Bill C-47, The Human Reproductive and Genetic Technologies Act, introduced to prohibit unacceptable RGT practices including cloning, surrogacy, non-medical sex selection, commercialization of gametes and embryos, maintenance of embryos outside the womb, post-mortem retrieval of gametes, embryo transfer between humans and other animals, and research on gametes or embryos without donor consent. The Bill dies on the Order Paper at the call of the 1997 federal election.

- 1996 – Minister of Health releases a discussion paper entitled New Reproductive and Genetic Technologies: Setting Boundaries, Enhancing Health, proposing a regulatory framework for national standards on permissible practices such as in vitro fertilization, donor insemination, use of fetal tissue, storage and donation of gametes and embryos, and embryo research including pre-implantation diagnosis.

- 1997 – Canada signs the UNESCO Universal Declaration on the Human Genome and Human Rights; also agrees with G-7 position on the need for a prohibition of nuclear transfer for human cloning.


This is the paper version of a Web document which is available online at http://intraparl/36/map_sv_lib-e.htm
1999 – Health Canada officials prepare an overview paper on reproductive and genetic technologies to further the discussion on the proposed approach and management of a regulatory framework.

2000 – Health Canada prepares a discussion paper entitled Reproductive and Genetic Technologies which outlines options for potential legislation. It includes proposed outlines of both prohibited and regulated practices.


March 2002 – the Canadian Institutes for Health Research present guidelines for embryonic stem cell research, making this research eligible for federal funding.

9 May 2002 – Bill C-56, The Assisted Human Reproduction Act, is tabled. At the time of summer recess, the bill had received second reading in the House of Commons and was at Committee stage.

International Comparison

The vast spectrum of reproductive technologies ranges from the very simple to the highly specialized and complex. For example, drug treatments to induce ovulation are simple and under the patient’s control, while in vitro fertilization is invasive to the patient. Genetic manipulation procedures are anticipated to be complicated for the near future. These procedures are available not only to those who are infertile, but also to those who are fertile but want to avoid producing a child with a genetically inheritable disease. Each of them raises particular medical, ethical, social and economic considerations; and each of them needs to be assessed from a legislative and regulatory perspective.

The following information compares the legislative and regulatory approaches taken in various countries by outlining:

- general legislative approaches in countries such as Australia and the United States that, like Canada, are federations;
- specific legislation of some European countries such as Denmark, Germany, Spain, Sweden, Switzerland and the United Kingdom (see Appendix 2 for a tabular comparison of the legislation in several European countries); and
- resolutions and conventions adopted by international organizations of which Canada is a member.

Australia and the United States

In these federal countries, individual states (or territories) have taken the lead in legislating reproductive and genetic technologies within their jurisdictional boundaries. Like Canada, their federal governments have a constitutionally defined role in health matters. As a result, national regulatory standardization requires careful collaboration with all levels of government.

Federally, Australia has invoked a ban on reproductive cloning. In April 2002 the Prime Minister of Australia instructed the Premiers that embryos could be used for stem cell research and that legislation would be drafted both to ban all cloning and also to set out the conditions pertaining to and governing the use of embryos for research purposes. On 27 June 2002, the bill was introduced in federal Parliament. Once passed, State legislation will have to be consistent with the federal framework.

Three Australian states (Victoria, South Australia, Western Australia) have comprehensive legislation. In 1984, the State of Victoria set a precedent in the common law world when it passed the Infertility (Medical Procedures) Act. This legislation covered diverse issues including the identity of sperm donors, counselling for prospective parents, embryo research,
and surrogacy; it also established a Standing Review and Advisory Committee to monitor and advise on any developments.

This legislation was replaced in 1995 by the *Infertility Treatment Act*, which contained most of the earlier Act but prohibited all destructive embryo research. It also required that the newly formed Infertility Treatment Authority be responsible for the issuing of licences to all centres, doctors, counsellors and researchers involved in reproductive technology practices.

New South Wales is currently considering similar legislation. It is reviewing its *Human Tissue Act 1983*, deciding whether to include assisted reproductive technologies. Five of Australia’s six states and the Australian Capital Territory have legislation pertaining to surrogacy.

The United States has no federal legislation regarding reproductive technologies except a requirement for all fertility clinics to report on pregnancy success rates. Several variations on bills banning cloning have been introduced federally in the United States. Although a bill banning all forms of cloning passed in 2001 in the House of Representatives, it was defeated in the Senate in 2002. Currently, a bill has been introduced that would ban only reproductive cloning.

Most states have passed legislation of varying degrees of comprehensiveness in this area; and they regulate reproductive technologies through their state health departments or permit self-regulation by professional bodies. Arkansas, for example, has legislation pertaining to determination of the legal parents in the case of artificial insemination. Florida also has comprehensive legislation, which deals with the determination of parentage. The American Society for Reproductive Medicine provides some information on state legislation pertaining to insurance coverage.

Presidential attempts at invoking a “Human Cloning Ban” have been unsuccessful. Federal legislative initiatives tend to be via voluntary moratoriums and refusal to fund certain research activities. For example, current federal law prohibits the use of federal funds to harm human embryos. This includes embryonic stem cell research. On 9 August 2001, the President declared that no federal funds could be used to conduct embryonic stem cell research, except on cell lines already in existence on that date.

**Europe**

Several European countries have legislation pertaining to reproductive and genetic technologies. Early efforts focused on medically assisted reproduction, while more recent actions have focused on genetic manipulations.

Sweden achieved one of the earlier attempts at regulation when it passed the *Insemination Act* in 1985. However, the purpose of this Act was not to restrict medically assisted reproduction but to protect resulting children in terms of the parents’ identities and responsibilities, both social and biological. Sweden has since introduced legislation pertaining to *in vitro* fertilization (1989) and the prohibition of human cloning (1991).

Spain, Germany, the United Kingdom and more recently Denmark followed with increasingly encompassing legislation. Broadly speaking, human cloning and embryo research are prohibited or severely restricted; the post-mortem use of eggs, sperm and embryos (stored cryogenically or extracted) is not permitted. Access to reproductive techniques is largely reserved for married, or long-time, heterosexual couples. The U.K. appears to have the most lenient legislation. It does not prohibit cloning outright, but recent legislation prohibits transferring a cloned embryo into a women. The table in Appendix 2 provides more specifics on these issues, as well as on pre-implantation diagnosis, surrogacy, inter-species hybrids, licensing of fertility clinics, etc.

**International Organizations**

Like other countries, Canada participates as a member or an observer in several international organizations that seek to achieve uniformity of practice beyond individual country borders. In these organizations with either select or broad-based membership, the
goal is often to develop and eventually achieve country-by-country ratification of international instruments and recommendations through legal adoption as national legislation.

The United Nations provides the dominant example in the area of reproductive and genetic technologies through the work of the United Nations Educational, Scientific and Cultural Organization (UNESCO) and the World Health Organization (WHO). For example, UNESCO declared its position on human cloning in the 1997 Universal Declaration on the Human Genome and Human Rights. This Declaration strictly prohibits reproductive human cloning and is signed by all UNESCO members, including Canada. The WHO passed a resolution in 1997, in which Canada joined the consensus, affirming that the use of cloning for the replication of human individuals is ethically unacceptable and contrary to human integrity and morality.

Conclusion

As this information suggests, Canada had many regulatory models to consider as examples for legislative action. Several countries are currently reviewing existing legislation, while others are considering initiating legislation in this area. The information provided in this document is current up to July 2002.

The RCNRT recommended the establishment of a national commission which would scrutinize all procedures and research on reproductive and genetic technologies. It argued that the following practices would be essential components: oversight of licensing and monitoring; guideline and standard setting; information collection, evaluation and dissemination; records storage; monitoring of future technologies and practices; and consultation, co-ordination and intergovernmental co-operation. If Canada does establish a comprehensive national authority, as proposed in Bill C-56, to oversee the full range of reproductive and genetic technologies, it could be a world leader in this area.

Notes

(1) Reproductive technologies include practices and research that manipulate the normal conception process, including donor insemination and in vitro fertilization.

Genetic technologies are techniques involving the examination or manipulation of eggs, sperm, embryos or other human genetic material for use in reproduction.

Most technical terms used in this document are defined in Appendix 1.
APPENDIX 1

Glossary of Terms(1)

Animal-Human Hybrids: The joining together of a human egg or sperm with an egg or sperm from an animal to create an embryo. To date, only animal-animal hybrids have been created.

Assisted Insemination: The process of inserting sperm from a woman’s husband or partner into her vagina or uterus by means other than sexual intercourse in order to achieve pregnancy.

Assisted Reproduction: The use of any new reproductive technology (NRT) for the purpose of overcoming infertility to produce a child (e.g., in vitro fertilization (IVF), assisted insemination, donor insemination, etc).

Bioethics: The development of judgements and compromises in order to produce guidelines and policies in matters of medicine and the life sciences.

Cloning: Producing genetically identical animals.

Donor Insemination: The process of inserting donor sperm into a woman’s vagina or uterus by means other than sexual intercourse in order to achieve pregnancy.

Ectogenesis: Growing a fetus to term in an artificial uterus or womb.

Egg Donation: The donation of one woman’s egg(s) to another woman. Eggs are usually removed from the ovary after the use of fertility drugs. An egg donor could be a healthy volunteer or a woman undergoing sterilization, hysterectomy or egg retrieval for her own reproduction. The egg donor is the genetic mother of any resulting child but she is not the woman who gives birth.

Embryo (human): In reproductive technology terminology, embryo refers to the developing structure from fertilization of the egg until about eight weeks of gestation. Traditionally, the embryonic stage of development begins when the structure becomes implanted in the uterus.

Embryo Research: Examination or manipulation of human embryos at the early stages of development (generally up to 14 days). Rationales for such research include improvement in infertility treatment (including IVF), increased knowledge of genetic diseases and improved contraception, and more recently for stem cell research.

Fertility Drugs: Compounds used to treat ovulatory dysfunction or to stimulate multiple ovulation, as in IVF.

Fetal Tissue: Tissue retrieved from fetal cadavers, for the purposes of research or transplantation (e.g., to adults with Parkinson’s disease).

Fetus (human): The developing human from about eight weeks after conception to birth.

Gamete: The mature male or female reproductive cell (sperm are the male gametes; eggs are the female gametes).

(1) Information derived from Health Canada’s June 1996 publication New Reproductive and Genetic Technologies: Setting Boundaries, Enhancing Health, Appendix B.
**Genetic Screening:** Use of tests to acquire genetic information about those who are at increased risk for having an inherited trait or disease.

**Genetic Technologies:** Techniques that involve the examination or manipulation of human hereditary material. Examples include germ-line genetic alteration and prenatal diagnosis (PND).

**Germ-Line Genetic Alteration:** The manipulation of the genetic material contained within the egg, sperm or embryo. Any changes to the germ-line may be passed on to the next generation.

**Human Embryo Cloning:** The process of dividing an embryo into sections, so that the genetic material is also divided among the separate parts. Resulting embryos are identical to each other in genetic makeup.

**In Vitro Fertilization (IVF):** Mature eggs are removed from a woman’s ovary, and fertilized with sperm. After fertilization and incubation, the fertilized egg is placed in the woman’s uterus. The embryo may also be transferred to another woman.

**Infertility:** The inability of a woman to have a live birth or of a man to impregnate his female partner over a period of time of about one to two years.

**Pre-Implantation Diagnosis:** Diagnosis of genetic disorders or fetal sex in an embryo formed through IVF before it is transferred to the uterus.

**Prenatal Diagnosis (PND):** Testing before birth to determine whether a fetus has a malformation or disorder; the sex of the fetus can also be determined.

**Reproductive Technology:** Technique or procedure used to overcome infertility.

**Retrieval of Eggs and Sperm from Fetuses and Cadavers:** The removal of eggs from fetuses obtained through abortion or miscarriage, and the removal of sperm from cadavers.

**Sex Selection for Non-Medical Reasons:** The use of various techniques either before or after conception to ensure the birth of a child of the desired sex. These techniques can also be used for medical reasons to prevent the birth of a child with a sex-linked disorder.

**Somatic Cell Gene Therapy:** The manipulation of the genetic material in body cells other than eggs and sperm (and embryos) to treat genetic disease. The effects of treatment are not passed on to the next generation.

**Surrogacy (or Preconception Arrangements):** An arrangement made before conception in which a child is to be produced for transfer from the woman who gives birth to another person or persons. The woman who gives birth may or may not receive some form of compensation, usually a monetary payment. There are two types of surrogacy:

- **Genetic surrogacy:** A woman is artificially inseminated, carries the pregnancy to term, and hands the baby over to the father and his wife or partner, if he is married, for adoption. The woman who gives birth to the child is the baby’s genetic mother.

- **Gestational surrogacy:** A woman undergoes IVF to receive and carry to term an embryo made up of another woman’s egg. She is not the genetic mother of the child. The couple whose egg and sperm produced the embryo then adopt the baby.
## APPENDIX 2

### Comparative Table of International Legislation on Reproductive Technologies

<table>
<thead>
<tr>
<th>Country</th>
<th>Year</th>
<th>Legislation</th>
<th>Details</th>
<th>Authority</th>
</tr>
</thead>
</table>
| Denmark | 1997 | Law no. 460 on “Medically assisted procreation in connection with medical treatment, diagnosis and research” | • Couples only (women under 45 years).  
• Prohibits: human cloning, post-mortem embryo transfer and insemination.  
• Permits embryo research (with restrictions). | |
| France  | 1994 | Law no. 94-654 relating to “…medically assisted procreation and prenatal diagnosis” | • Couples only.  
• Parental rights over stored embryos for five years.  
• Guarantees anonymity of gamete donors.  
• Prohibits: embryo research, post-mortem embryo transfer and insemination, mixing of gametes from more than one person.  
• Limits multiple births to five.  
• Permits genetic prenatal diagnosis only for medical purposes. | National Advisory Committee on Ethics for Life Sciences and Health. |
| Germany | 1990 | *Federal Embryo Protection Act: Directives of the Federal Order of Practitioners of Assisted Reproduction* | • Married couples (by directive).  
• Prohibits: human cloning, embryo research, post-mortem insemination, pre-implantation diagnosis. | |
• Permits embryo research; also permits embryo research on non-viable (or dead) embryos older than 14 days and on fetuses. | |
<p>|         | 1995 | Law no. 10 (Penal Code): “Genetic Manipulation” | | |
|         | 1998 | Law no. 42: “Use and Donation of Embryonic Tissue” | | |</p>
<table>
<thead>
<tr>
<th>Country</th>
<th>Year</th>
<th>Act</th>
<th>Prohibitions</th>
<th>Reporting Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sweden</td>
<td>1985</td>
<td><em>Insemination Act</em></td>
<td>• Protection of the child.</td>
<td>All fertility clinics report yearly to the National Board of Health and Welfare</td>
</tr>
<tr>
<td></td>
<td>1989</td>
<td><em>In Vitro Fertilization Act</em></td>
<td>• Married couples.</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Prohibits cloning.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Permits somatic cell gene therapy but prohibits germ-line genetic alteration.</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Allows embryo research on embryos less than 14 days old, must be destroyed after.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Prohibits: human cloning, embryo research, post-mortem embryo transfer and insemination, pre-implantation diagnosis.</td>
<td></td>
</tr>
<tr>
<td>United Kingdom</td>
<td>1990</td>
<td><em>Human Fertilisation and Embryology Act</em></td>
<td>• Prohibits only one form of human cloning.</td>
<td>Human Fertilisation and Embryology Authority (Code of Practice).</td>
</tr>
<tr>
<td></td>
<td>(modified in 1992)</td>
<td></td>
<td>• Allows embryo research (excluding stem cell research) on embryos less than 14 days only.</td>
<td>Determines the practices to be allowed.</td>
</tr>
<tr>
<td></td>
<td>2001</td>
<td><em>Human Reproductive Cloning Act</em></td>
<td>• Licensed clinics.</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>• Counselling of parents and consideration of potential child’s welfare.</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Informed consent.</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Prohibits implanting a cloned embryo into a woman</td>
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</tr>
</tbody>
</table>

Notes:
- Couples – refers only to heterosexual couples.
- Embryo research, where permitted, pertains strictly to embryos less than 14 days old.
- All countries prohibit the commercialization of any practices.