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## BACKGROUND PAPER



# Legal Status at the Federal Level of Assisted Human Reproduction in Canada

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(Background Paper)

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# LEGAL STATUS AT THE FEDERAL LEVEL OF ASSISTED HUMAN REPRODUCTION IN CANADA

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## 1 INTRODUCTION

The world's first "test-tube baby," the result of fertilizing a human ovum *in vitro* and transferring the resulting embryo to a woman's uterus, was born in England in 1978. This achievement followed decades of clinical and laboratory research. It also catalyzed interest in a new area of medical ethics as multiple technological advances, along with their implications for genetics, posed new ethical questions and responsibilities.

This paper provides an overview of the many steps that the Canadian federal government has taken to establish a legislative and regulatory framework for reproductive technologies and related research. This background includes a description of the Royal Commission on New Reproductive Technologies, early attempts at legislation and a discussion of the *Assisted Human Reproduction Act*, in force since 2004, including its list of prohibited activities. The constitutional challenge to the legislation that was brought by the Attorney General of Quebec and ultimately heard by the Supreme Court of Canada is reviewed. Finally, the federal government's response to the Supreme Court decision in the form of amendments to the Act is summarized. This paper does not examine how activities related to assisted human reproduction may be regulated by the provinces.

## 2 BACKGROUND

### 2.1 EMERGENCE OF NEW REPRODUCTIVE TECHNOLOGIES IN CANADA

The birth of the first infant conceived through *in vitro* fertilization (IVF) marked a new era for medical science. The term "new reproductive technologies" (NRTs) was coined to encompass a growing range of techniques to manipulate human reproductive biology. Couples faced with fertility challenges began to realize that they could explore NRT options, as well as adoption, in order to build their families. IVF, as well as artificial insemination, which has been practised for many years, also provided the opportunity for individuals without partners, as well as same-sex couples, to conceive and bear biological offspring. The practice has also extended to the use of gestational surrogates.

Many stakeholders have emphasized that NRTs raise ethical questions that need to be carefully explored. Others have claimed that the right to autonomy in reproductive choices relieves society of the need to resolve some of these perceived ethical struggles.<sup>1</sup> From a health perspective, concerns have been expressed that the long-term effects of NRTs are not clear and that a cautious approach supported by research on these effects is needed.<sup>2</sup>

## 2.2 THE BAIRD COMMISSION

In response to these mounting concerns and pressure from women's groups, religious groups, medical and legal professional groups, academics and NRT advocacy groups, the federal government appointed the Royal Commission on New Reproductive Technologies in October 1989. The mandate of the Commission was to conduct a comprehensive study and to report on developments in medical science related to new reproductive technologies, along with their social, ethical, health, research, legal and economic implications.<sup>3</sup>

The Commission, chaired by Dr. Patricia Baird, held public hearings across the country and received submissions from a multitude of stakeholders and interested parties; in November 1993 the Commission presented its final report, *Proceed with Care*, to the Governor General. The Commission recommended statutory prohibitions of several activities and the creation of a regulatory framework to ensure that NRTs are provided in a safe, ethical and accountable way. Further, the report recommended the creation of the National Reproductive Technologies Commission to develop and apply NRT policy in the national public interest. The report provides considerable detail on how to implement these main recommendations.<sup>4</sup>

## 2.3 INITIAL FEDERAL RESPONSES

As a preliminary response to *Proceed with Care*, the Minister of Health announced a voluntary moratorium<sup>5</sup> in July 1995 on nine practices specified in the report. This moratorium was described as a first step in the development of legislative prohibitions. The medical and research communities were asked to refrain from the following:

- cloning of human embryos;
- commercial preconception or “surrogacy” arrangements;
- buying and selling of eggs, sperm and embryos;
- egg donation in exchange for *in vitro* fertilization services;
- germ-line genetic alteration (genetic alteration that can be passed to subsequent generations);
- ectogenesis (creation of an artificial womb);
- sex selection for non-medical purposes;
- creation of animal/human hybrids; and
- retrieval of eggs from cadavers and fetuses for donation, fertilization or research.

In 1996, the Minister of Health introduced Bill C-47, an Act respecting Human Reproductive Technologies and Commercial Transactions relating to Human Reproduction (the Human Reproduction and Genetic Technologies Act). The bill was described as the first step of a two-step legislative process. A second bill, which would address the broader regulatory framework and place restrictions around a variety of other practices, was to be introduced at a later date; however, this process did not go forward.

Bill C-47, which died on the *Order Paper* in April 1997 at the dissolution of the 35<sup>th</sup> Parliament, proposed to prohibit those practices already banned under the moratorium, but included additional ones.<sup>6</sup> These were as follows:

- transfer of embryos between humans and another species;
- research on embryos beyond 14 days of development;
- creation of embryos solely for research purposes;
- use of human eggs, sperm or embryos for a reproductive procedure or for medical research without the informed consent of the donor; and
- offers to provide or pay for any prohibited practices.

## 2.4 RESEARCH GUIDELINES

Once the technology existed to create embryos through artificial means in the laboratory, controversy arose concerning the use of such embryos in research. Discussions of human embryonic research usually refer to the use of supernumerary (extra) embryos, those otherwise destined to be discarded when they are no longer required for *in vitro* fertilization. However, although many scientists maintain that these embryos are not produced *specifically* for research purposes, others point out that it is a simple thing to “overproduce” embryos for assisted reproduction with the intention of having many left over for research.

One of the uses of embryos in research is as a source of stem cells. Stem cells are undifferentiated cells that have the potential to develop into specialized cells. Pluripotent stem cells can, theoretically, become any type of cell, such as nerve cells, blood cells or liver cells. Stem cells removed from embryos are known to be pluripotent, whereas stem cells from adults, fetuses and umbilical cord blood are able to differentiate only into certain cell types. The allure of stem cell research is the potential to manipulate cells to grow into transplantable tissue or organs, potentially enabling the prevention, treatment or cure of several disorders.

During the same period, Canada’s three research funding agencies<sup>7</sup> were developing a set of ethical standards for research involving human beings. Their *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, released in 1998, contained specific guidelines for research involving the use of embryos and other reproductive material. Providing greater detail and clarification in this field was the publication in 2002 of *Guidelines for Human Pluripotent Stem Cell Research* (the Stem Cell Guidelines) by the Canadian Institutes of Health Research (CIHR). These guidelines, which are regularly updated, govern research involving embryonic stem cells that is either funded by CIHR or is conducted in an institution that receives CIHR funding. In 2014, the Stem Cell Guidelines were integrated into the revised Tri-Council Policy Statement.<sup>8</sup>

## **2.5 HISTORY OF CANADA'S ASSISTED HUMAN REPRODUCTION ACT**

The federal department of health (Health Canada) issued overview and discussion documents in the late 1990s on reproductive and genetic technologies and outlined options for legislation and regulatory oversight. After a public consultation process, the Minister of Health tabled, in May 2001, draft legislation on assisted human reproduction in the House of Commons. The House of Commons Standing Committee on Health (Health Committee) undertook a thorough study in order to recommend any necessary changes, including proposals for a regulatory body mandated to implement the legislation and future regulations, monitor developments and advise the Minister on future changes.

The Health Committee responded with 33 recommendations,<sup>9</sup> many of which were incorporated into the Government's response in the form of Bill C-56, an Act respecting Assisted Human Reproduction, which was tabled in 2002. The bill would establish a legislative and regulatory framework to address issues relating not only to assisted human reproduction but also to research involving human embryos produced artificially (*in vitro* embryos). The bill set out a number of prohibited practices as well as a licensing framework for controlled activities. Because of prorogations during the 37<sup>th</sup> Parliament, this bill was tabled two more times, each time at the stage that it had previously reached and in the same form.<sup>10</sup> On 29 March 2004 the *Assisted Human Reproduction Act* (AHRA)<sup>11</sup> received Royal Assent, and on 22 April of that year most of the prohibitions listed in the statute (sections 5 to 7 and 9) came into force. The Agency responsible for implementing the Act, the Assisted Human Reproduction Agency, was established in 2006.

The Assisted Human Reproduction Implementation Office (AHRIO) was established within Health Canada to draft regulations pursuant to the Act. Although AHRIO indicated shortly after it was created that public consultations on several regulatory issues would be carried out, public input has been sought for only a few issues, and only regulations pursuant to section 8 (consent) have been implemented.

The Government of Canada appealed a Quebec Court of Appeal decision regarding the constitutionality of the Act to the Supreme Court of Canada in 2008. At that time Health Canada indicated that it would not pre-publish further proposed regulations until the question was resolved.<sup>12</sup> This constitutional challenge is discussed below.

## **3 CHALLENGING THE VALIDITY OF CERTAIN PROVISIONS OF THE ASSISTED HUMAN REPRODUCTION ACT**

During consideration of Bill C-6 and its predecessor, C-13, the government of Quebec had expressed the opinion that sections of the bills encroached on the exclusive legislative authority of the provinces. After the bill received Royal Assent, the Attorney General of Quebec submitted a constitutional question to the Quebec Court of Appeal challenging the validity of certain provisions of the *Assisted Human Reproduction Act*.<sup>13</sup>



Initially, only sections 8 to 12 of the AHRA were disputed as being *ultra vires* (outside the legislative power of) Parliament; this was later expanded to include sections 13 to 19, 40 to 53, 60, 61 and 68. The Attorney General of Quebec never argued that section 5 (which includes prohibiting human cloning and creating an embryo *in vitro* for a purpose other than creating a human being), section 6 (prohibiting payment for surrogacy and establishing other restrictions relating to surrogacy) or section 7 (which includes prohibiting the purchase of gametes, and prohibiting the purchase and sale of *in vitro* embryos) was *ultra vires* Parliament. The Quebec Court of Appeal decision was ultimately considered by the Supreme Court of Canada. Both decisions are summarized below.

### 3.1 THE QUEBEC COURT OF APPEAL DECISION

The constitutional question submitted by the Attorney General of Quebec was answered by the Quebec Court of Appeal on 19 June 2008. All three justices of the Court of Appeal agreed that the provisions in question were *ultra vires* the Parliament of Canada. To reach that conclusion, the judges described the analysis that was required to determine whether a statute was validly enacted and respected the division of powers set out in the *Constitution Act, 1867*. First, the dominant characteristic (the “pith and substance”) of the law or provision had to be determined. This involves examining the purpose of the statute as well as its legal effect. Once the dominant characteristic was identified, the constitutional power or powers that most closely relate to that characteristic must be identified.

Before embarking on its constitutional analysis of the impugned provisions, the Court reviewed the division of legislative powers generally as well as how they relate to health.

#### 3.1.1 DIVISION OF LEGISLATIVE POWERS

The Court emphasized that determining the head of power to which a statute or provision relates is not an exact science, and that a statute’s or provision’s encroachment on a matter outside of the jurisdiction of the legislative body that enacted it does not necessarily mean that it is invalid. In such a case, the Court needs to determine whether the statute or provision is part of a valid legislative scheme and whether it is sufficiently integrated with that scheme. In addition, since the classes of subjects set out in the *Constitution Act, 1867* are not “watertight compartments,” there may be instances where one level of government validly enacts legislation with respect to one aspect of a subject (such as health) and another level of government validly enacts legislation with respect to another aspect of that subject.

##### 3.1.1.1 PROVINCIAL JURISDICTION RELATING TO HEALTH

The Court pointed to four headings of power contained in sections 92 and 93 of the *Constitution Act, 1867* as the basis for jurisdiction of provinces in matters relating to health care. These provisions are:

- section 92(7) – exclusive responsibility to the provinces of the establishment, maintenance and management of health institutions, namely, hospitals, asylums, charities and eleemosynary institutions, other than marine hospitals;

- sections 92(13) and 92(16) – together, these provisions “give the provinces jurisdiction over the civil aspects of medical practice and the doctor-patient relationship, and have been recognized as having the power to establish and manage hospital systems, health insurances, and hospitalization insurance”;<sup>14</sup> and
- section 93 – exclusive provincial jurisdiction in relation to education, without restriction with regard to the nature and scope of this matter in Quebec.

### 3.1.1.2 THE CRIMINAL LAW POWER AND PARLIAMENTARY JURISDICTION RELATING TO HEALTH

Parliament can make laws in relation to some aspects of health by relying on its residual power to make laws for peace, order and good government, its general spending power and the criminal law power. It is the criminal law power that the Attorney General of Canada relies on as the basis for the *Assisted Human Reproduction Act*.

The Court described a crime in the following manner:

[A] crime is an act that is prohibited because it constitutes an evil or has an injurious or undesirable effect on the public. The prohibition exists to prevent the evil or to safeguard the interest threatened by the injurious or undesirable effect of the action. It must have a legitimate public purpose relating to the criminal law.<sup>15</sup>

There may be exceptions to the prohibitions that can be defined in regulations, and creating exceptions does not necessarily mean that Parliament is attempting to regulate a provincial matter. However, “the exemption must merely permit derogation from the general prohibition and not constitute the basis of the statute in question ... [t]hat is the difference between a criminal law and a regulatory statute.”<sup>16</sup>

### 3.1.2 PURPOSE AND EFFECTS OF THE *ASSISTED HUMAN REPRODUCTION ACT*

After reviewing the context of the AHRA, the Court concluded that the legislation was not a valid exercise of Parliament’s criminal law power:

The question is not whether the Act is good or bad, or whether it achieves its objectives or not, but whether its purpose is criminal in nature. In the present case, with the exception of the outright prohibitions, the record reveals no “evil” that needs to be repressed. Rather, it establishes the intent to control the clinical and research aspects of a medical activity in order to create a uniformity that is considered to be desirable. The appropriateness of a single piece of legislation applying to Canada as a whole and regulating a permitted and recognized activity is not a purpose that confers criminal law jurisdiction.<sup>17</sup>

## 3.2 THE SUPREME COURT OF CANADA DECISION

The Attorney General of Canada appealed the Quebec Court of Appeal’s opinion to the Supreme Court of Canada. The appeal was heard on 24 April 2009, but the Reasons for Judgment were not released until 22 December 2010. The Court was

split three ways: four judges rendered the opinion that all of the impugned provisions of the AHRA were valid, four judges concluded that all of the impugned provisions were *ultra vires* Parliament on the basis that they were not a valid exercise of the federal criminal law power, and one judge concluded that some of the impugned provisions were valid while others were *ultra vires*. All sets of reasons focused on a pith and substance analysis, similar to that carried out by the Quebec Court of Appeal. Each of these sets of reasons for judgment is summarized below.

### 3.2.1 REASONS FOR JUDGMENT OF CHIEF JUSTICE MCLACHLIN (JUSTICES BINNIE, FISH AND CHARRON CONCURRING)

Madam Chief Justice McLachlin framed the issue as follows:

Is the *Assisted Human Reproduction Act* properly characterized as legislation to curtail practices that may contravene morality, create public health evils or put the security of individuals at risk ... ? Or should it be characterized as legislation to promote positive medical practices associated with assisted human reproduction ... ?<sup>18</sup>

The Chief Justice noted that the object of the AHRA was to prohibit reprehensible conduct, and that it “incidentally permits beneficial practices through regulations. But that does not render it unconstitutional.”<sup>19</sup> Examining the effects of the AHRA, she agreed that it affected the regulation of medical research and practice, but concluded that this was not its dominant purpose or effect. Ultimately, she found that the AHRA was properly characterized as the prohibition of negative practices associated with assisted reproduction.

The Chief Justice then examined whether the AHRA met the requirements of a valid criminal law: namely, whether it contained a prohibition backed by a penalty and had a criminal law purpose.<sup>20</sup> She affirmed that the law met the first two criteria, and proceeded to describe the criminal law purpose:

Assisted reproduction raises weighty moral concerns. The creation of human life and the processes by which it is altered and extinguished, as well as the impact this may have on affected parties, lie at the heart of morality. Parliament has a strong interest in ensuring that basic moral standards govern the creation and destruction of life, as well as their impact on persons like donors and mothers. Taken as a whole, the Act seeks to avert serious damage to the fabric of our society by prohibiting practices that tend to devalue human life and degrade participants. This is a valid criminal law purpose, grounded in issues that our society considers to be of fundamental importance.

Overlapping with the morality concerns are concerns for public health ... [A]cts or conduct that have an injurious or undesirable effect on public health constitute public health evils that may properly be targeted by the criminal law. The question is whether the threats to donors of sperm or ova, surrogate mothers and persons created through the misuse of the techniques of assisted reproduction, fall within this principle. ... It is not difficult to project serious physical and psychological harms to the affected individuals. How assisted reproduction techniques are used can mean the difference between life and death, health and sickness. Conduct that abuses these processes poses risks to the health of the population and may legitimately be considered a public health evil to be addressed by the criminal law.<sup>21</sup>

She concluded that the prohibitions in sections 8 to 13 were valid criminal law.

Addressing the administrative provisions contained in the rest of the AHRA, the Chief Justice concluded that:

- Sections 14 to 19, which set up a system of information management, “are closely tied to the valid criminal prohibitions in ss. 5 to 13. These prohibitions fill a gap by addressing the practical considerations inherent in the functioning of the legislative scheme.”<sup>22</sup>
- Sections 40 to 44, which relate to issuing licences for controlled activities, are:
  - directly related ... to prohibiting harmful and immoral conduct, while excepting beneficial activity. Licensing helps to ensure that selective prohibition targets morally reprehensible conduct, and does so in a flexible manner that can adapt to changing circumstances. It does so by restricting and supervising the use of technologies associated with the artificial creation of human life. In this situation, licensing is about separating good from bad, not about promoting or encouraging the positive aspects of assisted reproduction.<sup>23</sup>
- Sections 45 to 53, which relate to inspection and enforcement, “are part and parcel of the scheme by which Parliament prohibits immoral and potentially harmful uses of human reproductive material. ... Without inspection and enforcement provisions, the prohibitions ... would be ineffective.”<sup>24</sup>
- Sections 60 and 61, which relate to offences and punishment, “simply provide the penal sanctions that are necessary for criminal law provisions. Like the penal provisions of the *Criminal Code* of Canada, they are valid.”<sup>25</sup>

### 3.2.2 REASONS FOR JUDGMENT OF JUSTICES LEBEL AND DESCHAMPS (JUSTICES ABELLA AND ROTHSTEIN CONCURRING)

Justices LeBel and Deschamps suggested that the Chief Justice should have focused first on the pith and substance of the impugned provisions instead of focusing on the pith and substance of the whole of the AHRA. In carrying out their pith and substance analysis, the judges reviewed the context leading to the AHRA:

It is clear that the Baird Commission wanted certain activities to be denounced and prohibited because, in its view, there was a consensus that they were reprehensible. But the Commission also wanted assisted human reproduction and related research activities to be regulated for the purpose of establishing uniform standards that would apply across Canada. Thus, it can be seen that the distinction drawn in the *AHR Act* between prohibited activities and controlled activities corresponds to the two distinct categories of activities for which the Baird Commission recommended two distinct approaches with different purposes.<sup>26</sup>

Justices LeBel and Deschamps concluded that the purpose of the impugned provisions “was to establish mandatory national standards for assisted human reproduction,”<sup>27</sup> and that they would have “a significant impact on the practice of medicine.”<sup>28</sup> They determined that the pith and substance of challenged provisions was “the regulation of assisted human reproduction as a health service.”<sup>29</sup>

They disagreed with the Chief Justice's characterization of the controlled activities:

Nothing in the record suggests that the controlled activities should be regarded as conduct that is reprehensible or represents a serious risk to morality, safety or public health. ... Parliament, in adopting the Baird Report's recommendation on controlled activities, intended to establish national standards for assisted human reproduction. The purpose was not, therefore, to protect those who might resort to assisted human reproduction on the basis that it was inherently harmful. Assisted human reproduction was not then, nor is it now, an evil needing to be suppressed. In fact, it is a burgeoning field of medical practice and research that, as Parliament mentions in s. 2 of the *AHR Act*, brings benefits to many Canadians.<sup>30</sup>

Justices LeBel and Deschamps concluded that "Parliament's intention was to enact legislation in relation to a matter outside its jurisdiction,"<sup>31</sup> and that, except to the extent sections 60 and 61 relate to provisions that were not challenged, the impugned provisions were *ultra vires* Parliament.

### 3.2.3 REASONS FOR JUDGMENT OF JUSTICE CROMWELL

Justice Cromwell framed the issue as "whether the federal criminal law power permits Parliament to regulate virtually all aspects of research and clinical practice in relation to assisted human reproduction."<sup>32</sup> Answering that question in the negative, he went on to agree with the Chief Justice that the prohibitions contained in sections 8, 9 and 12 "in purpose and effect prohibit negative practices associated with assisted reproduction and that they fall within the traditional ambit of the federal criminal law power."<sup>33</sup> However, he also agreed with Justices LeBel and Deschamps that sections 10 (use of human reproductive material and *in vitro* embryos except in accordance with the regulations and a licence), 11 (combining parts of human genomes with other genomes except in accordance with the regulations and a licence), 13 (undertaking a controlled activity on licensed premises only), 14 to 18 (privacy and access to information provisions), sections 40(2) to 40(5) (provisions relating to the Assisted Human Reproduction Agency of Canada), and sections 44(2) and (3) (relating to inspectors assuming the management of premises and the costs incurred) were *ultra vires* Parliament.

### 3.2.4 COMMENTARY RELATING TO THE SUPREME COURT OF CANADA DECISION

It has been suggested that the usefulness of the Supreme Court decision in determining the validity of any future federal criminal law-based health legislation is restricted by (1) the absence of a strong majority decision; and (2) the somewhat limited analysis with respect to "delineat[ing] the boundaries more clearly where federal legislative schemes meet provincially regulated areas such as medical practice and health research."<sup>34</sup>

One concern that has been expressed with respect to the Court's decision is that the absence of federal regulation of certain aspects of assisted human reproduction could lead to a "patchwork of provincial laws and regulations," increasing medical tourism as women seek services in provinces "with regulations most favourable to their particular situation."<sup>35</sup>

### 3.3 AMENDMENTS TO THE *ASSISTED HUMAN REPRODUCTION ACT*

In response to the Supreme Court of Canada decision, the federal government tabled amendments to the AHRA as part of Bill C-38, An Act to implement certain provisions of the budget tabled in Parliament on March 29, 2012 and other measures, on 26 April 2012.<sup>36</sup> That bill received Royal Assent on 29 June 2012. The amendments repeal all of the provisions of the AHRA that were found to be *ultra vires*. Consequently, the federal role relating to assisted human reproduction was reduced considerably, as was the need for administrative and regulatory enforcement. The amendments also included the dissolution of the Assisted Human Reproduction Agency, which had already been announced in Budget 2012, as well as the removal from section 12 of the AHRA of the requirement for a licence to reimburse expenditures.

As a result of Bill C-38, all implementation and enforcement responsibilities under the amended Act were transferred to the Minister of Health. The regulation-making responsibilities of the Assisted Human Reproduction Implementation Office were transferred to the Biologics and Genetic Therapies Directorate of the Health Products and Food Branch at Health Canada. In place of controlled activities requiring a licence, additional prohibitions were introduced to ensure proper testing of reproductive materials in order to reduce the risk to human health and safety.<sup>37</sup> Regulation-making authorities were amended to permit regulations respecting the following: tests to be conducted; disposition and tracing of reproductive material; reporting to the Minister; reimbursement of expenditures; and creation and maintenance of records by those involved in regulated activities, etc.

The provisions pertaining to the safety and testing of reproductive material, as well as the reimbursement of expenses, are not yet in force, pending the necessary regulations. However, no regulations have been implemented since 2008 (section 8, consent) and no other public consultations for regulatory development have been launched since that time. In addition, several of the administration and enforcement provisions are not yet in force.

### 3.4 ENFORCEMENT OF THE *ASSISTED HUMAN REPRODUCTION ACT*

There has been at least one prosecution under the *Assisted Human Reproduction Act*. Leia Picard was charged in February 2013 with 27 offences under both the *Criminal Code* and the *Assisted Human Reproduction Act* in relation to activities carried out through her company, Canadian Fertility Consultants (CFC).<sup>38</sup> Although the *Criminal Code* charges were dropped, Ms. Picard pleaded guilty to accepting payment for helping to arrange a surrogacy. CFC pleaded guilty to paying women to donate eggs and paying women to be surrogates. Altogether, Ms. Picard and CFC were fined \$60,000.

Some medical and legal professionals who specialize in assisted human reproduction issues expressed the concern that this case demonstrates a lack of clarity regarding the expenses that can be reimbursed, and they have indicated that Health Canada should clarify this issue by establishing the appropriate regulations under the AHRA.<sup>39</sup>

## NOTES

1. See for example, House of Commons, Standing Committee on Health, [Evidence](#), 1<sup>st</sup> Session, 37<sup>th</sup> Parliament, 26 November 2001, 1355.
2. See for example, House of Commons, Standing Committee on Health, [Evidence](#), 1<sup>st</sup> Session, 37<sup>th</sup> Parliament, 23 October 2001, 1125.
3. Royal Commission on New Reproductive Technologies, *Proceed with Care*, Final Report, Vol. 1, Ottawa, 1993, p. 2.
4. *Ibid.*, Vol. 2, pp. 1022–1023.
5. Nancy Miller Chenier and Sonya Norris, [Regulating Reproductive and Genetic Technologies Internationally](#), Publication no. TIPS-16E, Parliamentary Information and Research Service, Library of Parliament, Ottawa, June 2002, p. 1.
6. Nancy Miller Chenier and Marilyn Pilon, [Bill C-47: Human Reproductive and Genetic Technologies Act](#), Publication no. LS-269E, Parliamentary Information and Research Service, Library of Parliament, Ottawa, 28 April 1997.
7. The three agencies were the Medical Research Council (replaced in 2000 by the Canadian Institutes of Health Research), the Natural Sciences and Engineering Research Council and the Social Sciences and Humanities Research Council.
8. See Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada, [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans](#), December 2014.
9. House of Commons, Standing Committee on Health, *Assisted Human Reproduction: Building Families*, December 2001.
10. The bills were C-13 and C-6, respectively.
11. For a comprehensive description of the *Assisted Human Reproduction Act*, see Monique Hébert, Nancy Miller Chenier and Sonya Norris, [Bill C-6: Assisted Human Reproduction Act](#), Publication no. LS-466E, Parliamentary Information and Research Service, Library of Parliament, Ottawa, 17 February 2004.
12. Françoise Baylis, [“The Demise of Assisted Human Reproduction Canada,”](#) *Journal of Obstetrics and Gynaecology Canada*, Vol. 34, No. 6, June 2012, p. 512.
13. Section 1 of the Quebec *Court of Appeal Reference Act*, R.S.Q., c. R-23, provides that “The Government may refer to the Court of Appeal, for hearing and consideration, any question which it deems expedient, and thereupon the court shall hear and consider the same.” Section 5 of that Act further provides, “The court shall send to the Government for its information its opinion duly certified upon the questions so referred, giving its reasons in support thereof, in like manner as in the case of judgments rendered upon appeals brought before the said court.” Although a court’s response to questions posed on a reference is considered to be an advisory opinion, many authors have suggested that reference opinions are in fact treated as if they were binding judgments. See, for example, Gerald Rubin, [“The Nature, Use and Effect of Reference Cases in Canadian Constitutional Law,”](#) *McGill Law Journal*, Vol. 6, No. 3, 1959–1960, pp. 168–190.
14. *Québec (Procureur général) c. Canada (Procureur général)*, 2008 Carswell Que 9848, para. 72, [2008], 298 D.L.R. (4<sup>th</sup>) 712 (Q.C.A.).
15. *Ibid.*, para. 97.
16. *Ibid.*, para. 102.
17. *Ibid.*, para. 137.

18. [Reference re Assisted Human Reproduction Act](#), 2010 SCC 61, para. 21.
19. *Ibid.*, para. 30.
20. *Ibid.*, para. 36.
21. *Ibid.*, para. 61.
22. *Ibid.*, para. 146.
23. *Ibid.*, para. 149.
24. *Ibid.*, para. 150.
25. *Ibid.*, para. 155.
26. *Ibid.*, para. 206.
27. *Ibid.*, para. 226.
28. *Ibid.*
29. *Ibid.*, para. 227.
30. *Ibid.*, para. 251.
31. *Ibid.*, para. 280.
32. *Ibid.*, para. 283.
33. *Ibid.*, para. 291.
34. Barbara von Tigerstrom, "Federal Health Legislation and the *Assisted Human Reproduction Act* Reference," *Saskatchewan Law Review*, Vol. 74, No. 33, 2011, p. 41.
35. Laura Eggertson, "[Patchwork regulations likely outcome of reproductive technologies ruling](#)," *Canadian Medical Association Journal*, Vol. 183, No. 4, 8 March 2011, p. E215.
36. *Jobs, Growth and Long-term Prosperity Act* (S.C. 2012, c. 19), part 4, division 56, [ss. 713–745](#).
37. *Ibid.*, s. 716.
38. Tom Blackwell, "[Canadian fertility consultant received \\$31K for unwittingly referring parents to U.S. 'baby-selling' ring](#)," *National Post*, 15 December 2013.
39. Alison Motluk, "[First prosecution under Assisted Human Reproduction Act ends in conviction](#)," *Canadian Medical Association Journal*, Vol. 186, No. 2, 4 February 2014.



**APPENDIX – CHRONOLOGY OF ACTIONS RELATED TO  
THE REGULATION OF ASSISTED HUMAN  
REPRODUCTION IN CANADA**

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- 1989** The federal government established the Royal Commission on New Reproductive Technologies.
- 1993** The Royal Commission issued its final report, *Proceed with Care*.
- 1995** The Minister of Health announced a voluntary moratorium on certain activities specified by the Commission; an advisory committee was subsequently established to monitor compliance by researchers and health professionals.
- 1996** Health Canada implemented regulations for the processing and distribution of semen for assisted conception pursuant to the *Food and Drugs Act*.
- 1996–1997** Minister of Health introduced Bill C-47, the Human Reproductive and Genetic Technologies Act, which proposed to prohibit several practices. The bill died on the *Order Paper* at the dissolution of the 35<sup>th</sup> Parliament.
- 1997** Health Canada released *New Reproductive and Genetic Technologies: Setting Boundaries, Enhancing Health*, a discussion document for a proposed regulatory framework of reproductive and genetic technologies.
- 1998** Canada's three research funding agencies, the Medical Research Council, the Natural Sciences and Engineering Research Council and the Social Sciences and Humanities Research Council, produced the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*.
- 2001** The Minister of Health requested that the House of Commons Standing Committee on Health study the Government of Canada's *Proposals for Legislation Governing Assisted Human Reproduction* and provide recommendations on the draft legislation. The Committee made several recommendations and requested that the Government introduce legislation as soon as possible.
- 2002** The Canadian Institutes of Health Research (CIHR), Canada's primary funding agency for health research, issued *Guidelines for Human Pluripotent Stem Cell Research* governing CIHR-funded stem cell research including both adult and embryonic stem cell research. These have been regularly updated, most recently in June 2010.

## LEGAL STATUS AT THE FEDERAL LEVEL OF ASSISTED HUMAN REPRODUCTION IN CANADA

The Minister of Health introduced Bill C-56, an Act respecting Assisted Human Reproduction, which proposed a number of prohibited activities as well as several other activities that would be prohibited unless specifically permitted by licence. Bill C-56 also proposed the establishment of a regulatory body to license, monitor and enforce the Act. This bill died at prorogation of the 1<sup>st</sup> Session of the 37<sup>th</sup> Parliament.

Renamed Bill C-13, an Act respecting Assisted Human Reproduction, the bill was reinstated at the same stage in the legislative process it had reached when the previous session was prorogued. It reached 2<sup>nd</sup> reading in the Senate when it died on the *Order Paper* at the prorogation of the 2<sup>nd</sup> Session of the 37<sup>th</sup> Parliament.

- 2003** Renamed Bill C-6, an Act respecting Assisted Human Reproduction was reinstated at the same stage in the legislative process it had reached when the previous session was prorogued.
- 2004** Bill C-6 received Royal Assent in March 2004.
- The Government of Quebec filed a reference with the Quebec Court of Appeal, challenging the constitutional validity of some sections of the *Assisted Human Reproduction Act*.
- 2006** The Assisted Human Reproduction Agency was established.
- 2008** The Quebec Court of Appeal rendered its opinion that all challenged provisions were beyond the scope of the federal criminal law power and were therefore unconstitutional.
- 2009** The Government of Canada appealed the opinion of the Quebec Court of Appeal, and in April 2009 the Supreme Court of Canada heard the reference.
- 2010** The Supreme Court of Canada found in December 2010 in a 4-4-1 decision that some of the challenged provisions were constitutional while others were unconstitutional.
- 2012** The federal government tabled amendments to the *Assisted Human Reproduction Act*, within Bill C-38, An Act to implement certain provisions of the budget tabled in Parliament on March 29, 2012 and other measures, in April to address the decision of the Supreme Court of Canada. The bill received Royal Assent in June 2012.