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The Tale of Assisted Human Reproduction Canada: A Tragedy in Five Acts

Françoise Baylis and Jocelyn Downie

Au printemps 2012, l'Agence canadienne de contrôle de la procréation assistée (ACCPA)—l'organisme fédéral devant surveiller la procréation assistée au Canada—a été abolie lorsqu'on a adopté la loi omnibus sur le budget. Cette fin ignominieuse était en partie une réaction au renvoi de la Cour suprême du Canada relatif à la Loi sur la procréation assistée. Cependant, comme nous le verrons dans le présent article, c'était aussi le résultat d'une série d'occasions manquées de réglementer la procréation assistée afin de protéger ceux et celles qui utilisent les techniques de procréation assistée et ceux qui en naissent. Le présent article décrit la création, la vie et la disparition de l'ACCPA; nous concluons qu'il s'est dépensé inutilement plusieurs millions de dollars publics, ainsi que de nombreuses heures d'experts.

In the spring of 2012, Assisted Human Reproduction Canada (AHRC)—the federal agency tasked with the oversight of assisted human reproduction in Canada—was abolished through the passage of the omnibus budget bill. This ignominious end was in part a response to the Supreme Court of Canada's Reference re Assisted Human Reproduction Act. However, as we recount in this article, it was also a result of a series of squandered opportunities to regulate assisted human reproduction in the interests of those who use or are born of assisted human reproductive technologies. This article details the genesis, life, and death of the AHRC. We conclude that many millions of public dollars and many hours of experts' time have been spent, all for naught.

Françoise Baylis was a member of the Board of Directors of Assisted Human Reproduction Canada (AHRC) from December 2006 to March 2010, at which time she resigned on the grounds that the board was being prevented from fulfilling its legislated mandate. Jocelyn Downie was a member of the expert selection committee tasked with reviewing the applications submitted for the AHRC's Board of Directors, chair, and chief executive officer. More specifics regarding their involvement in the story will be referenced at appropriate points throughout the article. Both authors are bound by confidentiality agreements, and all claims made in this article are referenced to publicly available documents. With the closure of the AHRC, all AHRC webpages were erased (as opposed to archived). As such, all links to these pages (which we have preserved in this document as part of the public record) are now broken. In anticipation of such an eventuality, the authors captured the website, and so all AHRC web documents are on file with the authors.

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Prologue

This sorry tale unveils no secrets. Nonetheless, it will be surprising to many. The facts carefully pieced together by the authors—at times, actors in this story—provide a clear picture of events that led to the decimation of the *Assisted Human Reproduction Act* (AHRA) and the demise of Assisted Human Reproduction Canada (AHRC).¹ The “what” of this story is a tragedy; the “why” remains a mystery.

Sadly, as a result of squandered opportunities and wasted money in the arena of the regulation of assisted human reproduction, Canadians are worse off now than they were before the Royal Commission on New Reproductive Technologies (Royal Commission) recommended national oversight of assisted human reproduction. At the time of the Royal Commission, there was genuine hope that we would have a responsible federally regulated system that would protect the interests of Canadians. It took a long time, but we did get legislation that may have been flawed from the perspective of some but did nonetheless seriously attend to the interests of women and children. Unfortunately, this legislation was never fully operationalized and, as most will know, was eviscerated by the Supreme Court of Canada. The net result is that we no longer have some of the significant protections that were once in the AHRA, and there is little prospect of getting those protections back in the near future.

Behind the publicly available (albeit frequently difficult to find) facts are individual actors who made decisions for reasons that are known only to themselves and (maybe) to a few close friends or colleagues. Speculation might have once explained the past with reference to changes in staff at Health Canada, to personal agendas in the Prime Minister’s Office and various ministries, to a general lack of political will, to incompetence at the AHRC, or to the Québec government’s constitutional challenge to the AHRA. However, the fact is that we cannot know why history played out as it did.

Act One: 1989 to 2007

In 1989, Canada’s Royal Commission was announced²—the fruition of many years of intense lobbying for the regulation of *in vitro* fertilization (IVF) and related interventions.³ The commission’s mandate was to

1. *Assisted Human Reproduction Act*, SC 2004, c 2 [AHRA].

2. Françoise Baylis was contracted to write several papers on informed consent for the Royal Commission on New Reproductive Technologies.

3. For example, the work of the Canadian Coalition for a Royal Commission on New Reproductive Technologies. See Margrit Eichler and Marie Lavigne, “Women’s Movement,” *Canadian Encyclopedia* (2012), online: Canadian Encyclopedia <<http://www.thecanadianencyclopedia.com/articles/womens-movement>>.

inquire into and report upon current and potential medical and scientific developments related to new reproductive technologies, considering in particular their social, ethical, health, research, legal and economic implications and the public interest, recommending what policies and safeguards should be applied.⁴

In 1993, the Royal Commission issued its final report, *Proceed with Care: Final Report of the Royal Commission on New Reproductive Technologies*.⁵ This report included 293 policy recommendations, a majority of which required action by the federal government. Furthermore, the final report specifically enjoined the federal government to develop comprehensive legislation:

Given what we learned through extensive consultation, data collection, and analysis over the life of our mandate, we share the widely held public view that new reproductive technologies raise issues of a magnitude and importance that not only warrant but *require* a national response. We reject the argument that new reproductive technologies as a general matter should continue to be subdivided into component parts and left to the provincial legislatures, or delegated to self-governing professional bodies, for regulation on a province-by-province or even an institution-by-institution basis. Considering the overarching nature, profound importance, and fundamental inter-relatedness of the issues involved, we consider that federal regulation of new reproductive technologies—under the national concern branch of the peace, order, and good government power, as well as under the criminal law, trade and commerce, spending, and other relevant federal constitutional powers—is clearly warranted.⁶

Acting on the recommendations of the Royal Commission, the federal government introduced Bill C-47 (*An Act Respecting Human Reproductive Technologies and Commercial Transactions Relating to Human Reproduction*) in 1996.⁷ This bill was very brief and focused narrowly on prohibited activities. It did not include controlled activities and did not include a federal oversight agency. Before the legislative process was completed, however, an election was called. When Parliament was dissolved in the spring of 1997, the bill died on the order paper. Years later, in May 2001, *Proposals for Legislation Governing Assisted Human Reproduction*

4. Royal Commission on New Reproductive Technologies (Royal Commission), *Proceed with Care: Final Report of the Royal Commission on New Reproductive Technologies*, volumes 1 and 2 (Ottawa: Minister of Government Services, 1993) at 3.

5. *Ibid.*

6. *Ibid.*, volume 1 at 18.

7. Bill C-47, *An Act Respecting Human Reproductive Technologies and Commercial Transactions Relating to Human Reproduction*, introduced at 2nd Sess, 35th Parl (1997).

were presented by the minister of health to the House of Commons Standing Committee on Health.⁸ The committee's report was issued in December 2001. The report included a number of recommendations including the recommendation that a federal regulatory body be established to license, monitor, and enforce the Act.

In May 2002, a new bill, Bill C-56 (*An Act Respecting Assisted Human Reproduction*) was introduced in the House of Commons.⁹ This bill, based on the federal criminal law power, included controlled activities in addition to prohibited activities, and it also included provisions for the establishment of a federal oversight agency. That same year (2002), Parliament was prorogued. Again, the bill died on the order paper. When Parliament resumed, Bill C-56 was reinstated at the same stage in the legislative process as in the previous session of Parliament (but as Bill C-13).¹⁰ Bill C-13 met the same fate as its predecessor after the thirty-seventh Parliament was prorogued for a second time in 2003. And, finally, Bill C-6 (*An Act Respecting Assisted Human Reproduction and Related Research*) (formerly Bill C-13) was introduced and passed all three readings on 11 February 2004, received royal assent on 29 March 2004, and came into force on 22 April 2004.¹¹ Thus, the *AHRA* included prohibitions on conduct and the regulation of controlled activities within the domain of assisted human reproduction and provided for the establishment of a federal agency to be known as the AHRC.¹²

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8. Françoise Baylis participated in the government-sponsored press release of this initiative.
 9. Bill C-56, *An Act Respecting Assisted Human Reproduction*, introduced at 1st Sess, 37th Parl (2002) (the last stage completed was the second reading in the House of Commons on 28 May 2002).
 10. Bill C-13, *An Act Respecting Assisted Human Reproduction*, introduced at 2nd Sess, 37th Parl (2003). On 25 October 2003, Françoise Baylis and Jocelyn Downie penned an open letter to members of the House of Commons. A draft of the letter was given to Timothy Caulfield to review, and minor amendments were negotiated. The next day, Canadian colleagues in attendance at the Joint Meeting of the American Society for Bioethics and Humanities and the Canadian Bioethics Society, which was held in Montreal, were invited to sign the open letter. A total of sixty-five signatures were gathered and a press release was issued. All members of the House of Commons received a copy of the open letter. On 28 October 2003, the House of Commons passed Bill C-13. However, the last stage completed by Bill C-13 was the second reading in the Senate on 7 November 2003 as Parliament was prorogued before the bill could be passed by the Senate.
 11. Bill C-6, *An Act Respecting Assisted Human Reproduction and Related Research*, introduced at 3rd Sess, 37th Parl (2004) (assented to 29 March 2004). For more details on the legislative process from 1996 to 2004, see Françoise Baylis and Matthew Herder, "Policy Design for Human Embryo Research in Canada: A History," Part 1 of 2 (2009) 6:1 *Journal of Bioethical Inquiry* 109.
 12. *AHRA*, *supra* note 1: "(1) Sections 5 to 9 prohibit human cloning, the commercialization of human reproductive material and the reproductive functions of women and men, and the use of *in vitro* embryos without consent; (2) Sections 10 to 13 prohibit various activities unless they are carried out in accordance with regulations made under the Act, under licence and in licensed premises. These "controlled activities" involve manipulation of human reproductive material or *in vitro* embryos, transgenic engineering and reimbursement of the expenditures of donors and surrogate mothers; (3) Sections 14 to 19 set up a system of information management related to assisted reproduction; (4) Sections 20 to 39 establish the Assisted Human Reproduction

The *AHRA* set out the following praiseworthy objectives for the AHRC:

22. (a) to protect and promote the health and safety, and the human dignity and human rights, of Canadians, and
- (b) to foster the application of ethical principles, in relation to assisted human reproduction and other matters to which this Act applies.

To that end, the AHRC had the following statutory powers:

24. (1) (a) *exercise the powers in relation to licences under this Act*;¹³
- (b) provide advice to the Minister on assisted human reproduction and other matters to which this Act applies;
- (c) monitor and evaluate the developments within Canada and internationally in assisted human reproduction and other matters to which this Act applies;
- (d) consult persons and organizations within Canada and internationally;
- (e) *collect, analyse and manage health reporting information relating to controlled activities*;
- (f) provide information to the public and to the professions respecting assisted human reproduction and other matters to which this Act applies, and their regulation under this Act, and respecting risk factors associated with infertility;
- (g) *designate inspectors and analysts for the enforcement of this Act*; and
- (h) do anything that is reasonably necessary or incidental to achieving the Agency's objectives.

As well, additional AHRC powers related to the collection and analysis of health reporting information, licensing, inspection, and enforcement activities were provided through sections 14-19 (management of information) and sections 40-59 (administration, inspection, and enforcement) of the *AHRA*.

Agency of Canada; (5) Sections 40 to 59 charge the Agency with administering and enforcing the Act and regulations, and authorize it to issue licences for certain activities related to assisted reproduction; (6) Sections 60 and 61 provide for penalties; (7) Sections 65 to 67 authorize the promulgation of regulations; and (8) Section 68 gives the Governor in Council power to exempt the operation of certain provisions if there are equivalent provincial laws in force that cover the field." As cited in *Reference re Assisted Human Reproduction Act*, 2010 SCC 61 at court summary [*Reference re AHRA*].

13. Italics signify that the provisions did not come into force with the proclamation of the *AHRA* (and, indeed, never came into force).

Not long after the *AHRA* was passed, on 4 December 2004, the government of Québec applied to the Québec Court of Appeal for an answer to the following question:

Les articles 8 à 12 de la Loi sur la procréation assistée, L.C. 2004, ch. 2, excèdent-ils, en tout ou en partie, la compétence du Parlement du Canada en vertu de la Loi constitutionnelle de 1867?¹⁴

The constitutional question was modified and expanded on 14 February 2006:

Les articles 8 à 19, 40 à 53, 60, 61 et 68 de la Loi sur la procréation assistée, L.C. 2004, ch.2, excèdent-ils, en tout ou en partie, la compétence du Parlement du Canada en vertu de la Loi constitutionnelle de 1867?¹⁵

This was the beginning of what would ultimately result in the Supreme Court of Canada's decision in *Reference re Assisted Human Reproduction Act (Reference re AHRA)*.¹⁶

Meanwhile, efforts to establish the AHRC as mandated by the legislation stalled. It would be nearly two years from the time the *AHRA* was passed until the AHRC was formally established on 12 January 2006 by an Order in Council.¹⁷ And it would be nearly another year (21 December 2006) before the president, chairperson, and Board of Directors of the AHRC were named.¹⁸ In the interim, there was a change in government. The Liberal Party introduced the legislation and established the AHRC. The Conservative Party inherited the legislation and the AHRC but had control over the membership of the AHRC. Finally, on 14 February 2007, the AHRC opened its doors and the first Board of Directors meeting was held on 25-7 March 2007.¹⁹ In total, there was a three-year delay between the *AHRA* coming into force and the creation of the legally mandated federal agency responsible for the oversight of reproductive technologies through licensing, monitoring, inspection, and enforcement activities related to assisted human reproduction.

14. Décret 1177-2004 (15 décembre 2004), *Gazette Officielle du Québec* (5 janvier 2005), 137^e année, n° 1, Partie 2, at 62-3.

15. Décret 73-2006 (14 février 2006), *Gazette Officielle du Québec* (8 mars 2006), 138^e année, n° 10, Partie 2, at 1290.

16. *Reference re AHRA*, *supra* note 12.

17. *Order Designating Vancouver, British Columbia, as the Place in Canada Where the Head Office of the Assisted Human Reproduction Agency of Canada Shall Be Located, effective January 12, 2006*, PC 2005-0726 (5 May 2005); *Order Fixing January 12, 2006 as the Day on which Sections 21 to 39, 72, 74, 75 and 77 of this Act [Bill C-6], being chapter 2 of the Statutes of Canada, 2004, Come into Force, other than paragraphs 24(1)(a), (e) and (g)*, PC 2005-0725 (5 May 2005).

18. AHRC, *AHRC Chronology of Events* (20 February 2012), online: AHRC <<http://www.ahrc-pac.gc.ca/v2/aaa-app/www-qsn/chronology-chronologie-eng.php>> [AHRC Chronology].

19. *Ibid.*

Delay in establishing the AHRC was not the only early problem to plague the agency. In addition, there was “political interference” in the independent peer review process established under the Liberal government to identify suitable candidates for Board membership.²⁰ Shortly after the *AHRA* came into force, Canadians were invited to apply for board membership.²¹ An independent expert selection committee was created to review applications and to make recommendations to government.²² Recommendations were made to government but were not acted upon while the Liberal Party formed the government. When the Conservative Party formed the government in January 2006, they “eschewed the recommendations of the expert selection committee in favour of political appointments.”²³ Only two of the twenty-five candidates selected from the applicant pool, and recommended by the independent expert selection committee, were among those named to the Board of Directors.²⁴ At the time, concerns about “the possibility of political interests at work”²⁵ were voiced in relation to the perceived conservative background of four of the eight board members.²⁶

Furthermore, while the original list of recommended candidates included patients, the inaugural AHRC Board of Directors did not include a patient representative among its members.²⁷ Meanwhile, section 26 of the *AHRA* stipulated that board membership must “reflect a range of backgrounds and disciplines relevant to the Agency’s objectives.”²⁸ It is difficult (if not impossible) to imagine how the perspective of those who avail themselves of assisted reproductive technologies could not be seen as the most important of backgrounds relevant to the agency’s objectives. In this way, the original membership of the Board of Directors did not meet the spirit of the legislation.²⁹

Another important challenge for the agency was the absence of the regulations required for the AHRC to fulfil its mandate under the *AHRA*. Much of the

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20. Roger Chafe, Wendy Levinson, and Paul C Hébert, “The Need for Public Engagement in Choosing Health Priorities” (2011) 183:2 *Canadian Medical Association Journal* 165 at 165.
 21. Françoise Baylis applied for membership and actively encouraged others to apply.
 22. Jocelyn Downie was a member of the expert selection committee.
 23. Françoise Baylis, “The Demise of Assisted Human Reproduction Canada” (2012) 34:6 *Journal of Obstetrics and Gynaecology* 511 at 512.
 24. Laura Eggertson, “New Reproductive Technology Board Belies Expert Selection Process” (2007) 176:5 *Canadian Medical Association Journal* 611 at 611. Françoise Baylis was one of the two.
 25. Dr. Michael Rudnicki, scientific director of the Stem Cell Network, cited in Eggertson, *ibid*.
 26. Françoise Baylis was identified as conservative by media pundits despite the fact that she supports women’s right to access termination of pregnancy and the research use of human embryos that are no longer wanted for reproductive use.
 27. Eggertson, *supra* note 24 at 611; Laura Eggertson, “Demands Made for Inquiry into Operations of Reproductive Health Agency” (2011) 183:1 *Canadian Medical Association Journal* E-21 at E-22. Baylis, *supra* note 23 at 512.
 28. *AHRA*, *supra* note 1, s 26(2).
 29. At the first AHRC Board of Directors meeting, Françoise Baylis asked the then minister of health, Tony Clement, to consider adding a board member with experiential knowledge of assisted human reproduction.

substance of the *AHRA* was left to regulations, and, owing to the absence of regulations, key sections of the *AHRA* were held in abeyance. Most importantly, as noted earlier, the following sections of the *AHRA* concerning the powers of the AHRC never came into force:

24. (1) The Agency may
- (a) exercise the powers in relation to licenses under the Act . . .
 - (e) collect, analyse and manage health reporting information relating to controlled activities . . .
 - (g) designate inspectors and analysts for the enforcement of this Act.

Given the pivotal importance of the regulations in operationalizing the *AHRA*, one would have anticipated urgent action by Health Canada to get the regulations written and passed as quickly as possible. Instead, not a single regulation was introduced in the three years between the passage of the *AHRA* and the AHRC becoming operational.

The regulations for section 8 were registered on 14 June 2007 and came into force on 1 December 2007.³⁰ In between, the Québec Court of Appeal heard the Québec Attorney General's constitutional challenge to the *AHRA* in September 2007. Sadly, these myriad failings on the part of the federal government and the AHRC foreshadowed future failures to respect the terms and intentions of the *AHRA*. With such an inauspicious and foreboding beginning, we turn now to Act Two.

Act Two: 2008 to 2010

Act Two, Scene One: AHRC

In June 2008, the Québec Court of Appeal found in favour of the Attorney General of Québec and held that the challenged provisions of the *AHRA* were unconstitutional as falling outside the jurisdiction of the federal Parliament. The case then moved into the Supreme Court of Canada's appeal process. Against this backdrop, the AHRC still had a job to do. However, as noted earlier, regulations were needed to give effect to the AHRC's powers. Meanwhile, with the exception of the regulations for section 8, no regulations were introduced. By failing to introduce the necessary regulations, the federal government, and more particularly Health Canada, helped set the stage for the ultimate demise of the AHRC.

30. *Assisted Human Reproduction (Section 8 Consent) Regulations*, SOR/2007-137.

Two discrete official explanations have been offered by Health Canada for its failure to introduce the requisite regulations. One explanation was that

Health Canada must follow the *Cabinet Directive on Streamlining Regulation* in developing options and recommendations for Assisted Human Reproduction. The Directive is designed to protect and advance the public interest by working with Canadians and other governments to ensure that its regulatory activities result in the greatest overall benefit to current and future generations of Canadians. The Directive includes clear requirements for the development, implementation, evaluation and review of regulations. The Government must weigh the benefits of alternatives to regulations—and of alternative regulations—against their cost, and focus resources where they can do the most good.³¹

The problem with this explanation is that the *AHRA* came into force on 22 April 2004 and the *Cabinet Directive on Streamlining Regulation* only came into force 1 April 2007.³² This directive, therefore, cannot possibly account for the delay from April 2004 to April 2007. As for the subsequent two-year delay between the introduction of the directive in 2007 and this proffered explanation in 2009, no information or evidence is provided in regard to Health Canada's obligation under the directive to assess "the costs and benefits of regulatory and non-regulatory measures, including government inaction."³³

A second explanation for the delay was that

Health Canada has decided to delay the prepublication of draft regulations in *Canada Gazette*, Part I, until an opinion is provided by the Supreme Court of Canada on the constitutionality of parts of the *Assisted Human Reproduction Act* (*AHR Act*). Work continues unabated to develop proposed regulations under the Act.³⁴

Appearing before the Parliamentary Standing Committee on Health, the minister of health, Leona Aglukkaq, rehearsed this explanation:

In terms of the work that Assisted Human Reproduction Canada is doing, as the member [Member of Parliament Carolyn Bennett] is well aware,

31. Health Canada, *Assisted Human Reproduction: Frequently Asked Questions* (Ottawa: Health Canada, 2009), online: Health Canada <<http://www.hc-sc.gc.ca/hl-vs/reprod/hc-sc/faq/index-eng.php#q2>>.

32. Canada, *Cabinet Directive on Streamlining Regulation*, Doc BT 22-110 (Ottawa: Government of Canada, 2007), online: <<http://publications.gc.ca/collections/Collection/BT22-110-2007E.pdf>>.

33. *Ibid* at 8.

34. Health Canada, *Publication of Proposed Assisted Human Reproduction Regulations Delayed until Supreme Court Appeal Is Decided* (Ottawa: Health Canada, 2007), online: Health Canada <<http://www.hc-sc.gc.ca/hl-vs/reprod/hc-sc/legislation/delay-interruption-eng.php>>.

we are dealing with a situation that is before the Supreme Court. The agency is not able to fully implement the full scope of the legislation that is in place before us until the court decision has been made, particularly around the development of the regulations to further proceed.

So in the meantime, the agency continues to do work within the scope of the legislation, and it will continue to do so until the decision is rendered. Once a decision is made through the courts on the challenge that came forward from Quebec, we'll be able to proceed further related to the regulations that are required for the full implementation of the legislation.³⁵

The problem with this second explanation is that the Québec challenge included section 8 and yet the government brought forward and put into force the consent-to-use regulations after the Québec government had launched its challenge to the AHRA.³⁶ If active litigation was not a reason to hold off on developing and introducing regulations for section 8, then it could not legitimately be the reason for holding off on developing and introducing the other needed regulations.

While neither of the explanations provided by the federal government is satisfactory, the fact remains that, with the singular exception of the consent-to-use regulations, the regulations that were to accompany the legislation were not introduced and the AHRC was effectively marginalized. In the absence of the regulations required to fulfil much of its mandate, the AHRC's possible accomplishments were essentially limited to business undertaken with respect to a few subsections of section 24. In brief, consistent with general responsibilities outlined in section 24 (b), (c), and (d), the president and chair of the Board of Directors met with the minister; the AHRC established three sub-committees and one advisory panel (the Tripartite Committee, the Healthy Singleton Births Committee, the AHR/ART-Related Outcome Committee, and the Science Advisory Panel); and the AHRC commissioned a set of research papers on cross-border reproductive care and hosted the First Invitational International Forum on Cross-Border Reproductive Care: Quality and Safety.³⁷

Furthermore, consistent with section 24(f), the AHRC developed educational products (brochures and a website) and hosted a number of invitational meetings,

35. Canada, House of Commons, *Standing Committee on Health*, 40th Parl, 3rd Sess, No 26 (15 June 2010) at 1010 (Hon Leona Aglukkaq), online: <<http://www.parl.gc.ca/HousePublications/Publication.aspx?DocId=4626213&Language=E&Mode=1#Int-3231507>>.

36. Recall that the challenge was launched on 4 December 2004, that the regulations were not registered until 14 June 2007, and that they did not come into force until 1 December 2007.

37. *First Invitational International Forum on Cross-Border Reproductive Care: Quality and Safety*, Forum Report (Ottawa: AHRC, 14-16 January 2009). Françoise Baylis attended this event but did not present.

including a Multiple Births Round Table and an Oncofertility Symposium.³⁸ In anticipation of eventual responsibilities with respect to section 24(g) and sections 45–59, the AHRC entered into a memorandum of understanding with Health Canada to have Health Canada’s inspectorate enforce the *AHRA* under the direction of the AHRC.³⁹ The AHRC also entered into an agreement with the Royal Canadian Mounted Police for investigation of allegations of non-compliance with the *AHRA*.⁴⁰

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38. AHRC, *Oncofertility in Canada: Building Connections for the Preservation of Fertility for Young Cancer Patients* (Toronto: AHRC, 2010), online: AHRC <<http://www.ahrc-pac.gc.ca/v2/pubs/young-cancer-jeunes-atteints-eng.php>>. Françoise Baylis attended this event but did not present.
39. “For instance, the Agency has signed an MOU with Health Canada’s Health Products and Food Branch Inspectorate. Under its terms, Health Canada will provide inspection, compliance and enforcement services for the Assisted Human Reproduction Act under the direction of AHRC. This arrangement will address the need to respond to issues raised by AHR users and providers.” AHRC, *Hope, Health and Safety: Assisted Human Reproduction Canada Annual Report 2007-08* (Ottawa: AHRC, 2008) at 12, online: <<http://www.ahrc-pac.gc.ca/v2/pubs/alt-formats/pdf/pubs/pubs/annual-annuel/2007-2008-rap-eng.pdf>>. “The inspection and enforcement provisions of the AHR Act (sections 45-59), which includes authorizing AHRC to designate inspectors for the purpose of the enforcement of the AHR Act, have not yet come into force. As an interim measure, pursuant to section 5 of the Department of Health Act, inspectors employed by Health Canada’s Inspectorate have been designated by the Minister of Health for purposes of enforcement of the AHR Act. These inspectors have the powers provided for in section 22 to 29 and 35 of the Food and Drugs Act. AHRC has entered into a memorandum of understanding (MOU) with the Inspectorate. Under this MOU, the Inspectorate conducts activities related to the enforcement of the AHR Act and its Regulations, under the direction of AHRC.” AHRC, *Compliance and Enforcement Policy* (Ottawa: AHRC, 30 July 2010), online: <<http://www.ahrc-pac.gc.ca/v2/aaa-app/alt-formats/pdf/www-qntf/C-E-Policy-eng.pdf>> at 4 [AHRC *Compliance Policy*].
40. “Where a breach of the AHR Act is alleged, AHRC has an agreement with the RCMP, the federal authority that may assist in investigating such complaints. If, for example, an offer to buy an egg or pay for a surrogate mother’s services (both activities prohibited under the Act) were reported and an individual or business were deemed to be in violation of the Act, the case might be turned over to the RCMP for investigation.” AHRC, *supra* note 39 at 12. This agreement has not been made public. Rather, it has been referred to in AHRC documents: “AHRC and the Royal Canadian Mounted Police (RCMP) have established roles and responsibilities in relation to the enforcement of the AHR Act and its Regulations. Where there is accurate and reliable information that an offence may have been committed, AHRC may, at its discretion and under the appropriate circumstances, refer matters to a law enforcement agency, including the RCMP, for investigation.” AHRC *Compliance Policy*, *supra* note 39 at 4. In addition, “[i]n response to information regarding an alleged non-compliance, and following an assessment of the facts, AHRC may issue a compliance letter to notify a person subject to the Act of the non-compliance and to clarify what is necessary to achieve compliance. This type of letter will usually request a response within a specified time period to confirm that corrective actions will be taken. AHRC will then verify that the corrective actions have been implemented. When this is unsuccessful, as when the person subject to the Act is unable or unwilling to correct a non-compliance that may result in a risk to health and safety, other compliance and enforcement actions are available including, warning letters, on-site visits, and as appropriate, referral to a law enforcement Agency, including the RCMP for investigation. It is their role to then determine if there is sufficient evidence to bring the matter forward for prosecution and seek the consent of the Attorney General of Canada to do so. AHRC may also notify any interested authority, such as a professional licensing or disciplinary body if there are reasonable grounds to believe that a person may have acted in breach of their professional codes of conduct. Such actions may be undertaken independently, concurrently or sequentially with other actions” (at 8).

Consistent with section 24(h), the AHRC implemented the section 8 consent-to-use regulations under the *AHRA*. Finally, presumably also under section 24(h), the AHRC transferred funds to the Canadian Institutes of Health Research in support of research on assisted human reproduction.⁴¹

While the AHRC was active with respect to some of its powers, it could hardly be characterized as a robust agency for the protection and promotion of the health and well-being of children born through the use of assisted human reproductive technologies and of other persons affected by these technologies, most particularly women.⁴² As noted earlier, some of this inactivity most certainly was due to the lack of regulations. However, a number of unchallenged important provisions did not require regulations (for example, sections 5-7), so the AHRC could have been more proactive with respect to its responsibility to promote the enforcement of the Act. There is no evidence of such activity on the part of the AHRC. Furthermore, the AHRC had the power to advise the minister of the imperative for Health Canada to introduce regulations. There is no evidence that the AHRC provided such advice to the minister. The AHRC also had the power to direct the Health Canada Inspectorate to be more active with respect to the enforcement of the *AHRA*. There is no evidence that the AHRC so directed the Health Canada Inspectorate.

This lack of activity is all the more troubling when the AHRC's costs are taken into consideration. The actual annual expenditures were substantial (\$134,000

41. Canada, House of Commons, *Standing Committee on Health*, 40th Parl, 3rd Sess, No 37 (16 November 2010) at 1125 (Françoise Baylis), online: <<http://www.parl.gc.ca/HousePublications/Publication.aspx?DocId=4782428&Language=E&Mode=1#Int-3522112>>. See also Memorandum to AHRC Board of Directors from Dr. John Hamm, Chair re: CIHR Funding, 2 April 2009 [on file with the authors].

42. Section 2: The Parliament of Canada recognizes and declares that:

- (a) the health and well-being of children born through the application of assisted human reproductive technologies must be given priority in all decisions respecting their use;
- (b) the benefits of assisted human reproductive technologies and related research for individuals, for families and for society in general can be most effectively secured by taking appropriate measures for the protection and promotion of human health, safety, dignity and rights in the use of these technologies and in related research;
- (c) while all persons are affected by these technologies, 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;
- (d) the principle of free and informed consent must be promoted and applied as a fundamental condition of the use of human reproductive technologies;
- (e) persons who seek to undergo assisted reproduction procedures must not be discriminated against, including on the basis of their sexual orientation or marital status;
- (f) trade in the reproductive capabilities of women and men and the exploitation of children, women and men for commercial ends raise health and ethical concerns that justify their prohibition; and
- (g) human individuality and diversity, and the integrity of the human genome, must be preserved and protected (*AHRA*, *supra* note 1, s 2).

for 2006–07;⁴³ \$4,898,000 for 2007–08;⁴⁴ \$5,289,000 for 2008–09;⁴⁵ \$5,200,000 for 2009–10;⁴⁶ and \$5,200,000 for 2010–11).⁴⁷ These are arguably exorbitant amounts of money to pay for not much more than some Board of Director meetings, committee meetings, workshops, pamphlets, a website, and one international forum.

It should be noted here that this admittedly harsh assessment is supported by the *Core Control Audit of Assisted Human Reproduction Canada* from the Office of the Comptroller General.⁴⁸ The objective of the audit was “to ensure that controls over financial management were effective and conducted in a manner that was compliant with corresponding legislation, policies, and directives at Assisted Human Reproduction Canada.”⁴⁹ The audit covered fiscal years 2008–09 and 2009–10. The assistant comptroller general concluded that “[d]uring the period covered by this audit, the Agency did not have effective controls in place over financial management and were [*sic*] not conducted in a manner compliant with the requirements contained in eleven of thirteen policies, directives and corresponding legislation.”⁵⁰

43. AHRC, *2006-2007 Departmental Performance Report* (Ottawa: AHRC, 1 November 2007), online: Treasury Board of Canada Secretariat <<http://www.tbs-sct.gc.ca/dpr-rmr/2006-2007/inst/rap/rap01-eng.asp>> [archived].

44. AHRC, *2007-2008 Departmental Performance Report* (Ottawa: AHRC, 2008), online: Treasury Board of Canada Secretariat <<http://www.tbs-sct.gc.ca/dpr-rmr/2007-2008/inst/rap/rap01-eng.asp>> [archived].

45. AHRC, *2008-2009 Departmental Performance Report* (Ottawa: AHRC, 2009), online: Treasury Board of Canada Secretariat <<http://www.tbs-sct.gc.ca/dpr-rmr/2008-2009/inst/rap/rap01-eng.asp>> [archived].

46. AHRC, *2009-2010 Departmental Performance Report* (Ottawa: AHRC, 2010), online: Treasury Board of Canada Secretariat <<http://www.tbs-sct.gc.ca/dpr-rmr/2009-2010/inst/rap/rap01-eng.asp>> [archived].

47. AHRC, *2010-2011 Departmental Performance Report* (Ottawa: AHRC, 2011), online: Treasury Board of Canada Secretariat <<http://www.tbs-sct.gc.ca/dpr-rmr/2010-2011/inst/rap/rap01-eng.asp>> [archived].

48. Treasury Board of Canada Secretariat, Office of the Comptroller General of Canada, *Core Control Audit of Assisted Human Reproduction Canada* (Ottawa: Treasury Board of Canada Secretariat, July 2011), online: AHRC <<http://www.ahrc-pac.gc.ca/v2/pubs/cca-vcb-eng.php>> [*Core Control Audit*]. The three board members who resigned from the AHRC (see details later in this article) recommended, during testimony before the parliamentary Standing Committee on Health, that a forensic audit be undertaken.

49. *Ibid.*

50. *Ibid.* The following policies and directives were tested and found to qualify as “not met”: the *Directive on Delegation of Financial Authorities for Disbursements*, the *Directive on Expenditure Initiation and Commitment Control*, the *Directive on Account Verification*, the *Directive on Acquisition Cards*, the *Directive on Accountable Advances*, the *Directive on Financial Management of Pay Administration*, the *National Joint Council Travel Directive*, the *Policies on Contracting, Hospitality, Membership Fees, and Performance Pay Administration* (which includes the *Policy on the Management of Executives*, the *Directive on Terms and Conditions of Employment for Certain Excluded and Unrepresented Employees*, and the *Directive on Executive Compensation*). *Core Control Audit*, *supra* note 48.

Act Two, Scene Two: The AHRC Board of Directors

As noted earlier, the AHRC Board of Directors was named in December 2006 and held its first meeting in March 2007.⁵¹ The board was established with the following responsibilities:

30. The board of directors is responsible for the overall management of the Agency, including
 - (a) the provision of advice to the Minister on assisted human reproduction and other matters to which this Act applies, or on any matter referred to the Agency by the Minister;
 - (b) the approval of the Agency's goals and operational policies;
 - (c) the approval of the Agency's budget; and
 - (d) the evaluation of the Agency's performance.⁵²

In the spring of 2010, three board members resigned: Françoise Baylis, professor and Canada Research Chair in Bioethics and Philosophy at Dalhousie University in Halifax, Nova Scotia; Barbara Slater, policy expert (formerly with the Ontario government) in Toronto, Ontario; and Irene Ryll, patient representative from Edmonton, Alberta. The first to resign was Françoise Baylis “after coming to the conclusion that the agency was failing to enforce, or was actively undermining, the principles of the Assisted Human Reproduction Act.”⁵³ In the fall of 2010, these board members testified before the parliamentary Standing Committee on Health in regard to the many problems that had spurred them to resign.⁵⁴ With respect to the Board of Directors’ legislated responsibilities, the following problems were identified: the Board of Directors of the AHRC (as distinct from the AHRC) never gave advice to the minister (section 30(a)); the Board of Directors gave approval for agency goals and operational policies identified by the president but was prevented from shaping or directing these goals or policies (section 30(b)); the Board of Directors did not vote on the 2008–09 AHRC annual budget (section 30(c));⁵⁵ and the Board of Directors’ approval for other annual budgets can at best be described as *pro forma* (section 30(c)).

Following the resignations of three board members, further problems with the AHRC budgets were identified, including “difficulty getting line-item annual budgets,

51. As noted earlier, Françoise Baylis was a member of the inaugural Board of Directors.

52. Under s 32(2) of the *AHRA*, the responsibilities set out in ss 30(a), (b), and (c) are non-delegable powers. *AHRA*, *supra* note 1, s 32(2).

53. Eggertson, *supra* note 24 at E21.

54. Standing Committee on Health, *Administrative Review of Assisted Human Reproduction Canada*, 40th Parl, 3rd Sess (16 November 2010), online: <<http://www.parl.gc.ca/HousePublications/Publication.aspx?DocId=4782428&Language=E&Mode=1#Int-3522112>>.

55. Eggertson, *supra* note 24 at E21.

a lack of recorded votes, trouble getting the agency's president to reveal what percentage of the budget was being spent on board governance . . . concerns over more than \$2 million the agency allocated to consulting contracts in 2009–2010, while offering the board members little information about the services to be provided.”⁵⁶ More generally, “requests for information about the budget consistently met with resistance from the president.”⁵⁷ For example, board members were not told, despite repeated requests, the cost to taxpayers for the First Invitational International Forum on Cross-Border Reproductive Care: Quality and Safety, which was hosted by the AHRC.

Act Three: 2010 to 2012

On 22 December 2010, the Supreme Court of Canada issued its ruling in response to the Québec government's challenge to the constitutionality of the *AHRA*.⁵⁸ Sections 10, 11, 13, 14–18, 40(2), (3), (3.1), (4), and (5), and sections 44(2) and (3) were struck down. Sections 8, 9, 12, 19, and 60 were upheld. Sections 40(1), (6), and (7), 41–3, 44(1) and (4), 45–53, 61, and 68 were upheld to the extent they related to constitutionally valid provisions. As a result of the decision, the AHRC lost much of its *raison d'être*. The agency nonetheless retained the following powers:

- 24 (1) (b) provide advice to the Minister on assisted human reproduction and other matters to which this Act applies;
- (c) monitor and evaluate the developments within Canada and internationally in assisted human reproduction and other matters to which this Act applies;
- (d) consult persons and organizations within Canada and internationally;
- (f) provide information to the public and to the professions respecting assisted human reproduction and other matters to which this Act applies, and their regulation under this Act, and respecting risk factors associated with infertility;
- (h) do anything that is reasonably necessary or incidental to achieving the Agency's objectives.

56. *Ibid.*

57. *Ibid.*

58. *Reference re AHRA*, *supra* note 12.

The AHRC also retained powers with respect to administration, inspection, and enforcement in relation to the following activities:

- prohibited procedures, offering to do or advertising of prohibited procedures, payment or offering consideration for doing any prohibited procedures;⁵⁹
- payment for surrogacy, acting as an intermediary for surrogacy, payment to intermediaries for surrogacy, minimum age of surrogate mothers;⁶⁰
- purchase of gametes, purchase or sale of embryos, purchase of other reproductive material;⁶¹
- use of reproductive material without consent (*inter vivos* or post-humous);⁶²
- obtaining of gametes from minors;⁶³ and
- reimbursement of expenditures in relation to gametes, embryos, and surrogacy.⁶⁴

Significantly, while much of the *AHRA* was struck down, the prohibition on the purchase, offer to purchase, or advertising for purchase of gametes and embryos and the provisions with respect to the regulation of reimbursements for gametes,

59. Section 5(1): No person shall knowingly:

- (a) create a human clone by using any technique, or transplant a human clone into a human being or into any non-human life form or artificial device;
- (b) create an *in vitro* embryo for any purpose other than creating a human being or improving or providing instruction in assisted reproduction procedures;
- (c) for the purpose of creating a human being, create an embryo from a cell or part of a cell taken from an embryo or foetus or transplant an embryo so created into a human being;
- (d) maintain an embryo outside the body of a female person after the fourteenth day of its development following fertilization or creation, excluding any time during which its development has been suspended;
- (e) for the purpose of creating a human being, perform any procedure or provide, prescribe or administer anything that would ensure or increase the probability that an embryo will be of a particular sex, or that would identify the sex of an *in vitro* embryo, except to prevent, diagnose or treat a sex-linked disorder or disease;
- (f) alter the genome of a cell of a human being or *in vitro* embryo such that the alteration is capable of being transmitted to descendants;
- (g) transplant a sperm, ovum, embryo or foetus of a non-human life form into a human being;
- (h) for the purpose of creating a human being, make use of any human reproductive material or an *in vitro* embryo that is or was transplanted into a non-human life form;
- (i) create a chimera, or transplant a chimera into either a human being or a non-human life form; or
- (j) create a hybrid for the purpose of reproduction, or transplant a hybrid into either a human being or a non-human life form.

AHRA, *supra* note 1, s 5(1).

60. *Ibid*, s 6.

61. *Ibid*, s 7.

62. *Ibid*, s 8.

63. *Ibid*, s 9.

64. *Ibid*, s 12.

embryos, and surrogacy and the implementation and enforcement of these sections were upheld. Thus, the agency retained extremely important responsibilities and powers.

Presumably in recognition of these responsibilities and powers, implementation of the agency's compliance and enforcement program was identified among the activities for 2010–11 and listed among the priorities for 2011–12.⁶⁵ However, as with previous years, there is no evidence available suggesting that progress was made with respect to this aspect of the mandate. Activities undertaken in 2010–11 included:

- frequent interactions with health care professionals, patient support groups, and individual Canadians to educate and inform;
- promotion of evidence-based best practices;
- educational products (brochures/website); and
- oncofertility symposium.⁶⁶

Priorities listed for 2011–12 included:

- knowledge transfer and promotion of evidence-based best practices;
- implementation of stakeholder outreach program;
- delivery of patient/client group outreach strategy;
- integration of the results of the Canadian Community Health Survey Infertility Rapid Response Module into health promotion and educational planning; and
- activities to increase awareness of the risk factors associated with infertility.⁶⁷

Meanwhile, during this same time period, regulations were desperately needed for the legislation to become operational and for the AHRC to fulfil its mandate (for example, regulations with respect to reimbursement for expenditures under section 12).⁶⁸ The earlier rationale for perpetual delays in introducing the requisite regulations, namely waiting for the *Reference re AHRA*, was no longer plausible.

65. AHRC, *Making a Difference: Annual Report 2010-2011* (Ottawa: Health Canada, 2011), online: Health Canada <<http://www.ahrc-pac.gc.ca/v2/pubs/alt-formats/pdf/pubs/pubs/annual-annuel/2010-2011-rap-eng.pdf>>.

66. *Ibid* at 4.

67. *Ibid* at 5.

68. Section 12(1): No person shall, except in accordance with the regulations, and a licence:

- (a) reimburse a donor for an expenditure incurred in the course of donating sperm or an ovum;
- (b) reimburse any person for an expenditure incurred in the maintenance or transport of an *in vitro* embryo; or
- (c) reimburse a surrogate mother for an expenditure incurred by her in relation to her surrogacy.

(2) No person shall reimburse an expenditure referred to in subsection (1) unless a receipt is provided to that person for the expenditure.

Sections of the *AHRA* upheld by the Supreme Court of Canada required regulations, and yet these regulations were not forthcoming. While the AHRC did not have the authority or responsibility to draft and introduce the regulations, it certainly had the authority (and, we would argue, the responsibility) to advise the minister to press Health Canada to draft and pass regulations.

During this time period, neither the law member who had resigned previously for personal reasons nor any of the board members who had resigned in 2010 (as described earlier) were replaced. As a result, the law, ethics, policy, and patient backgrounds were not represented on the Board of Directors. Indeed, of the allowable maximum number of members (thirteen), there were only seven members. While the *AHRA* required that “the membership of the board of directors must reflect a range of backgrounds and disciplines relevant to the Agency’s objectives,” the membership only included three physicians, one senior health administrator, one president of a project management and communications company, a chair of Jewish Studies, and the director of research and senior communications consultant for the Archdiocese of Toronto.

In addition, during this time period, allegations of non-compliance with the constitutionally valid parts of the *AHRA* were brought to the AHRC’s attention.⁶⁹ And yet, no effective action appears to have been taken. Once again, the mandate and powers far outstripped the activities. Once again, the lack of activity and impact is particularly troubling when held up to the annual price tag—in 2010-11, the agency spent \$5.2 million.⁷⁰ The AHRC had a staff of fourteen full-time equivalent employees (FTEs).⁷¹ It is not at all evident from the record that there was anything close to good value for fourteen FTEs and \$5.2 million.

Act Four: Spring 2012

On 29 March 2012, the federal government announced in its budget that it would wind down the AHRC:

The Government will introduce legislation to wind down Assisted Human Reproduction Canada, with final closure of operations by March 31, 2013.

(3) No person shall reimburse a surrogate mother for a loss of work-related income incurred during her pregnancy, unless

(a) a qualified medical practitioner certifies, in writing, that continuing to work may pose a risk to her health or that of the embryo or foetus; and

(b) the reimbursement is made in accordance with the regulations and a licence.

AHRA, *supra* note 1, s 12(1).

69. Alison Motluk, “The Human Egg Trade: How Canada’s Fertility Laws Are Failing Donors, Doctors, and Patients,” *The Walrus* (April 2010), online: The Walrus <<http://walrusmagazine.com/articles/2010.04-health-the-human-egg-trade/>>; “Infertile Canadians Buy Frozen Human Eggs from US,” *CBC News* (22 April 2012), online: CBC News Health <<http://www.cbc.ca/news/health/story/2012/04/20/eggs-frozen-fertility.html>>.

70. AHRC, *supra* note 47.

71. *Ibid.*

The winding down of the Agency responds to the 2010 ruling of the Supreme Court of Canada that significantly reduced the federal role in assisted human reproduction. Health Canada will take over responsibility for any remaining federal functions such as compliance and enforcement, and outreach.⁷²

On 26 April 2012, the federal government introduced legislation to give effect to the budget.⁷³ The bill was passed and received royal assent on 29 June 2012. The minister of health was given the authority to prevent or mitigate contravention of the *AHRA* immediately upon the bill receiving royal assent. The rest of the changes affecting the responsibilities, authority, and, indeed, very existence of the AHRC came into effect on 30 September 2012.⁷⁴

Act Five: Beyond 2012

So it is that an extraordinary opportunity to protect and promote the interests of those who use, or are born of, assisted human reproductive technologies was squandered. Many millions of dollars were wasted. Many hours of experts' time were squandered. Chaos was allowed to reign. As lamented by Françoise Baylis, "[t]here has been close to 30 years invested in terms of effort, energy and money [on the issue] and it's all for naught."⁷⁵ The promise and hope of 1989 (with the announcement of the Royal Commission) was renewed in 1993 (with the report of the Royal Commission), in 2004 (with the coming into force of the *AHRA*), and again in 2007 (with the first meeting of the AHRC's Board of Directors). But the promise and hope was eroded in 2010 (with the Supreme Court of Canada's decision in *Reference re AHRA*) and dashed in 2012 (with the abolition of the AHRC). As noted at the outset, the "why" of this denouement remains a mystery; the "what" is a tragedy. The onus is now on the provinces and territories to exercise their responsibility to protect and promote the interests of those who use assisted reproductive technologies and those who are born of these technologies.

72. Government of Canada, *Jobs, Growth and Long-Term Prosperity: Economic Action Plan 2012* (Ottawa: Government of Canada, 29 March 2012), online: Government of Canada <<http://www.budget.gc.ca/2012/plan/pdf/Plan2012-eng.pdf>> at 219.

73. *Act to Implement Certain Provisions of the Budget Tabled in Parliament on March 29, 2012 and Other Measures*, 1st Sess, 41st Parl, 2012, s 713-51 (assented to 29 June 2012).

74. *Order Fixing September 30, 2012 as the Day on Which Subsection 713(2) and Certain Sections of the Act Come into Force*, PC 2012-1136 (2012) C Gaz II, 21.

75. Tom Blackwell, "Government Shuttters Agency That Oversees Canada's Fertility and Assisted Reproduction Industry," *National Post* (30 March 2012), online: National Post <<http://news.nationalpost.com/2012/03/30/government-shuttters-agency-that-oversees-canadas-fertility-and-assisted-reproduction-industry/>>.