

Appendix 2 The Regulation of Assisted Human Reproductive Technologies and Related Research: A Public Health, Safety and Morality Argument [Expert Opinion for the Federal Government]

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On December 15, 2004, the Québec government filed a reference with the Québec Court of Appeal in which it challenged the constitutionality of the *Assisted Human Reproduction Act (AHR Act)*,¹ specifically sections 8–19, 40–53, 60, 61, and 68. In support of this challenge, the Québec government obtained an expert report from Professor Bartha Maria Knoppers and Ms Petit. In response, the federal government solicited an expert report from me in which I argued that federal legislation was needed to protect and promote public health, safety, and morality for current and future generations of Canadians through the pursuit of ethical and therapeutic science and technologies.

Arguments presented to the Québec Court of Appeal in support of the constitutional validity of the *AHR Act* did not succeed. The Court held that all of the challenged provisions were unconstitutional.² In the wake of this advisory opinion, the Government of Canada appealed to the Supreme Court of Canada (SCC). The SCC handed down its ruling on December 22, 2010.³ In a 4–4–1 decision, it determined that many (but not all) of the challenged provisions were *ultra vires* the federal government. Below is my expert report, which is cited in the SCC decision.

Statement of Expertise

I am a philosopher with ethics expertise on assisted human reproductive technologies, genetic technologies, and embryo research. This expertise dates back to the mid[-]1980s and includes both academic

research and national policy work. Some of the work is briefly detailed below in chronological order.

From 1987 to 1988, I was Academic Secretary for the Medical Research Council of Canada Working Group on Guidelines for Somatic Cell Gene Therapy (the Working Group was chaired by Dr. Patricia Baird,) who later chaired the Royal Commission on New Reproductive Technologies).⁴ In 1989, I completed my Philosophy PhD dissertation on “The Ethics of Ex Utero Research on ‘IVF’ Human Embryos[.]” In the dissertation, the main chapter of which is published in *Bioethics*,⁵ I introduced a novel ethical distinction between viable and non-viable human embryos.

In 1990 and 1991, I was a consultant to the University of Western Ontario research team on early Pre-Implantation Cell Screening – the first Canadian site to do research on pre-implantation genetic diagnosis. In 1991, I was a consultant to the Royal Commission on New Reproductive Technologies. My work on informed choice is included in Volume 1 of the Commission’s Research Studies.⁶

From the mid[-]1990s onward I developed an independent peer-reviewed research program with funding primarily from: Associated Medical Services Inc., the Social Science and Humanities Research Council of Canada, the Canadian Institutes of Health Research, and the Stem Cell Network, a member of the Network of Centres of Excellence program. This research has focused on women’s reproductive health, the ethics of research involving women, embryo research, gene transfer research, stem cell research, human cloning, and obligations to future generations.

In tandem with this research, I continued to be involved in national policy work. For example, from 1994 to 1997 I was a member of the Ethics Committee of the Society of Obstetricians and Gynaecologists of Canada and from 1997 to 1998 I was a Consultant with the Society of Obstetricians and Gynaecologist[s] of Canada and the Canadian Fertility and Andrology Society on their *Joint Policy Statement: Ethical Issues in Assisted Reproduction*.⁷ From 1998 to 2000 I was a member of the National Council on Ethics in Human Research.

On the strength of this record, in January 1999, I was invited to testify before the US National Bioethics Advisory Commission on the ethics of embryonic stem cell research.⁸

In the same year, I was appointed by the Governor in Council to the Canadian Biotechnology Advisory Committee.⁹ I then served on the Science and Industry Advisory Committee of Genome Canada from

2000 till 2003. In the Fall of 2000, I was named to the Canadian Institutes of Health Research (CIHR) *Ad hoc* Working Group on Stem Cell Research and I co-authored the guidelines published in 2002.¹⁰ From 2001 to 2004 I was a member of the CIHR Governing Council appointed by the Governor in Council (prior to this I completed a year of service in 2001 on the CIHR Genetics Institute Advisory Board).

From 2002 to 2004, as the federal legislation on assisted human reproductive technologies and related research was being developed, I was consulted by Health Canada on various aspects of Bill C-6 (formerly Bill C-13; formerly Bill C-56). I also testified, by invitation, in support of the draft legislation before the Standing Committee on Health and the Senate Committee on Social Affairs, Science and Technology.¹¹ Since the *Assisted Human Reproduction Act* received Royal Assent March 29, 2004, I have continued to be consulted by the government of Canada on various aspects of the legislation.

In 2004, I was awarded a Canada Research Chair in Bioethics and Philosophy to explore fundamental philosophical questions concerning our obligations to future generations in the development and use of biotechnologies.¹²

It is on the basis of this extensive and wide[-]ranging academic research and national policy experience that I offer the following opinion. I have read the décret #73-2006 of February 14, 2006 "Renvoi à la Cour d'appel du Québec relatif à la Loi sur la procréation assistée" (L.C. 2004, ch. 2) and the expert report (both the original French text and the English translation) filed by Professor Knoppers and Ms Petit. The purpose of my ethics expert report is to answer this report.

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Introduction

The Province of Québec has challenged the constitutionality of the *Assisted Human Reproduction Act* (hereafter, the *AHR Act*),¹³ specifically Sections 8–19, 40–53, 60, 61, and 68. From an ethical perspective this challenge is deeply problematic as the federal legislation is clearly needed to protect and promote public health, safety, and morality for current and future generations of Canadians through the pursuit of

ethical and therapeutic science and technologies. This need is articulated by the Commissioners of the Royal Commission on New Reproductive Technologies (including Professor Knoppers)¹⁴ and echoed in subsequent Health Canada documents, parliamentary committee reports, an open letter from Canadian health care ethics and health law experts, and the legislation itself.

In the 1993 Final Report of the Royal Commission on New Reproductive Technologies, *Proceed With Care*, the following statement appears:

Given what we have 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.¹⁵ [emphasis added]

The Commissioners re-emphasize the point in concluding their report and recommending criminal legislation including federal regulatory oversight:

We have judged that certain activities conflict so sharply with the values espoused by Canadians and by this Commission, and are so potentially harmful to the interests of individuals and of society, that they must be prohibited by the federal government under threat of criminal sanction. These actions include human zygote/embryo research related to ectogenesis, cloning, animal/human hybrids, the transfer of zygotes to another species, or the maturation and fertilization of eggs from human fetuses; the sale of human eggs, sperm, zygotes, fetuses, and fetal tissue; and advertising for or acting as an intermediary to bring about a preconception arrangement, receiving payment or any financial or commercial benefit for acting as an intermediary, and making payment for a preconception arrangement.¹⁶ [emphasis added]

In 1996, with the introduction of Bill C-47, the *Human Reproductive and Genetic Technologies Act*, Health Canada published *New Reproductive and Genetic Technologies: Setting Boundaries, Enhancing Health* outlining the government's intention to introduce a regulatory framework. The following statement, explaining the purpose of the legislation, appears in this document:

The major objectives of the new legislation are the following: first, *to protect the health and safety of Canadians in the use of human reproductive materials for assisted reproduction, other medical procedures and medical research*; second, to ensure the appropriate treatment of human reproductive materials outside the body; and third, *to protect the dignity and security of all persons, especially women and children*. These goals are best accomplished through legislation where certain practices are criminalized.¹⁷ [emphasis added]

In May 2001, the Minister of Health presented the Standing Committee on Health with a draft legislative proposal -- Bill C-56, *An Act Respecting Assisted Human Reproduction* -- for review and discussion. At this time, Health Canada published "Frequently Asked Questions" and directly addressed the purpose of federal legislation in the area of assisted human reproduction:

Why is the federal government legislating in this area -- isn't it an area where the provinces have control? The draft legislation is *founded upon the federal responsibility for criminal law, as is other federal health protection legislation such as the Food and Drug Act and the Tobacco Act*. In Canada, the courts have affirmed that the criminal law power will support the creation of prohibitions which serve a public purpose, including public peace, order, security, health and morality. The draft legislation on assisted human reproduction contains prohibitions pertaining to a number of unacceptable activities including cloning and commercial surrogacy. *The proposal that is now before the Standing Committee on Health is the result of consultations with the provinces and territories, as well as with numerous stakeholder groups and concerned members of the public. A consensus exists that the Government of Canada should provide leadership by putting in place a legislative framework that would ensure consistency of measures governing assisted human reproduction.*

Which activities would be regulated? One of the main purposes of the regulations would be to *protect the health and safety of Canadians -- particularly of women and of the children who are born through assisted human reproductive procedures*.¹⁸ [emphasis added]

Later the same year, in December 2001, the House of Commons Standing Committee on Health issued the following recommendations:

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

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

The Statutory Declaration set forth the following guiding principles:

... (f) human reproductive technologies provide benefits to individuals, families, and society in general; (g) those benefits can be most effectively secured by taking appropriate measures *for the protection and promotion of human health, safety, dignity, and rights in the use of such technologies*.¹⁹ [emphasis added]

And, correspondingly, Bill C-13 (as reported to the House on December 12, 2002), later Bill C-6, and finally the *AHR Act* (as assented to March 29, 2004) declare:

2(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 related research*. [emphasis added]

Significantly, the general purpose of Bill C-13 found favour with health care ethics and health law academics and consultants in Canada who, in an open letter dated October 26, 2003, applauded the Government for introducing the assisted human reproduction legislation and insisted that "the safety and well-being of Canadian women and children depends upon them passing the legislation now."²⁰ Never before, or since, have members of the Canadian bioethics community taken a public stance on a matter of bioethical import.²¹

In sum, extensive studies and reports (including a Royal Commission) have concluded that the legislation now being challenged by the Province of Québec is needed to protect and promote public health, safety and morality. This conclusion not only remains valid today, but is even more urgent and persuasive given the changing technology landscape, and the current political and economic climate.

To explain, assisted human reproduction is different from other medical technologies and areas of research insofar as reproduction plays

a central role in the lives of women, families, and society. As a result, it is anticipated that assisted human reproduction will have a direct impact on: women's reproductive health and well-being, particular groups of women, children, family structure, people with disabilities and society in general in terms of our understanding of how we relate to each other. Second, the ever expanding range of available technologies requires us to confront profound moral questions about the extent to which human life can be created, manipulated, redesigned and commodified. Third, the risks associated with assisted human reproductive technologies and related research are serious, new, and complex, not only for those who access the technologies or participate in the research, but for all Canadians given the potential use of these technologies to alter fundamental species characteristics and thereby call into question our understanding of personhood and humanness. Fourth, the potential commercial opportunities in this area of practice and research allow unusual threats of conflict of interest on the part of clinicians and researchers. These concerns, taken together, underscore the need for federal legislation.

Outline

The ethical argument in defence of the federal government's decision to legislate in this area is in three parts.

Part One explains how federal oversight of assisted human reproductive technologies and related research is necessary for both principled and practical reasons to protect and promote public health and safety for all Canadians, especially women and children (irrespective of their place of residence).²² Further, Part One explains the need to protect and promote public morality especially in relation to the commercialization and commodification of human reproduction, human reproductive materials and human embryos. The alternative to federal legislation – a fragmented, variable, province-by-province-by-territory approach – is morally unsound. As explained below, diversity among the provinces and territories in regard to the regulation of assisted human reproductive technologies and related research is contrary to the health and safety interests of Canadians, and to Canadian social values – i.e., “the ideals that we as a society espouse and consider fundamental to our ability to thrive both individually and collectively.”²³

Part Two explains why the provincial “multi-institutional regulatory partnership” constructed by Professor Knoppers and Ms Petit

is not a sound alternative to the current federal legislation. Part Two also draws attention to the fact that Professor Knoppers herself elsewhere concedes that the federal government has jurisdiction in this area. Indeed, in places she has even advocated for the exercise of this jurisdiction (both through controlled and prohibited activities).²⁴ It follows that her expert report can only be taken to be presenting an alternative approach to federal legislation. The existence of an alternative approach, however, does not in any way undermine the claim of federal jurisdiction.

Part Three highlights the moral foundation for the current federal legislation. The *AHR Act* is the fruit of an unprecedented, comprehensive, public consultation initiated in the late 1980s and culminating in the 1993 Final Report of the Royal Commission on New Reproductive Technologies, *Proceed with Care*.²⁵ Canadian social values, as recorded in the Commission's Final Report (and reaffirmed in subsequent parliamentary committee reports, government policy papers, as well as expert testimony before the Standing Committee on Health), underpin the current federal legislation.

1. The Need for Federal Oversight of Assisted Human Reproductive Technologies and Related Research to Protect and Promote Public Health, Safety and Morality

The *AHR Act* is needed to protect and promote the public health and safety of current and future generations of Canadians through the pursuit of ethical and therapeutic science and technologies. Indeed, the development and use (or non use) of assisted human reproductive technologies and the pursuit (or non pursuit) of related research raise significant public health and safety concerns that need to be addressed in a comprehensive and consistent manner. To briefly illustrate this point, consider the risk of zoonosis – the transfer of an infectious disease from nonhuman animals to humans – when creating interspecific hybrids, transgenics or chimeras.²⁶ This is a significant public health and safety concern that knows no geopolitical boundaries. No less significant a public health risk is sex selection for non-medical reasons, as this could alter the usual ratio of boys to girls. Indeed, in India and China where sex determination followed by female foeticide, infanticide and homicide is practiced, there is a significant imbalance in the boy-girl ratio²⁷ as well as an increase in gender discrimination.

Second, the *AHR Act* is also needed to safeguard Canadian social values. Assisted human reproductive technologies and related research raise profound moral questions about the extent to which human life can be created, manipulated, redesigned and commodified, and the answers to these questions have profound implications for the values of respect for human life and human dignity. For example, while the possibility of human cloning to produce children raises important health concerns, it is the ethical issues and the anticipated social and legal consequences that are most troubling and that render policy-making about human cloning a federal priority. The same can be said of commercial surrogacy (i.e., contractual pregnancy) where, for a fee, a woman agrees to become pregnant and bear a child for another. She does so not only at increased health risk to herself, but in a context of increased risk of coercion and exploitation for all women. In addition, there are worries about the commodification of human reproductive labour as well as the commodification of human reproductive materials and embryos.

The *AHR Act* addresses these public health, safety and morality concerns by enacting clear prohibitions and by introducing a federal regulatory framework for the responsible and ethical use of those assisted human reproductive technologies and services that are permitted.

1.1 The Appointment of a Royal Commission on New Reproductive Technologies

In the late 1980s, the Canadian government established a Royal Commission on New Reproductive Technologies (Commission) with a broad and expansive mandate. In its own words, the Commission understood its mandate as follows:

The appointment of a royal commission was an opportunity to collect much-needed information, to foster the public awareness and debate that are necessary to create an informed social consensus, and, above all, to provide a principled framework for Canadian public policy on the use or restriction of these technologies. The Commission was thus placed squarely in the gap between technological development and policy development, with the task of helping to close it.²⁸

....

A royal commission's role is to clarify facts and issues, to analyze them from an ethical and social perspective, and to make principled

recommendations chosen from among clearly described alternatives. The over-riding goal of the Royal Commission on New Reproductive Technologies was to do this for the consideration of the Government, Parliament, and the people of Canada.²⁹

After several years of research, consultation and deliberation, the Commission concluded that the individual and collective interests of Canadians were best served by developing comprehensive policies and regulations at the federal level.

... the research, development, and use of new reproductive technologies involve national concerns that cut across social, ethical, legal, medical, economic, and other considerations and institutions. This characteristic of new reproductive technologies generates the needs for a *distinct* regulatory and organizational response – one capable of responding to and dealing with the issues in a comprehensive way.³⁰ [emphasis added]

The following are among the many reasons given by the Commission for the broad national framework it proposed:

Canada's response to reproductive technologies must reflect constitutional values with respect to promoting equality and accommodating diversity, in the overall context of establishing congruence and consistency with Canadians' values and priorities and Canada's changing social fabric.

Finally, no existing legislation or regulatory regime is broad enough and no public or private organization is equipped or has demonstrated the capacity to deal with these questions in the comprehensive, timely fashion we believe is necessary.³¹

1.2 The Need for Federal Oversight, and the Problems with Independent Provincial or Territorial Oversight

Over the course of its mandate, the Commission was repeatedly reminded "of the *dangerous* and inequitable situation created by the existing patchwork of laws, standards, programs, and services across Canada"³² [emphasis added]. The *AHR Act* corrects this problem by ensuring a pan-Canadian approach to the regulation of assisted human reproduction and related research. The *AHR Act* introduces minimum federal safety and ethical standards for controlled activities. These regulations apply in all provinces and territories, except for those provinces

that: "agree in writing that there are law of the province in force that are equivalent to those sections and the corresponding provisions of the regulations."³³

The most significant problem with independent provincial or territorial oversight is reproductive and scientific tourism. Indeed, the need for comprehensive, coherent, harmonized standards of practice across the country to discourage any form of reproductive tourism was identified by the provinces and territories in consultation with Health Canada as a reason for federal leadership.³⁴ In the realm of therapy, the *AHR Act* seeks to prevent an interprovincial and territorial human resource drain (which could result in shortages not only for assisted reproduction but also for basic reproductive care) by eliminating the incentive for clinicians to move to another province or territory simply to practice in a place with no rules or "less onerous" rules. In the realm of research, the *AHR Act* seeks to avoid similar mobility issues for researchers and research sponsors and achieves this for human embryo research (whether the research involves the use of human reproductive materials for the purpose of creating an embryo (including a transgenic embryo), or research on existing embryos), by having this be a controlled activity for which a license is required. This is an important achievement given emerging evidence in the United States of the ways in which a regulatory patchwork of research policies can affect the mobility of stem cell researchers interested in embryo research. Indeed, a recent study shows that researchers are being actively solicited to relocate to countries and states with permissive embryonic stem cell research policies.³⁵ In addition to the issue of mobility, there is the issue of standards. With research involving humans it has already been noted that "if provinces and territories continue to vary in their oversight of research, we will likely see a 'race to the bottom' as research sponsors will disproportionately situate research in jurisdictions perceived to be the most 'research friendly' or, put differently, with the lowest standards."³⁶ The same risk applies to human embryo research.

Consider now the public health, safety and morality protection and promotion aspects of some of the sections of the *AHR Act* contested by the Québec government.

Section 8 of the *AHR Act* requires written consent from gamete donors to use reproductive material (from a live donor or from a donor's body after death) to create an embryo, as well as written consent to use in vitro embryos. This requirement is clearly in the interest

of those who use assisted human reproductive technologies. Without this federal legislation, the disposition of reproductive materials and in vitro embryos might not be under the legal control of the gamete providers, but under the legal control of IVF clinic directors. Persons unable to produce their own gametes might seek out clinic directors prepared to give them donor gametes with no attention being paid to the wishes of the donors. Also, without the current federal legislation (with its coherent set of national norms) moribund patients or corpses might be transported from one province or territory that would prohibit the posthumous use of reproductive material to create an embryo, to another province or territory that would allow this practice. In neither scenario would the public health, safety, and morality interests of Canadians be protected or promoted.

Section 9 prohibits obtaining gametes from minors (i.e., persons under 18 years of age) "except for the purpose of preserving the sperm or ovum or for the purpose of creating a human being that the person reasonably believes will be raised by the donor."³⁷ Without the federal legislation that is currently being challenged, there might be no age limit and young girls at the age of menarche might be approached to donate gametes for others' reproductive or research use. This could hardly be consistent with their health and safety interests, especially when one considers both the short- and long-term health risks of ovulation induction and oocyte retrieval. One reasonably well-documented short-term risk of ovulation induction is ovarian hyperstimulation syndrome (OHSS). Mild forms of OHSS include: "transient lower abdominal discomfort, mild nausea, vomiting, diarrhea, and abdominal distention (observed in up to a third of superovulation cycles)."³⁸ These symptoms may persist or worsen resulting in serious illness marked by one or more of the following: "rapid weight gain, tense ascites, hemodynamic instability (orthostatic hypotension, tachycardia), respiratory difficulty, progressive oliguria and laboratory abnormalities. Life-threatening complications of OHSS include renal failure, adult respiratory distress syndrome (ARDS), hemorrhage from ovarian rupture, and thromboembolism."³⁹ The long-term risks to women of OHSS are less well documented, but there are two studies that suggest a link between ovarian stimulation and ovarian cancer.⁴⁰ In addition to these physical risks, there are the twin risks of coercion and exploitation. Taken together, these risks speak loudly to the need for clear, legislated limits on the permissible as found in the *AHR Act*.

Section 10 provides the framework for the regulations concerning the alteration, manipulation, treatment, use, obtention, storage, transfer, destruction, import or export of human reproductive materials and in vitro embryos in order to address the health and safety risks associated with these procedures. Consider the option of cryostorage of excess embryos (i.e., embryos in excess of the maximum for transfer in a single cycle). Women who undergo the painful and risky procedure of ovarian stimulation as part of infertility treatment in the hope of building a family have a strong interest in cryopreserving embryos that are not transferred in the original stimulated cycle.⁴¹ Failure to cryopreserve embryos for future reproductive use means: (i) an increase in the number of uncomfortable, painful or risky procedures that women undergo in pursuit of their reproductive project (physical harms); (ii) an increase in the psychological stress associated with the use of assisted human reproductive technologies (psychological harm); (iii) a decrease in the chance of pregnancy (psychological and social harm); (iv) an increase in the social disruption associated with the use of assisted human reproductive technologies (social harm); and (v) an increase in the financial burden of infertility treatment (economic harm).⁴² It is important that the regulations pursuant to the *AHR Act* protect and promote the health and safety of women whilst safeguarding them from the twin risks of coercion and exploitation by researchers who would prefer that women donate their fresh embryos to research instead of cryopreserving them for later reproductive use.⁴³

Section 11 provides the framework for regulations concerning the combination of "any part or any proportion of the human genome specified in the regulations with any part of the genome of a species specified in the regulations."⁴⁴ Without the *AHR Act* transgenic research might go unregulated and this could result in serious public health consequences (consider, for example, the possibility of zoonosis).⁴⁵ Research that involves crossing species boundaries is not only potentially dangerous, it is also ethically controversial. Many perceive this research as a threat to human dignity because it raises fundamental questions about who we are and will become as a species. Allowing unregulated transgenic research would be clearly inconsistent with the public health, safety, and morality interests of Canadians.

Section 12 is about setting limits on reimbursement for expenditures incurred in relation to gamete donation or embryo transfer as well

as surrogacy (i.e., contract pregnancy). The purpose of limiting reimbursement (in addition to prohibiting outright payment for reproductive materials and services), is to further minimize the commodification of women's reproductive materials and reproductive labour as well as minimize the risks of coercion and exploitation. Without this legislation, reimbursement or payment practices in some provinces or territories might make gamete and embryo selling as well as contract pregnancy very attractive options for some women who will be at increased risk of commodification. In turn, this commodification can lead to objectification and exploitation because where there is a market for gametes, embryos or contract pregnancy women in certain economic conditions may "agree to use their bodies in ways that demean their humanity."⁴⁶ The Commission writes most eloquently on this point with specific reference to contract pregnancy:

Allowing or ignoring the practice of preconception agreements in one province while it is prohibited elsewhere would have a harmful impact, not only on gestational mothers and other women in the province in question, but on Canadian women generally. Such permissiveness in one jurisdiction – quite apart from the "reproductive tourism" it would encourage – would convey tacit acceptance, or even affirmative state sanction, of a practice that is likely to undermine the value, dignity, reproductive capacity, and bodily integrity of Canadian women. Again, because of the great mobility of Canadians, failure to impose adequate controls on the safety of assisted conception technologies in one province or region would inevitably have social, health, and economic consequences as those affected moved elsewhere.⁴⁷

Section 13 establishes the need for uniform high quality standards for the clinics and research facilities where assisted human reproductive technologies are provided and related research is conducted. Canadian families, women and children are entitled to access high quality treatment and research premises across the country. Indeed, their health and safety depends on it.

Section 14 mandates the collection of health reporting information from persons providing human reproductive material and in vitro embryos. This mandatory reporting of health information on a national scale is crucial to the public health and safety of Canadians as this means data will be available on the basis of which to assess safety, efficacy and effectiveness.

Section 15 addresses privacy issues. More specifically, it aims to protect the personal identity of persons providing health reporting information. The promise of anonymity means that gamete donors are not at risk of having parental responsibilities for genetic offspring with whom they have no social, familial ties. It also means, however, that children born of donor gametes can only have access to non-identifying health information about the donor. The balance of harms and benefits in relation to this issue remains contested; for now the legislation serves to ensure a consistent approach across the country which arguably is preferable to the current situation in Canada with adoption.

Sections 16 to 19 deal with a range of issues concerning access to health reporting information, the destruction of such information, the destruction of human reproductive material, the maintenance of a health information registry, the use of information in the registry, the disclosure of such information, and so on. These issues are absolutely critical to the public health, safety, and morality interests of Canadians. It is only through careful, comprehensive, standardized, national reporting and data analysis that we can come to understand the long-term safety, efficacy and effectiveness of various interventions and identify risks to public health and safety, or possible human rights abuses. Mandating health reporting information from all clinics across the country ensures the largest, most reliable database (which is needed to develop sound, evidence-based standards of care). It also permits identification of clinics that have unusually high incidence of poor health outcomes which may indicate that they are engaging in excessively risky interventions. Also, with a national registry there can be important economies of scale. Considerable public resources are required to develop and maintain a health information registry, a monitoring system, a cadre of expert inspectors, etc. Resources saved in this context, might be available to respond to other public health needs.

In sum, a fragmented, variable, province-by-province-by-territory approach to the regulation of assisted human reproductive technologies and related research raises important health and safety concerns for Canadians (especially women and children) and potentially undermines the dignity and rights of Canadians. In contrast, the AHR Act serves to protect and promote public health, safety, and morality for current and future generations of Canadians. It does so by introducing comprehensive, coherent, harmonized standards of practice across the country for both therapy and research involving assisted human reproductive technologies.

2. A Multi-Institutional Regulatory Partnership as an Alternative to Federal Legislation

The expert report prepared by Professor Knoppers and Ms Petit describes a "multi-institutional regulatory partnership" in Québec for the regulation of assisted human reproductive technologies and related research. This regulatory partnership involves the provincial government, provincial professional organizations, local research ethics boards (REBs), and the provincial research funding organization, Fonds de la recherche en santé du Québec. Professor Knoppers and Ms Petit suggest that together these provincial "institutions" provide sufficient regulatory oversight.

Below I carefully review the regulatory partnership approach. First, I critically examine the limitations of provincial legislative action, as well as administrative and institutional actions. I then summarize the problems with relying on provincial professional organizations' ethics codes and guidelines. Next, I rehearse some of the problems with the role of research ethics boards (REBs), and then I identify the problem of conflict of interest with the Fonds de la recherche en santé du Québec. Finally, I comment on the apparent inconsistency in Professor Knoppers' views on the regulation of assisted human reproductive technologies and related research.

2.2.1 Provincial Legislative Action and Administrative and Institutional Actions

Professor Knoppers and Ms Petit briefly summarize current provincial legislative action in Québec in the area of family law (addressing the legal status of children born of assisted human reproduction), public health protection law (with the *Act respecting medical laboratories, organ, tissue, gamete and embryo conservation, and the disposal of human bodies*), and tax law (introducing a system of refundable tax credits to help defray the costs of certain reproductive technologies). They also refer to general laws of the province, and they mention Bill 89, *An Act respecting clinical and research activities as regards assisted human reproduction and amending other legislative provisions*.

The problem with this summary of provincial legislative action is that it looks at Québec in isolation from the other Canadian provinces and territories. This is problematic because the ultimate issue is not what is acceptable for one province (in this case Québec), but rather what is

acceptable for all ten provinces, for all three territories, and for Canada as a country. More precisely, the issue in this case is whether to allow a fragmented, variable, province-by-province-by-territory approach to the regulation of assisted human reproductive technologies and related research, or whether to embrace a comprehensive and coherent federal legislative approach as found in the *AHR Act* that will protect and promote public health, safety and morality for Canadians whilst preserving the provinces' ability to legislate in this area. The *AHR Act* allows the Governor in Council to "declare that any or all of sections 10 to 16, 46 to 53 and 61 and any corresponding provisions of the regulations do not apply in a province ... [where] the Minister and the government of that province agree in writing that there are law[s] of the province in force that are equivalent to those sections and the corresponding provisions of the regulations."⁴⁸

The same criticism applies to provincial administrative and institutional actions in Québec. It follows that diversity and full flexibility in the regulation of assisted human reproductive technologies and related research is contrary to the collective interests of current and future generations of Canadians. This does not mean that provincial or territorial legislation should be precluded, but simply that it should be part of a coherent, consistent, national framework. To quote the Commission on this point:

This [i.e., the need for national leadership] does not obviate the need for decisive action by provinces and professional bodies as well, but action at the national level must provide the leadership and impetus for a new approach to managing reproductive technologies.⁴⁹

In brief, provincial government action, should harmonize with federal legislation so as to further protect and promote public health, safety and morality, in a manner consistent with the *AHR Act*. Provincial action (in Québec or any other province) is insufficient in the absence of national legislation that (i) is consistent with Canadian social values, (ii) is protective of the public health, safety, and morality of Canadians, and (iii) ensures equal access and non-discrimination. Only with national legislation providing minimum ethical and safety standards is it possible to guard against (i) reproductive and scientific tourism, (ii) potentially harmful assisted human reproductive technologies and related research, and (iii) the attendant risks to women and children that a fragmented, variable, province-by-province-by-territory approach would allow for.

2.2.2 Provincial Professional Organizations

A common problem for self-regulating professions, especially when setting the rules for safety, quality assessment, and ethics is conflict of interest. In very general terms, professional health organizations have a primary interest in promoting the health of patients. They also have a secondary interest in protecting their members' professional monopoly. When the primary and secondary interests conflict, decisions regarding the dominant interest (improved health care) may be unduly influenced by professional self-interest in maintaining professional power and privilege. Deference to professional interests is evident in the expert report prepared by Professor Knoppers and Ms Petit where they suggest that regulatory mechanisms (such as guidelines and codes) are accepted and adhered to by the members of the scientific and medical community as they are consonant with their interests, "ces dispositifs évoluent selon des critères propres à la communauté médicale et scientifique, lesquels sont gages d'une acceptabilité et d'une mise en oeuvre appropriée par ces membres."⁵⁰ But why privilege criteria of interest to the scientific and medical community over and above criteria of interest to infertile patients, especially as these criteria may diverge significantly from those of researchers and clinicians?

Another point worth noting is that in the past when there was an absence of legislation, the codes of ethics and ethical practice guidelines of relevant professional organizations were not particularly effective in promoting public health, safety and morality. Consider, for example, the long-term failure of relevant professional health organizations to develop sound ethical practice guidelines and policies regarding the maximum number of embryos for transfer per cycle. Indeed, to this day [2006], despite considerable evidence of the harmful consequences associated with multiple pregnancy and multiple birth for both women and children,⁵¹ there is nothing mandating Canadian clinicians to limit the number of embryos transferred per cycle.⁵² Indeed, in a 2005 publication summarizing 2001 Canadian data, the IVF Directors Group of the Canadian Fertility and Andrology Society eschews responsibility for directing Canadian centers to reduce the number of embryos transferred per cycle:

One issue of great concern to all providers and consumers of ART is that of multiple pregnancy. Although it is not the role of CARTR [Canadian Assisted Reproductive Technologies Register] to encourage its member

centers to reduce their multiple pregnancy rates through limiting the number of embryos transferred, it is our responsibility to provide data to inform centers about the situation in Canada. Whereas many policy makers, in Europe especially, are pushing for single-embryo transfers to virtually eliminate multiple pregnancy, in Canada, more than half of the fresh ETs [embryo transfers] in 2001 involved three or more embryos.⁵³ [emphasis added]

To date [2006], there are no professional guidelines in Canada dealing with this important public health issue.

Further long-standing evidence of the failure of professional organizations to promote public health, safety and morality include (i) the failure to develop and to enforce uniform standards for reporting fertilization, clinical pregnancy, live birth and multiple birth rates, (ii) the failure to insist upon the practice of evidence-based medicine, (iii) the failure to clearly distinguish research interventions from therapeutic interventions, and (iv) the failure to develop uniform consent procedures for both therapy and research (with, for example, standardized descriptions of the potential harms and benefits). Now, in recent years, some of the failures noted above have been addressed. For example, for the first time, in 2005, the IVF Directors Group of the Canadian Fertility and Andrology Society published aggregate data for 2001 for 19 of the 22 clinics providing assisted reproductive technologies at that time (the three Québec clinics elected not to provide any data). Hereafter, these data are to be published on an annual basis.

As professional standards and practices have been developed, however, there has been an evident interest in shielding members of the profession "from outside knowledge of their deviance [from standards, as this] also shields the profession from embarrassment, with its potential for precipitating a decline in public trust."⁵⁴ For example, in Canada the data on fertilization, clinical pregnancy, live birth and multiple birth rates are provided as aggregate data (i.e., data that is combined from several measurements), not per clinic data.⁵⁵ In other jurisdictions (including the United States and the United Kingdom), these data are provided separately per clinic which allows patients to make comparisons between clinics. In this way, there is information about the performance of individual clinics as well as general information about all clinics taken together. While the IVF Directors Group of the Canadian Fertility and Andrology Society offers several reasons for this difference in practice, the fact remains that there is clear professional self-interest

(especially in a context of voluntary reporting) in not making clinic specific data publicly available in Canada.

The *AHR Act* overcomes problems of professional conflict of interest. The regulations pursuant to the legislation are developed by government, not interest groups (though relevant stakeholders have been, and no doubt will continue to be, consulted). As well, Assisted Human Reproduction Canada (AHRC) – a federal regulatory body mandated "(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 [AHR] Act applies"⁵⁶ [–] is governed by an independent board of experts. Excluded from membership on the board are persons who "hold a licence or are an applicant for a licence or a director, officer, shareholder or partner of a licensee or applicant for a licence."⁵⁷ In these ways the *AHR Act* addresses some of the failures noted above. For example, AHRC would have both individual and aggregate data about a range of therapeutic and research practices undertaken in Canadian clinics and could use this data to effectively protect and promote the health and safety of Canadians.

2.2.3 Role of Research Ethics Boards

There are 105 health care institutions in Québec with REBs (9 of which are mixed research and clinical ethics committees).⁵⁸ The problems these local REBs face are many and include (i) the lack of expert ethics review owing, in part, to the absence of a *required* education and certification program for REB members to ensure that they are adequately trained for the job,⁵⁹ (ii) the potential for compromised ethics review depending upon the volume of protocols submitted for review (too few protocols and REB members may not develop the requisite expertise; too many protocols and REB members may "cut corners"), (iii) the failure to effectively promote the collectivization of learning and thereby reduce ad hoc decision-making owing, in part, to the isolation of REBs and the absence of an accreditation program for REBs, (iv) the lack of appropriate administrative support and operating funds for REBs to do the job well, (v) continued, inappropriate reliance on volunteer REB members, and (vi) the inability of REBs (that rely on volunteers and are typically under-staffed and under-funded) to properly monitor the research they approve (which raises significant problems of accountability).⁶⁰ Indeed, in a 2001–2002 study of the day-to-day challenges

faced by Québec REBs, only published in 2004, 100% of REBs surveyed reported major problems resulting from inadequate financial resources (and explained how this had a direct impact on the ability of REBs to maintain an adequate level of expertise); 96% reported major problems resulting from inadequate human resources (in part because of continued reliance on volunteers); 84% reported problems to do with the isolation of independent REBs; 82% reported problems owing to the lack of time for proper ethics review; and the list goes on.⁶¹

Importantly, the *AHR Act* addresses some of these problems, at least with respect to embryo research. Such research is a controlled activity for which a license must be issued by AHRC. AHRC is to be adequately resourced both in terms of finances and personnel. Moreover, AHRC has the authority to set terms and conditions on any license it issues and is also empowered to amend, suspend or revoke a licence, as appropriate. Further, AHRC “may take all reasonable measures that [it] ... considers necessary to prevent, reduce or mitigate any threat to human health or safety that results, or may reasonably be expected to result from a controlled activity.”⁶² This cannot but count as an improvement on the *status quo* where review by local REBs is potentially lacking in adequate resources, expertise and authority. AHRC can also designate inspectors and analysts for the purpose of enforcing the *AHR Act* and monitoring research facilities, thereby effectively addressing the issue of accountability[,] which remains a significant challenge for local REBs that struggle to meet the mandated requirement that “les comités d’éthique de la recherche verront à préparer et mettre en place un mécanisme de suivi éthique pour les projets de recherche en cours.”⁶³

2.2.4. Role of the Provincial Research Funding Organization

The Fonds de la recherche en santé du Québec (FRSQ) has fairly comprehensive ethics guidelines that apply to researchers and research institutions that receive FRSQ funding.⁶⁴ However, as with other research ethics guidelines in Canada, there are problems with enforcement as well as conflict of interest.

As regards enforcement, there are questions about compliance with the ethics guidelines and about the failure to impose serious sanctions on researchers and research institutions that violate the ethics guidelines. These concerns extend beyond the provincial FRSQ ethics guidelines, and include the national ethics guidelines – the Tri-Council Policy Statement (TCPS)⁶⁵ – which apply to all Québec researchers and

research institutions that receive federal funding from the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada, or the Social Sciences and Humanities Research Council of Canada. Evidence of noncompliance with the TCPS notwithstanding,⁶⁶ as at 2005, there were no documented cases of Québec research institutions having been disciplined through freezing or withdrawal of research funding for noncompliance with the TCPS.⁶⁷

A further problem with enforcement is that the FRSQ guidelines only apply to researchers and research institutions that receive FRSQ funding. Meanwhile, a significant proportion of research and innovative practice involving reproductive technologies and human embryos is conducted in private clinics that may not rely on public (provincial or federal) funding, in which case the provincial and federal ethics guidelines simply have no force. Article 21 of the *Code civil du Québec*⁶⁸ requires REB approval of publicly- and privately-funded research, but only for research that involves minors and incompetent persons. Nothing in this law or any other Québec law requires REB approval for privately-funded research involving competent persons.

Second, there is the problem of structural conflict of interest. The FRSQ is an agency of the government of Québec, created under the *Act Respecting the Ministère du Développement économique et régional et de la Recherche*.⁶⁹ It is an organization with competing interests and obligations, such that the protection of public health, safety and morality is not clearly its sole or even primary obligation. The FRSQ’s mission is not only to promote and provide financial support for scientifically and ethically sound research, it is also to contribute to Québec’s economic growth:

Le FRSQ n’est pas un conseil de recherche mais bien un Fonds dont la mission est de contribuer au développement de la recherche scientifique et technologique dans le domaine de la santé des personnes et des populations et de participer au développement économique du Québec.⁷⁰

These are laudable goals, but what happens when ethics and economics conflict as with research involving assisted human reproductive technologies and related research?

Importantly, with the *AHR Act*, embryo research is not plagued with problems of enforcement or conflict of interest. The *AHR Act*

introduces clear prohibitions on certain types of research and creates enforceable rules for all research that is a controlled activity. The criminal prohibitions and research regulations apply equally to publicly- and privately-funded research and any person who contravenes the *AHR Act* is potentially subject to a significant fine or term of imprisonment.⁷¹ As well, there is AHRC with the power to issue, amend, suspend, or revoke research licenses, and to monitor research sites for compliance with the *AHR Act*.⁷²

2.2.5 Conclusion

In response to the above analysis, Professor Knoppers and Ms Petit might object that it is inappropriate to assess the merits of each regulatory mechanism in isolation given that they have proposed a "regulatory partnership" in which the weaknesses of one regulatory mechanism might be compensated for by the strengths of another. However, as the Commission argued [including Professor Knoppers, as one of the Commissioners]:

*... it is unrealistic to expect self-regulating professional bodies, or the provinces, individually or together, to provide the necessary level of regulation and control on issues that transcend not only provincial but national and intergenerational boundaries and that have implications for all Canadians, regardless of where they live. It is the view of Canadians, and Commissioners' view as well, that given rapidly expanding knowledge and rapid dissemination of technologies, immediate intervention and concerted leadership are required at the national level.*⁷³ [emphasis added]

In their expert report, Professor Knoppers and Ms Petit do not contest the need for "concerted leadership at the national level," nor do they challenge the federal government's authority in criminal matters. Indeed, in the Foreword, Professor Knoppers is supportive of (at least some of) the criminal prohibitions in the *AHR Act*. She writes (in reference to her work with the Commission), « J'adhérais par ailleurs à la proposition visant à criminaliser certaines activités moralement répréhensibles notamment, le clonage reproductif humain. »⁷⁴ Also, the closing sentence in the Foreword states: « Les activités prohibées par la législation fédérale et les dispositions du projet de loi n° 89 offriront ensemble une protection adéquate des citoyens et citoyenne tout en respectant leur liberté et valeurs individuelles. »⁷⁵ Bill 89 is surely

irrelevant, however, to any analysis of whether the legal patchwork in Québec meets the federal standard of equivalence and adequately promotes and protects public health, safety and morality for Canadians living in Québec. The Bill has not been passed and so could still be significantly modified or even abandoned. As such, it can play no role in a debate about the sufficiency of the proposed multi-institutional regulatory partnership.

In any case, the point I wish to make here is that Professor Knoppers and Ms Petit appear to be of the view that criminal prohibitions are a matter of federal jurisdiction, while the controlled activities are in provincial jurisdiction, and are best handled by a conglomeration of provincial government action, professional organization ethics codes and guidelines, REBs, and the Fonds de la recherche en santé du Québec.

Interestingly, this perspective contrasts markedly with Professor Knoppers' earlier writings for the public[,] which support a federal approach to controlled activities. In an August 2001 Comment for *The Globe and Mail* Professor Knoppers writes:

The law has many positive attributes. Unfortunately, these are outweighed by one major problem, the continued reliance on criminal prohibitions ... The federal government could create a regulatory body empowered to both issue licences for a defined set of activities (similar to what is currently proposed) and produce, modify and monitor a "moratorium list" ... *a regulatory scheme with some criminal sanctions aimed at responding to legitimate public health concerns of all citizens would still be within federal jurisdiction. It would parallel other areas of federal oversight, such as Ottawa's work to protect the environment and control the marketing of tobacco and pharmaceuticals.*⁷⁶ [emphasis added]

Slightly less than a year later, in May 2002, also in *The Globe and Mail*, Professor Knoppers writes:

As one of the last Western countries to legislate in the area, Canada can learn from the mistakes of others and *produce a regulatory system* that could be a model for the world.⁷⁷ [emphasis added]

A week later, still in *The Globe and Mail*, Professor Knoppers writes:

We urge the [Canadian] government not to criminalize nuclear transfer, but to tightly regulate it ... It is possible to regulate controversial technologies such as

nuclear transfer without using criminal bans. The U.K. Human Fertilization and Embryology Authority is a working model of a regulatory body, one with a long and honourable history.⁷⁸ [emphasis added]

Together, these excerpts advocate support for federal criminal initiatives, with regulatory authority, and also concede that a federal law with some criminal sanctions is within federal jurisdiction.⁷⁹ These writings are therefore inconsistent with the perspective that federal regulations for assisted human reproduction and related research are not warranted because the development of such regulations is a provincial responsibility.

In my opinion, a federal approach to assisted human reproduction and related research that includes some criminal sanctions, and to which regulatory powers attach, is necessary to protect and promote public health, safety and morality for Canadians. And, until recently, it would appear that Professor Knoppers was also of this opinion.

In sum, the proposed alternative to the AHR Act – a multi-institutional regulatory partnership – is not a sound alternative. Only comprehensive, coherent, harmonized standards of practice across the country for both therapy and research involving assisted human reproductive technologies effectively serves to protect and promote public health, safety, and morality for current and future generations of Canadians.

3. The Moral Underpinnings of the Current Federal Legislation

The AHR Act includes six explicit and one implicit guiding principles: the principles of autonomy, equality, respect for human life and dignity, protection of the vulnerable, non-commercialization of reproduction, balancing individual and collective interests, and accountability. These principles mirror those of the Commission and as such (as at 1993) they (i) cohere with Canadian views and values, (ii) are consistent with ethical principles in other international inquiries, and (iii) are grounded in sound ethical reasoning.⁸⁰ These points all lend the current legislation unique moral credibility. It is also worth noting that in the years between the Commission's Final Report and the enactment of the AHR Act there is no evidence of a shift in core social values. For example, in 2001, the House of Commons Standing Committee on Health, identified the following overarching considerations for federal legislation: [r]espect for human individuality, dignity and integrity; precautionary approach to protect and promote health; non-commodification

and non-commercialization; informed choice; and accountability and transparency.⁸¹

3.1 The Commission's Ethical Framework and Guiding Principles

In 1993, following nearly four years of research, consultation and deliberation on a wide range of scientific, medical, ethical, legal, social, and economic aspects of assisted human reproductive technologies and related research, the Commission published its Final Report *Proceed with Care*. This report explains in considerable detail the ethical framework and guiding principles that informed the Commission's deliberations and policy recommendations.

The Commission adopted a modified ethic of care – a theoretical perspective with currency “in secular mainstream ethics, in feminist theory, and in religious thinking” that sees people as “connected to one another in families, communities, and social bonds of all sorts.”⁸² An ethic of care, in contrast to other ethical frameworks, prioritizes mutual care and connectedness; it aims to recognize interdependent interests, to build relationships and to prevent (or at the very least reduce) conflict. Not all conflict is avoidable, however. When there is conflict, the Commission recommends the use of guiding principles within the overall perspective of an ethic of care where the priority remains “on helping human relationships to flourish by seeking to foster the dignity of the individual and the welfare of the community.”⁸³

The guiding principles that, in the Commission's view, give “concrete expression to the ideal of care”⁸⁴ are individual autonomy, equality, respect for human life and dignity, protection of the vulnerable, non-commercialization of reproduction, appropriate use of resources, accountability, and balancing individual and collective interests.⁸⁵ These principles, which are to serve “as a sort of bottom line of social justice when all else fails,”⁸⁶ were identified through public hearings (oral testimony and written submissions), a review of reports from other countries, and a review of the bioethics literature. Most importantly, the Commission found that

the eight principles we identified ... reflect widespread consensus in Canadian society on the ethical basis that should guide decision making.

Indeed, these principles were endorsed by a very broad range of groups – professionals and laypeople, women and men, religious and secular

groups, members of racial and ethnic minorities, people with disabilities, doctors, and patients. That these principles were endorsed by groups with diverse experiences and interests confirms our belief that they capture important ethical considerations.⁸⁷

Indeed, an important feature of these mid-level principles is that they can be supported by multiple ethical theories.

In addition to identifying Canadian views and values regarding the use of assisted human reproductive technologies and related research, the Commission also carefully researched and reviewed myriad ethical issues surrounding the use (or non use) of human reproductive technologies in a Canadian legal, political, economic and cultural context with particular attention to Canadian systems and institutions. In this way, the Commission sought to provide the public, those working in the field of assisted human reproductive technologies (clinicians and researchers), and federal policy makers with a clear account of the moral reasoning and ethical analysis informing its deliberations and underlying its policy recommendations – the goal being to provide a morally sound basis for establishing uniquely Canadian “humane and caring” policies on assisted human reproductive technologies and related research.

Of note in this regard is the fact that the Commission identified balancing individual and collective interests as the area in which their most difficult social policy decisions arose. The Commission recognized the interests of infertile persons, and persons at risk of having a child afflicted with a genetic disease, in using reproductive technologies. The Commission also recognized the interests of researchers in having access to human reproductive materials and embryos to research and develop therapeutic interventions for persons afflicted with certain diseases or disorders. But no less important than these individual interests are our collective (societal) interests in the just allocation of finite health resources and the safety of the population and future generations. According to the Commission, sometimes, for the good of Canadian society (or specific groups within Canadian society), individual interests must be curtailed as when these interests are “harmful or prohibitively costly for the rest of society.”⁸⁸

Following wide consultation with Canadians, careful research into the ethical, legal, social, scientific and medical issues, the Commission

“found consistent and widespread demand for national leadership and action in relation to assisted human reproductive technologies.”⁸⁹ The Commission concluded that

Canada must move forward into the new reality with a clear, coordinated approach that permits us to resolve and manage the critical issues involved. To allow Canada’s response to be delayed or fragmented by the existing web of jurisdictional and administrative arrangements would, in the view of Commissioners [again, including Professor Knoppers as one of the Commissioners], be a mistake of enormous proportions. Failure to intervene constructively and decisively would amount to an abdication of social responsibility and a failure of political will.⁹⁰

In the years that followed, in consultation with the provinces and territories, as well as various interested stakeholder organizations, the federal government undertook to develop legislation on reproductive and genetic technologies.⁹¹ During the consultation process, there was general acknowledgment of the need for federal leadership in this morally charged arena, and a desire on the part of most stakeholders for this leadership to be manifested through legislation.⁹² Among the reasons for federal leadership were (i) the need for leadership “rooted in Canadian societal values such as respect for human rights,” (ii) “the need for consistency and coherence across the country to discourage any form of ‘reproductive tourism,’” and (iii) the lack of resources to self-regulate.⁹³

3.2 Principles in the AHR Act

The fruit of the Commission’s work – to develop a perspective that policy makers could apply in developing public policy for assisted human reproductive (and other emerging) technologies and related research – is the *AHR Act*[,] which received Royal Assent March 29, 2004. The *AHR Act* entrenches the care perspective and seven of the eight guiding principles found in the Commission’s Final Report. As such, the *AHR Act* is congruous with the views and values of Canadians as carefully researched and documented by the Commission.

In the Principles section of the *AHR Act*, there is explicit reference to the following six principles: protection for the vulnerable; respect for human life and dignity; individual autonomy; equality; non-

commercialization of reproduction; and balancing individual and collective interests. The principle of accountability though not explicitly identified in the Principles section is clearly important as evidenced by the requirement to create AHRC to:

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.

In pursuit of these objectives, AHRC is empowered to issue licences to persons providing assisted reproduction services and conducting research involving in vitro human embryos, to inspect clinics and research laboratories, to collect, analyse and manage health reporting information, and to monitor and review ethical and scientific issues as they emerge and evolve.⁹⁴

The only principle in the Commission's Final Report that is not an integral part of the *AHR Act* is the principle of appropriate use of resources – a principle relevant to resource decision-making concerning the provision of new assisted reproductive services and technologies in relation to a broad range of clearly defined reproductive and other health needs and priorities. The absence of this principle is not surprising as this is clearly an area of provincial jurisdiction.

The principle of *protection for the vulnerable* finds its clearest expression in the first and third principles of the *AHR Act*:

2 (a) the health and well-being of children born through the application of assisted human reproductive technologies must be given priority in all decision respecting their use;

2 (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;

The second principle articulated in the *AHR Act* provides further endorsement for the principle of *protection for the vulnerable* and also entrenches the principle of *respect for human life and dignity*:

2 (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;

The principle of *individual autonomy* is understood in terms of a commitment to promote informed consent. The fourth principle in the *AHR Act* stipulates that

2 (d) the principle of free and informed consent must be promoted and applied as a fundamental condition of the use of human reproductive technologies;

Next comes the principle of *equality*:

2 (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;

The principle of *non-commercialization of reproduction*:

2 (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;

Finally, there is the principle of *balancing individual and collective interests*:

2 (g) human individuality and diversity, and the integrity of the human genome, must be preserved and protected.

In sum, the AHR Act is based on the findings of the Commission, findings that (i) continue to cohere with Canadian social values, (ii) were consistent with ethical principles found in other international inquiries at the time of writing, and (iii) remain well grounded in sound ethical reasoning. More generally, the AHR Act not only effectively protects and promotes public health and safety for Canadians (especially women and children), it also protects and promotes morality for current and future generations of Canadians.

Conclusion

Notwithstanding claims to the contrary, the issue in this case is not whether the province of Québec has a demonstrated interest in, or commitment to monitoring the development of, assisted human reproductive technologies and related research, nor is it whether the various provincial regulatory mechanisms described by Professor Knoppers and Ms Petit taken together (with or without some version of Bill 89) could make for a coherent regulatory framework in Québec. Rather, the issue in this case is whether the *AHR Act* is needed to protect and promote public health, safety, and morality for Canadians. My answer to this question is a resounding "yes."

In closing, I agree with the prescient remarks made by the Commission more than a dozen years ago when it noted that how our country regulates assisted human reproductive technologies and related research "will say much about Canada as a society – what we value, what our priorities are, what kind of society we want to live in." "How we choose to use, or not to use, these technological capacities will shape society for our children and for their children."⁹⁵ Indeed, no less than who we are as a people is evidenced by our response to the ever increasingly complex array of available (and possible) scientific and medical developments related to assisted human reproductive technologies.

The AHR Act is based on clear, explicit and ethically sound principles and coheres with Canadian social values. It effectively protects and promotes public health, safety and morality for all Canadians.

NOTES

- 1 *Assisted Human Reproduction Act*, S.C. 2004, c 2.
- 2 *Renvoi relative à la Loi sur la procréation assistée (Canada)*, [2008] J.Q.J. No. 5489, 2008 QCCA 1157, 298 D.L.R. (4th) 712 (Q.C.C.A.).
- 3 Reference re *Assisted Human Reproduction Act*, 2010 SCC 61.
- 4 Canada, Medical Research Council of Canada, *Guidelines for Research on Somatic Cell Gene Therapy in Humans* (Ottawa: Minister of Supply and Services Canada, 1990).
- 5 Françoise Baylis, "The Ethics of Ex Utero Research on Spare 'Non Viable' IVF Human Embryos" (1990) 4:4 *Bioethics* 311.
- 6 Françoise Baylis, "Assisted Reproductive Technologies: Informed Choice" in *New Reproductive Technologies: Ethical Aspects Vol. 1 of the research studies of the Royal Commission on New Reproductive Technologies* (Ottawa: Minister of Government Services Canada, 1993) 47.
- 7 Society of Obstetricians and Gynaecologist of Canada and Canadian Fertility and Andrology Society, "Joint Policy Statement: Ethical Issues in Assisted Reproduction," <http://www.cfas.ca/english/library/jps%20Ethical%20Issues.pdf> [subscription required] [SOGC & CFAS Joint Statement].
- 8 Françoise Baylis, "Research Involving Human Embryonic Material: Ethical Considerations" (Paper presented to the National Bioethics Advisory Commission, Washington, D.C., January 19, 1999) [unpublished]; and F. Baylis, "Embryological Viability" (2005) 5:6 *American Journal of Bioethics* 17.
- 9 Françoise Baylis, "In Brief. The Canadian Biotechnology Advisory Committee" (2000) 30:3 *Hastings Center Report* 52.
- 10 Canada, Canadian Institutes of Health Research, Ad Hoc Working Group on Stem Cell Research. *Human Pluripotent Stem Cell Research: Recommendations for CIHR-Funded Research*, http://www.cihr.ca/about_cihr/ethics/stem_cell/stem_cell_recommendations_e.shtml [no longer available online].
- 11 Françoise Baylis, "Bill C-6 An Act respecting assisted human reproduction and related research" (Paper presented to the Government of Canada, Senate Committee on Social Affairs, Science and Technology, Ottawa, February 26, 2004) [unpublished]; Françoise Baylis, "Bill C-13 An Act respecting assisted human reproduction" (Paper presented to the Government of Canada, Standing Committee on Health, Ottawa, November 19, 2002) [unpublished]; and Françoise Baylis, "Assisted Human Reproduction" (Paper presented to the Government of Canada, Standing Committee on Health, Ottawa, May 31, 2001) [unpublished]. See, Françoise Baylis, "Brickbats and Bouquets for the Draft Legislation on Assisted Human Reproduction" (2001) 10:1 *Health Law Review* 3.
- 12 Canada Research Chairs, http://www.chairs.gc.ca/web/home_e.asp [now <http://www.chairs-chaires.gc.ca/home-accueil-eng.aspx>].
- 13 *Assisted Human Reproduction Act*, S.C. 2004, c 2 [AHR Act].
- 14 In her expert opinion "Le Québec: pionnier dans l'encadrement de la PMA et de la recherche au Canada," at ii et iii, Professor Bartha Maria Knoppers disavows the Commission's finding that the regulation of assisted reproductive technologies should not happen on a province-by-province basis. She further states that during the Commission's deliberations « J'étais la seule à promouvoir l'institution d'une agence interprovinciale plutôt que 'nationale' » [Knoppers & Petit, "Le Québec:

- pionnier"]. This view is not recorded in the Commission's Final Report; nor is there a dissenting opinion from Professor Knoppers explaining her perspective (an option that was available to her and indeed was exercised by Commissioner Suzanne Scorsone in relation to different concerns).
- 15 Canada, Royal Commission on New Reproductive Technologies, *Proceed with Care: Final Report of the Royal Commission on New Reproductive Technologies*, vol. 1 (Ottawa: Minister of Government Services Canada, 1993) at 18; see similar passages at 17, 22, and 124 [Commission, *Proceed With Care*, vol. 1]. (Commission royale sur les nouvelles techniques de reproduction, Un virage à prendre en douceur (Rapport final), vol. 1, à la p. 20. Voir également pp. 19, 24-25 et 141-42 [Virage en douceur, vol. 1]).
 - 16 Canada, *Proceed With Care: Final Report of the Royal Commission on New Reproductive Technologies*, vol. 2 (Ottawa: Minister of Government Services Canada, 1993) at 1022 [Commission, *Proceed With Care*, vol. 2]. (Commission royale sur les nouvelles techniques de reproduction, Un virage à prendre en douceur (Rapport final), vol. 2, à la p. 1159 [Virage en douceur, vol. 2]).
 - 17 Canada, Health Canada, *New Reproductive and Genetic Technologies: Setting Boundaries, Enhancing Health* (Ottawa: Minister of Government Services Canada, 1996) at 25, http://www.hc-sc.gc.ca/dhp-mps/alt_formats/cmcd-dcmc/pdf/tech_reprod_e.pdf [no longer available online].
 - 18 Canada, Health Canada, "Frequently Asked Questions" May 2001, http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/2001/2001_44bk2_e.html [no longer available online].
 - 19 Canada, House of Commons, Standing Committee on Health, *Assisted Human Reproduction: Building Families* (December 2001), <http://www.parl.gc.ca/InfocomDoc/37/1/HEAL/Studies/Reports/healrp01/08-rap-e.htm#SECTION%201> [now <http://www.parl.gc.ca/content/hoc/Committee/371/HEAL/Reports/RP1032041/healrp02/healrp02-e.pdf>] [Standing Committee on Health, Building Families].
 - 20 Open Letter from 65 Canadian Health Care Ethics and Health Law Experts on Bill C-13. October 26, 2003 Press Release; distributed to members of Parliament [on file with the author].
 - 21 This open letter was drafted by Professor Jocelyn Downie and myself the evening of October 25th while attending the Joint Meeting of the American Society for Bioethics and Humanities and the Canadian Bioethics Society in Montréal. We wrote this letter in response to a heightened concern about the future of Bill C-13. A draft of the letter was given to Mr. Timothy Caulfield to review, and minor amendments were negotiated. On the last day of the Joint Meeting, during the final coffee break and as people

- were leaving the meeting, Professor Downie and I invited Canadian colleagues still in attendance (many had already left the meeting) to sign the open letter. The response was very positive and we garnered a total of 65 signatures. Professor Knoppers was invited to sign the open letter but declined to do so. On October 28, 2003 the House of Commons passed Bill C-13; all members of the House had received a copy of the open letter.
- 22 Though all persons who avail themselves of assisted reproductive technologies are affected by their use, it is widely recognized that women and children are more directly and significantly affected by their use. This fact is explicitly recognized in the *AHR Act*, see *supra* note 1, s 2(c).
 - 23 Angela Campbell, "A Place for Criminal Law in the Regulation of New Reproductive Technologies" (2002) 10 *Health Law Journal* 77 at 82.
 - 24 Bartha Knoppers and Timothy Caulfield, "Don't Make Science a Crime: Criminal Law Is Too Blunt a Tool to Cope with Genetic Research," *Globe and Mail*, 20 August 2001, A13 [Knoppers and Caulfield, "Don't Make Science a Crime"]; Timothy Caulfield, Abdallah Daar, Bartha Knoppers, and Peter Singer, "MPs Have the Wrong Focus," *Globe and Mail*, 2 May 2002, A21 [Caulfield, Daar, Knoppers, and Singer, "MPs Have the Wrong Focus"]; Abdallah Daar, Timothy Caulfield, Bartha Knoppers, and Peter Singer, "Ban Cloning, Not Its Life-Saving Cousin," *Globe and Mail*, 9 May 2002, A21 [Daar, Caulfield, Knoppers, and Singer, "Ban Cloning"] *infra* notes 58, 59, 60.
 - 25 Canada, Royal Commission on New Reproductive Technologies, *Proceed with Care: Final Report of the Royal Commission on New Reproductive Technologies*, vol. 1 (Ottawa: Minister of Government Services Canada, 1993) at 18; see similar passages at 17, 22, and 124.
 - 26 Françoise Baylis and Jason Scott Robert, "Primer on Ethics and Crossing Species Boundaries," *ActionBioscience*, May 2006, http://www.actionbioscience.org/biotech/baylis_robert.html [now http://www.actionbioscience.org/biotechnology/baylis_robert.html].
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 - 28 See *supra* note 25 at 4.
 - 29 See *ibid* at 9.
 - 30 See *ibid* at 16.
 - 31 See *ibid* at 12.

- 32 See *ibid* at 124.
- 33 See *supra* note 1, s 68.
- 34 Canada, Health Canada, *Feedback Report: Discussion and Written Comments on Proposed Federal RGTs Legislation*, Ottawa, June 2000, at 2.
- 35 Aaron Levine, "Research Policy and the Mobility of US Stem Cell Scientists" (2006) 24 *Nature Biotechnology* 865.
- 36 Jocelyn Downie, "The Canadian Agency for the Oversight of Research Involving Humans: A Reform Proposal" (2006) 13 *Accountability in Research* 75 at 81.
- 37 See *supra* note 1, s 9.
- 38 Practice Committee of the American Society for Reproductive Medicine, "Ovarian Hyperstimulation Syndrome" (2003) 80:5 *Fertility and Sterility* 1309.
- 39 *Ibid*.
- 40 A.S. Whittemore, R. Harris, and J. Itnyre *et al.*, "Characteristics Relating to Ovarian Cancer Risk: Collaborative Analysis of 12 US Case-control Studies. II Invasive Epithelial Ovarian Cancers in White Women" (1996) 136:10 *American Journal of Epidemiology* 1184; M.A. Rossing, J.R. Darling, N.S. Weiss *et al.*, "Ovarian Tumors in a Cohort of Infertile Women" (1994) 331:12 *New England Journal of Medicine* 771.
- 41 Ian S. Tummon, Mark Wentworth, and Alan Thornhill, "Frozen-Thawed Embryo Transfer and Live Birth: Long-term Follow-Up after One Oocyte Retrieval" (2006) 86:1 *Fertility and Sterility* 239.
- 42 Carolyn McLeod and Françoise Baylis, "Donating Fresh Versus Frozen Embryos to Stem Cell Research: In Whose Interests?" (2007) 21 *Bioethics* 465.
- 43 See *ibid*. See also Françoise Baylis and Caroline McInnes, "Women at Risk: Embryonic and Fetal Stem Cell Research in Canada" (2007) 1 *McGill Journal of Law and Health* 53.
- 44 See *supra* note 1, s 11.
- 45 See *supra* note 26.
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- 47 See *supra* note 25 at 21.
- 48 See *supra* note 1, s 68.
- 49 See *supra* note 25 at 12–13.
- 50 Bartha Maria Knoppers and Elodie Petit, Expert Report "Le Québec: pionnier dans l'encadrement de la PMA et de la recherche au Canada" at 13.
- 51 E.Y. Adashi, P.N. Barri, R. Berkowitz, P. Braude, *et al.*, "Infertility Therapy-Associated Multiple Pregnancies (Births): An Ongoing Epidemic"

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- 52 In practice, the maximum number of embryos transferred varies from clinic to clinic and, more specifically, from patient to patient (based on age, reason for treatment, number of previous cycles, etc.). In policy, a maximum of three embryos is mentioned. See Society of Obstetricians and Gynaecologists of Canada and Canadian Fertility and Andrology Society, *Joint Policy Statement: Ethical Issues in Assisted Reproduction* (p. 19), http://www.cfas.ca/images/stories/pdf/joint_policy_statement_ethical_issues.pdf.
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- 56 See *supra* note 1, s 22.
- 57 See *supra* note 1, s 26(8).
- 58 Présentation du répertoire des comités d'éthique du Québec, <http://ethique.msss.gouv.qc.ca/site/repertoire.phtml> [now <http://ethique.msss.gouv.qc.ca/lethique-de-la-recherche/repertoire-des-etablissements-du-rsss-des-cer-et-des-cec.html>].
- 59 In May 2005, the Quebec government introduced an elective online tutorial on research ethics review, <http://ethique.msss.gouv.qc.ca/didacticiel>. Some REBs have made this a mandatory requirement for their members (personal communication Carolyn Ells, Assistant Professor, Biomedical Ethics Unit, McGill University, and co-author of the online tutorial). As at 24 April 2006, four hundred people had registered for the tutorial (these registrants may or may not be REB members, and they may or may not have completed the online tutorial).
- 60 Comité d'experts sur l'évaluation des mécanismes de contrôle en matière de recherche clinique. Rapport sur l'évaluation des mécanismes de

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- 61 See *supra* note 60 [Malouin]. Note: In October 2005 the Ministre de la Santé et des Services sociaux du Québec announced that it would be updating this report, and that it expected the update to be completed in Spring 2006.
- 62 See *supra* note 1, s 44.
- 63 Ministre de la Santé et des Services sociaux du Québec. Plan d'action ministériel en éthique de la recherche et en intégrité scientifique, 1998, p. 14.
- 64 Fonds de la recherche en santé du Québec, Éthique, intégrité scientifique et bonnes pratiques de la recherche, <http://www.frsq.gouv.qc.ca/fr/ethique/ethique.shtml> [now <http://www.frqs.gouv.qc.ca/ethique>].
- 65 Canada, Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, 1998 with 2000, 2002, and 2005 amendments, http://www.pre.ethics.gc.ca/archives/tcps-eptc/docs/TCPs%20October%202005_E.pdf. The second edition of the TCPS was published in December 2010.
- 66 Trudo Lemmens, *Report of the Three Granting Agencies from the Ethics Review Committee Regarding the Assessment of Institutional Policies with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (2002) (unpublished, on file with the author).
- 67 Michael McDonald, "Canadian Governance for Ethical Research Involving Humans" (2005) 13:2&3 *Health Law Review* 5 at 8.
- 68 Code civil du Québec, L.Q., 1991, art. 21.
- 69 L.R.Q., c M-30.01.
- 70 Fonds de la recherche en santé du Québec, Mission intégrale, http://www.frsq.gouv.qc.ca/fr/a_propos/popup/misson_integrale.html.
- 71 See *supra* note 1, ss 60 and 61.
- 72 See *supra* note 1, ss 40-53.
- 73 See *supra* note 25 at 12-13. In her expert report, see *supra* note 50 at ii and iii. Knoppers disavows the commission's finding that the regulation of assisted reproductive technologies should not happen on a province-by-province basis. She further states that during the Commission's deliberations « j'étais la seule à promouvoir l'institution d'une agence interprovinciale plutôt que 'nationale.' » This view is not recorded in the commission's Final Report; nor is there a dissenting opinion from Professor Knoppers explaining her perspective (an option that was available to her and indeed was exercised by commissioner Suzanne Scorsone in relation to different concerns).
- 74 See *supra* note 50 at i.
- 75 See *ibid* at iii and iv.
- 76 See *supra* note 24 (Knoppers and Caulfield, "Don't Make Science a Crime").
- 77 See *supra* note 24 (Caulfield, Daar, Knoppers, and Singer, "MPs Have the Wrong Focus").
- 78 See *supra* note 24 (Daar, Caulfield, Knoppers, and Singer, "Ban Cloning").
- 79 To my knowledge these claims (which have also been made in oral presentations) have not been repudiated.
- 80 Will Kymlicka, "Approaches to the Ethical Issues Raised by the Royal Commission's Mandate," in *New Reproductive Technologies: Ethical Aspects*, vol. 1 of the research studies of the Royal Commission on New Reproductive Technologies (Ottawa: Minister of Government Services Canada, 1993) 1, at 18-27; and see *supra* note 7 at 53 and 58-9.
- 81 Canada, House of Commons, Standing Committee on Health, *Assisted Human Reproduction: Building Families* (December 2001), <http://www.parl.gc.ca/InfocomDoc/37/1/HEAL/Studies/Reports/healrp01/08-rap-e.htm#SECTION%201> [now <http://www.parl.gc.ca/content/hoc/Committee/371/HEAL/Reports/RP1032041/healrp02/healrp02-e.pdf>].
- 82 See *supra* note 25 at 51, 50, respectively.
- 83 See *ibid* at 52.
- 84 See *ibid* at 52.
- 85 See *ibid* at 53.
- 86 See *ibid* at 50.
- 87 See *ibid* at 58.

88 See *ibid* at 63.

89 See *ibid* at 11.

90 See *ibid* at 10.

91 See *supra* note 16.

92 Provinces and territories, although supportive of federal legislation, were concerned about the possible impact of such legislation on their health care system and existing laws. Quebec officials were not supportive of federal regulations governing reproductive and genetic technologies. They did recognize, however, that this was not an area of practice with geopolitical borders, hence their interest in having standards and regulations that were coherent with those developed in other provinces and territories. See *supra* note 34 at 3.

93 See *ibid* at 2.

94 See *supra* note 1, s 24.

95 See *supra* note 25 at 1, 2, respectively.

Appendix 3 Response to the Second Opinion of Françoise Baylis Entitled “The Regulation of Assisted Human Reproductive Technologies and Related Research: A Public Health, Safety and Morality Argument”

BARTHA MARIA KNOPPERS

- The expert report submitted by F. Baylis does not, indeed cannot – despite her assertions to the contrary – constitute a response to our own expert report. Our presentation was meant to shed light on an intervention articulated and pioneered in Quebec as part of the *legal* regulation of assisted human reproduction (AHR) and related research, while Ms. Baylis’ report clearly falls within the ethical realm.
- A significant point of confusion underlies Ms. Baylis’ report. The construction of her ethical intervention as to the merits of federal oversight appears to presume that we refuse to recognize that the federal government has any legitimate role to play. As we stated in our introduction, neither our report, nor the referral to the Court of Appeal, challenges the legitimacy of limited criminal prohibitions for non-controversial activities. Therefore, to present the federal law as an indivisible whole, an “all or nothing” proposition, including its criminal prohibitions, its contested provisions, and sections 13–19 (p. 10–18) without making any distinctions, is an attempt to discredit Quebec’s multi-institutional partnership by suggesting that the latter is meant to be an alternative to the federal legislation in its entirety. This is completely groundless.
- Ms. Baylis speaks of the need for sections 8–12 of the federal Act, indicating that there would be a risk of “inter-provincial tourism” if these sections were omitted. Let us cite, for example, the reference

Regulating Creation

*The Law, Ethics, and Policy of Assisted
Human Reproduction*

EDITED BY TRUDO LEMMENS,
ANDREW FLAVELLE MARTIN,
CHERYL MILNE, AND IAN B. LEE

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