Supreme Court of Canada Decision on the *Assisted Human Reproduction Act* Creates Urgent Need for Action

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In North America, 8% to 12% of women are unable to conceive without medical assistance.[1] For women in heterosexual relationships, 40% of the time this is due to male factor infertility, 40% of the time to female factor infertility, and 20% of the time to combined or unexplained infertility. A subset of these women, alongside single women (who may or may not have an infertility problem), women in non-heterosexual relationships (who may or may not have an infertility problem), and women undergoing chemotherapy, radiation therapy, and surgery for cancer treatment (that may cause temporary or permanent infertility), use assisted human reproduction.

Until the *Assisted Human Reproduction Act 2004*[2] came into force, the market and the views of individual physicians largely determined what services might or might not be available and to which women. For a variety of reasons this was deemed unacceptable,[3] and with the *AHR Act,* a clear set of prohibitions and controlled activities were introduced.

Shortly after the *AHR Act* was passed, however, Quebec challenged the constitutionality of the legislation; it argued that several sections of the *AHR Act* were beyond the federal government's legislative authority. On June 19, 2008, the Quebec Court of Appeal held that sections 8 to 19, 40 to 53, 60, 61, and 68 of the *AHR Act* were not a valid exercise of the federal government's criminal law power and, as such, were unconstitutional. The Government of Canada appealed this decision on the ground that the law was a valid exercise of its authority to act to safeguard morality, safety, and public health. On April 29, 2009, the Supreme Court of Canada (SCC) heard the appeal, and on December 22, 2010, released its decision.[4] The SCC held that some, but not all, of the contested sections were indeed unconstitutional.

The constitutional issue before the Court was whether the "pith and substance" (i.e., purpose and effects) of the contested sections of the legislation were:

1. to protect morality, safety, and public health (which is a federal responsibility under the *Constitution Act, 1867*[5])

2. to regulate and promote the benefits of medical practice and research related to assisted human reproduction (which is a provincial responsibility under the *Constitution Act, 1867*[5]).

I wrote an expert ethics opinion for the federal government when the case was before the Quebec Court of Appeal.[6] I argued that the ever-increasing ability to manipulate human reproductive material (in pursuit of any number of objectives) raised unique ethical issues warranting federal attention. More precisely, I defended the view 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."[6]

> 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,

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> 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.[6]

This view is consonant with the findings of four of the SCC Justices, according to whom the primary purpose of the legislation was to prohibit practices that "would undercut moral values, produce public health evils, and threaten the security of donors, donees, and persons conceived by assisted human reproduction" [para 20]. Sadly, this view did not hold sway. Several sections of the *AHR Act* were found to be unconstitutional (Sections 10, 11, 13, 14 to 18, 40(2), (3), (3.1), (4) and (5) and ss. 44(2) and (3)).

As a direct and immediate consequence of this decision, Canada will have a fragmented, province-by-province-by-territory approach to the regulation of assisted human reproduction, with the absence of regulations in some jurisdictions and variability in regulations among other jurisdictions. The federal prohibitions against such activities as human cloning, creating in vitro embryos for research purposes, manipulating embryos to increase the probability of a particular sex, payment for surrogacy or for the purchase of gametes remain in force. Against this backdrop, however, each province and territory is free to regulate (or not) the delivery of reproductive services and the conduct of related research.

Areas of activity that are now in urgent need of uniform provincial regulation include

1. the use of reproductive material (sperm, ovum or other human cell or a human gene or part thereof), the use of in vitro embryos, or the keeping or handling of gametes and embryos (formerly s. 10 of the *AHR Act*)
2. the creation of transgenics (i.e., combining any part of the human genome with any part of a genome from another species) (formerly s.11 of the *AHR Act*)
3. the collection and management of health reporting information (formerly ss. 14–18 of the *AHR Act*)
4. research involving in vitro embryos (formerly ss.40(2–5) of the *AHR Act*).

If these areas of practice remain unregulated, or are inadequately regulated, then the health and safety of women who use assisted human reproductive technologies, women who assist others by donating genetic material or lending their bodies, and children born of these technologies will be at risk.

Consider two examples of threats to the health and safety of children born of assisted human reproduction in the absence of the *AHR Act* norms that established safety and ethical standards. In the absence of s.10, there are the harms associated with the practice of multiple embryo transfer (which can result in triplets and higher order multiple births, with all of their consequential risks). In the absence of ss. 14–18, there are the harms that may result from the failure to collect genetic information and family medical history of gamete donors (which may compromise the quality of care for a presenting health problem or preventive care).

First, as a result of the SCC decision, altering, manipulating, treating, obtaining, storing, transferring, destroying, importing, or exporting human reproductive material or in vitro embryos are no longer federally regulated activities. Provinces and territories can choose to regulate these activities, but need not. An area of practice where there is likely to be considerable diversity concerns the number of embryos transferred per cycle. There are sound medical and ethical reasons to actively promote (if not legislate) single embryo transfer—as this is clearly in the best interest of children born of assisted human reproduction. Some provinces may address this issue (as Quebec has done with recent regulations about financing assisted human reproduction), but other provinces may ignore this issue. As a result, clear differences in practice may emerge across the country, with women and couples in some jurisdictions continuing to transfer several embryos per cycle, notwithstanding the risks to themselves and to their children.

Second, again as a result of the SCC decision, persons born of assisted human reproduction may never have access to genetic and medical information about those who provided

the genetic material used to create them. The collection of such information is no longer a federally legislated requirement, and there is no guarantee that each province and territory will legislate in this area. The absence of regulations governing the collection and management of health reporting information represents a direct threat of harm to persons born of assisted human reproduction.

For reasons that are unclear to me, a majority of the Justices were not persuaded of the need to pre-empt these and other potential threats to morality, safety and public health through the *AHR Act*. We can now only hope that all provinces and territories will act immediately to regulate in the area of assisted human reproduction to introduce standards that prevent these threats from being realized. The Wild West culture of the past, to which the *AHR Act* was responding, cannot be allowed to continue. The women who use assisted human reproduction and the children born of assisted reproductive technologies deserve no less.

REFERENCES

1. Fisher J. Infertility and assisted reproduction. In: World Health Organization. Mental health aspects of women's reproductive health: a global review of the literature. Geneva: WHO Press;2009:128–46.
2. *Assisted Human Reproduction Act,* S.C. 2004, c. 2 [*AHR Act*].
3. Canada. Royal Commission on New Reproductive Technologies. Proceed with care: final report of the Royal Commission of New Reproductive Technologies. Ottawa: Minister of Government Services Canada;1993.
4. Reference re *Assisted Human Reproduction Act,* 2010 SCC 61.
5. *Constitution Act, 1867,* ss. 91, 92.
6. Baylis F. The regulation of assisted human reproductive technologies and related research: a public health, safety and morality argument. Expert opinion;August 2006.

Erratum

Ehijie Enato, Myla Moretti, Gideon Koren. The Fetal Safety of Benzodiazepines: An Updated Meta-Analysis. J Obstet Gynaecol Can 2011;33(1):46–48.

On page 47, the same figure is shown twice: correctly as "Figure 1. Meta-analysis of major malformations related to benzodiazepine use in cohort studies," and incorrectly as "Figure 2. Meta-analysis of cardiovascular malformations related to benzodiazepine use in case-control studies." The correct version of Figure 2 is shown below.

The Journal of Obstetrics and Gynaecology regrets the error and any inconvenience it may have caused.

Figure 2. Meta-analysis of cardiovascular malformations related to benzodiazepine use in case–control studies