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Moral Evils v. Health and Safety Evils: The case of an ovum ‘obtained’ from a ‘donor’ and used by the ‘donor’ in her own surrogate pregnancy

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INTRODUCTION

One of the many criticisms levelled at Canada’s Assisted Human Reproduction Act, 2004 has been its lack of regulatory certainty. By early 2018, only one set of regulations – Section 8 (Consent) Regulations – had been passed. Ethicists, lawyers, and clinicians have repeatedly called on the federal government to take legislative action to update Canada’s 1998 human sperm screening and testing regulation, address the lack of health protections for patients using donated ova, and to bring clarity to the law regarding reimbursement of gamete donors and surrogates.

The tide now appears to be finally turning. On October 1, 2016, Health Canada announced its intentions to bring forward a number of long awaited Assisted Human Reproductive Act 2004 (AHRA) regulations. It plans to revise the 1996 Semen Regulations and move them from the

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1 SOR/2007-137 Assisted Human Reproduction (Section 8 Consent) Regulations.
9 SOR/96-254 Processing and Distribution of Semen for Assisted Conception Regulations.
Food and Drugs Act to the AHRA (amended 2012), develop regulations for the screening and testing of ova donors, establish gamete tracing protocols, clarify reimbursable expenses for parties involved in surrogacy arrangements and sperm and ova donation, and institute inspection procedures. Health Canada cites three reasons for undertaking this long overdue legislative renewal: i) reduce the risks to human health and safety from using donor sperm and eggs (ova), including the risk of transmitting disease; ii) make clear what expenses may be reimbursed to donors and surrogates; and, iii) allow the appointment of inspectors who will manage and enforce the AHRA.

Since the October 2016 announcement, Health Canada has undertaken web-based consultations and invited stakeholders and interested parties to comment on its proposed directions for regulatory change. Consultation has occurred alongside the Standards Council of Canada’s re-development and re-release in late 2017 of a revised National Standard of Canada, CAN/CSA-Z900.2.1.-17 Tissues for assisted reproduction. This updated Standard is a propriety set of guidelines though it should be noted that its development like the earlier versions was funded by Health Canada. It is expected that the 2017 CAN/CSA Standard will shape the detailed screening, testing, labelling and packaging and reimbursement regulations likely to be tabled in

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13 In January 2018, the cost for the standard was $165.00 plus HST. This cost provides the purchaser with an independent licence to access the Standard. The purchaser is also entitled to obtain updates.
In early February 2018, Health Canada released a short overview report entitled “What We Heard”. It summarized the “57 sets of comments” received during the 2016-17 consultation period but did not reveal the direction that the government was likely to take in response to identified concerns. Nor did it suggest how conflicting views might be addressed.

While these initiatives indicate that the federal government has at long last decided to take action to resolve some of the longstanding AHRA regulatory inadequacies, the approach falls short of a much-needed legislative renewal being requested by those seeking changes to the sections that ban commercial surrogacy and gamete donation and limit research. Also, there has been very little attention paid to the legal and policy implications of the amendments made in 2012 to the AHRA.

This paper critically examines one of the 2012 AHRA amendments. At section 10 of the Act, a new requirement was added mandating screening and testing of ‘obtained’ ovum ‘donated’ by a ‘donor’ and used in her own surrogate pregnancy. The stated rationale for this amendment cites

the federal government’s obligation to reduce harm to human health and safety arising from use of sperm or ova for human reproduction, including the risk of the transmission of disease.\footnote{S.10(1) as amended by Jobs, Growth and Long-term Prosperity Act, S.C. 2012, c-19, at s.714.} The 2016 Health Canada regulatory initiative advanced to establish the mandated screening and testing regime instituted to ensure the health of Canadian fertility patients will be required to address this recently added legislative requirement.

The paper identifies three issues raised by the amendment targeting traditional surrogacy\footnote{Traditional surrogates are genetically related to the child they agree to carry for intended parent(s). They supply their own ova used in their surrogate pregnancy.} when carried out as a result of assisted reproduction technologies.\footnote{Most traditional surrogacy occurs as a result of assisted insemination. The amendment is directed at IVF treatments whereby the surrogate’s ovum (ova) are obtained as a result of ovarian stimulation. The ex utero ovum would then be fertilized using sperm from the intended parent or by sperm obtained for the reproductive use of the intended parent(s).} The first observes that failure to screen and test a woman’s obtained ovum used in her own surrogate pregnancy carries criminal code penalties. The Supreme Court of Canada (SCC) decision in Reference re Assisted Human Reproduction Act (Ref re AHR)\footnote{Assisted Human Reproduction Act S.C.2004, c2. s 10(2)(c) amended 2012.} permits the federal government to legislate in areas where a ‘health evil’ is present. The paper investigates the ‘health evil’ that requires the application of federal criminal law powers to mandate screening and testing of an ‘obtained’ ovum ‘donated’ by a woman and used in her own surrogate pregnancy?\footnote{Reference re Assisted Human Reproduction Act, 2010 SCC 61, [2010] 3 S.C.R. 457.} It asks: Are we satisfied that the amendment meets the harm test for application of criminal law powers established by the SCC in Ref re AHR?\footnote{Ubaka Ogbugu, 2013. “The Assisted Human Reproduction Act Reference and the Thin Line Between Health and Crime” Constitutional Forum constitutionnel 22(1), 93-97.}

The second issue concerns the term ‘donor’. The paper argues that a muddling of the meaning of...
the word ‘donor’ appears to have been introduced by the amendment. I suggest that
terminological confusion created by the AHRA, use of a different definition by the 2017
Canadian Standards Association Standard, provincial statutes, and Canadian Fertility and
Andrology Society treatment guidance documents may be contributing to a misunderstanding
regarding the health and safety risks encountered by a woman using her own ‘obtained’ ova in
her own surrogate pregnancy. I critically explore the implications of this confusion for
reproductive law and policy.

The third issue raised by the amendment centres on the transformation of an ‘own ova’ into a
‘third-party’ gamete. This occurs in part by the confusion over the word ‘donor’ but it is a more
complex matter. I argue that the multi-faceted fertility treatment roles taken on by the traditional
surrogate can result in her being both an ‘egg donor’ and a ‘surrogate.’ The paper asks us to
focus our attention on elements of consent that could become especially problematic for
traditional surrogates, including consent for testing and screening, consent to donate, consent for
treatment as a donor and as a traditional surrogate, and consent to create an embryo. This
multiplicity of roles demands that assisted reproduction legislation and accompanying
regulations need to regard her as an autonomous, consenting fertility patient and not as a “spare
part”27 provider or as a “treatment option” for infertile patients and intended parent(s).28

28 Pamela M. White, “Why we don’t know what we don’t know’ about Canada’s surrogacy practices and outcomes”
in A. Cattapan, A. Campbell and V. Gruben (eds). Critical Approaches to Canada’s Surrogacy Law. Irwin Law.
2018 (forthcoming).
To undertake the analysis of the three substantive issues, the first section of the paper conducts a review of Canada’s assisted reproduction legal landscape. It then examines the AHRA definition of ‘donor’ and considers how the AHRA concept differs from the terminology used in provincial statutes, the 2017 CAN/CSA Standard, and fertility association guidelines. The paper then chronicles the amendments made to the AHRA in 2012 that require screening and testing of human reproductive tissue used in fertility treatments. In this section, I explore a number of implications of the amendment for issues such as consent, reproductive autonomy, and health risks.

Once establishing the parameters and factors included in the legislative AHR Act amendment, the second section of the paper undertakes an analysis of health and safety harms that could be viewed as conditions sufficient to require the imposition of criminal law sanctions were untested and unscreened ‘obtained’ traditional surrogate ova used in the traditional surrogate’s pregnancy. I seek to establish whether the health and safety harms would be to the traditional surrogate herself, the clinic, other fertility patients, surrogate-born child, or to society in general. It asks whether the identified health and safety harms meet the test set out by the SCC in Re AHR.

The final section of the paper critically analyses a number of problems identified with the amendment, including whether there exists a sufficient health and safety justification to impose criminal code penalties in cases where unscreened and untested ‘obtained’ ova ‘donated’ by a traditional surrogate are used in her own surrogate pregnancy. It probes whether the proposed regulatory actions it triggers function as a thinly disguised attempt to discourage the practice of
traditional surrogacy when undertaken using IVF. It asks whether the screening and testing requirement could be an attempt to turn traditional surrogates into a special group of designated ova donors: women who also take on an additional role as surrogate. In conclusion, it focuses our attention on several of the worrisome regulatory problems that are likely to be created as a result of inconsistent application of the term ‘donor’, reliance on unelected bodies to determine regulatory framework parameters, and an uncritical sanctioning of fertility industry practices.

**BRIEF HISTORY OF ASSISTED HUMAN REPRODUCTION ACT, 2004**

Canada’s AHRA 2004 passed after nearly 20 years of extensive consultation, in-depth study and at times acrimonious debate is considered by many legal and policy scholars to be seriously flawed. Barely had the Act achieved Royal Assent when Quebec contested the use of federal criminal law powers to regulate the practice of fertility medicine. In 2010, the SCC agreed with Quebec’s position in its contested and divided decision (4:4:1) Ref re AHR which rendered ultra vires the sections of the Act legislating in areas under provincial constitutional

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31 Ibid. note 12. Baird Commission research report “Proceed with Care” was voluminous. List of research studies and researchers, Appendix E at 1253-71.
jurisdiction, notably the practice of medicine and research. The SCC decision left intact the sections protecting human health and safety, such as the testing and screening of human reproductive materials used for assisted reproduction. The prohibition of activities deemed to be morally unacceptable such as cloning, sex selection, discrimination and commodification of human gamete donation and surrogacy were upheld as were the sections enabling enforcement of permitted activities, including the reimbursement of expenses incurred by gamete donors and surrogates.

The pith and substance of the SCC 2010 decision, Ref re AHR, centres on the use of federal criminal law powers to uphold morality and to prohibit a public health evil. Relying on the argumentation advanced by Rand J in the Margarine reference, Ref re AHR reaffirms that the evil or threat must be real and legitimate. Moreover, the decision serves to remind Canadian legislators that in matters of health, an area of provincial constitutional responsibility, criminal law when used to achieve a public purpose is restricted to suppression of a public health evil. It underscores that mere identification of public purpose is not sufficient justification for invoking

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35 2010 SCC 61 [2010] 3 S.C.R. 457. Sections rendered ultra vires: s. 10, 11, 13-18; ss 40(2) (3), (3.1), (4) and (5) and ss. 44(2) and (3).
36 See the new section 10, Assisted Human Reproductive Act, 2004 as amended in 2012.
37 Supra note 8, sections 5-9.
41 Reference re Validity of Section 5 (a) of the Dairy Industry Act, [1949] SCR 1, 1 DLR 433.
federal criminal law powers. As the SCC stated that the “evil must be real and the apprehension of harm must be reasonable.” I argue that it is through this interpretive lens that subsequent AHRA legislative amendments and regulatory reform such as the one recently undertaken by Health Canada must be critically assessed and evaluated.

2012 Legislative Amendments to the AHRA

In March 2012, more than two years after the decision in Re A HR, the federal government used omnibus tax legislation, Bill C-38: Jobs, Growth and Long-term Prosperity, to amend the Assisted Human Reproductive Act, 2004. The Assisted Human Reproduction Agency was eliminated thereby saving the federal government some $10 million though it soon become apparent that any fiscal savings were likely to be considerably less given that the Agency had never managed to spend even half of its annual budget. Furthermore, Health Canada was being asked to assume a limited number of assisted reproduction regulatory, enforcement, and outreach responsibilities.

The 2012 Jobs, Growth and Long-term Prosperity Act amendments also performed a legal administrative housekeeping function consistent with a regulatory stance current at the time that

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of eliminating one regulation for every new one it established.\textsuperscript{49} The sections of the Act rendered ultra vires by the SCC decision in Re AHR were repealed. At the same time, it consolidated a number of regulatory responsibilities found in or identified as being absent from accompanying legislation. For example, sections of the AHRA 2004 that regulated the use of human ova and sperm under the Human Pathogens and Toxic Materials Act\textsuperscript{50} along with the regulation that had mandated the testing and screening regime for human sperm under the federal Food and Drugs Act\textsuperscript{51} were repealed. Human sperm and ova screening and testing along with tracing and identification requirements are now found within the ambit of the AHRA at the amended s.10. The investigative abilities of Health Canada were strengthened. Inspection provisions associated with the as-yet-to-be promulgated regulations were revised\textsuperscript{52}.

The 2012 AHRA amendments have been characterised by some scholars as a repeat performance of a failed legislative project,\textsuperscript{53} while others have been less generous in their criticism of Canada’s renewed legislative foray into the law of assisted reproduction.\textsuperscript{54} However, none of the critiques of the 2012 AHR Act amendments have examined the implications of imposing screening and testing regulations on ‘obtained’ ova ‘donated’ by a traditional surrogate for use in

\textsuperscript{49} Laura Jones, 2015. “Cutting Red Tape in Canada: A Regulatory Reform Model for the United States?” Mercatus Research, Mercatus Center at George Mason University, Arlington, VA, November:3.

\textsuperscript{50} Jobs, Growth and Long-term Prosperity Act, S.C. 2012, c-19, at s.714.


\textsuperscript{52} AHRA 2004 s.45-68.


her own surrogate pregnancy\textsuperscript{55}; a requirement added to the Act without public consultation or discussion by Parliament.\textsuperscript{56}

In the absence of careful scrutiny, we need to look closely at the implications for reproductive law and policy of a legislative change involving traditional surrogates. If the objective is to discourage the practice, then the requirement to screen and test obtained own ova used by a traditional surrogate delivers an unexpected punitive punch. On the other hand, if the purpose is to protect the traditional surrogate and her offspring from a health harm, the identified health risks need to be real and the protective measures proportionate. Finally, if the goal is to shelter Canadians from the harm of a moral evil, one needs to be able to determine why traditional surrogacy when performed through IVF as that is the only way to ‘obtain’ ova from a woman constitutes an evil that is absent when traditional surrogacy occurs as a result of artificial insemination, which is the more common practice.

\textbf{2012 AHRA Section 10 amendments}

The 2012 AHRA amendments at section 10 replace the original s.10\textsuperscript{57} rendered ultra vires by the SCC in Ref re AHR. The purpose of the impugned s.10 had been to support a federally controlled and managed licencing regime for human gametes used in assisted human

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\textsuperscript{56} Bill C-38 passed without discussion as to the amendments being made to the AHRA apart from Mr Wayne Marston (Hamilton East-Stony Mountain, NDP) noting that the Assisted Human Reproduction Agency would be shut down. Hansard, 1st Session, 41 Parliament. Monday, June 18, 2012, Vol.146, No. 142 (Part A) at 9693 and Ms Megan Leslie (Halifax, NDP) who asked about the fiscal savings to be achieved from the shutdown of the Assisted Human Reproduction Agency. Hansard, 1\textsuperscript{st} Session, 41\textsuperscript{st} Parliament, Friday June 15, 2012 at 9612.
\textsuperscript{57} Jobs, Growth and Long-term Prosperity Act, S.C. 2012, c-19 at s.717.
\end{flushright}
reproduction. With this type of federal activity ruled constitutionally invalid, the federal government repositioned its legislative responsibilities and subsequent use of criminal code powers to fall within a human health protection mandate. Indeed, at s.10(1) the health objective of testing and screening of human gametes used in assisted human reproduction is stated as being:

10. (1) The purpose of this section is to reduce the risks to human health and safety arising from the use of sperm or ova for the purpose of assisted human reproduction, including the risk of the transmission of disease.

In the subsections that follow on from s.10(1), human sperm and ova obtained from specified types of donors at s.10(2)(a, b, c) and used by certain categories of female persons at s.10(2)(a, b, c) for the purposes of assisted reproduction may be exempted from testing and screening as indicted in s. s. 10(3)) and can be distributed and imported pursuant to s.10(4)). It should also be noted that at s.10(5) the term ‘common-law partner’ is defined and at s. 61, an amended set of penalties for failure to abide by the regulations to be promulgated pursuant to s.10 are specified.

Finally, AHRA prohibits all uses of human gametes and embryos in assisted human reproduction unless the activity is expressly permitted by regulation. The amendments made in 2012 preserve this position. As a result, assisted reproduction is characterised as a non-normative and unnatural activity. This characterization may have had salience in the 1980s when the practice was innovative but is less defensible today. Certainly, the acceptability of the practice was focus of debate in the SCC decision in Ref re A HA. The AHRA, at s.10, explicitly legalises a fertility

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58 2010 SCC 61 [2010] 3 S.C.R. 457. Sections rendered ultra vires: s. 10, 11, 13-18; ss 40(2) (3), (3.1), (4) and (5) and ss. 44(2) and (3).
59 The Section 8 (Consent) Regulations are silent with respect to destruction of embryos no longer wanted for reproductive use, training or research.
patient’s use of their own unscreened and untested ova and the unscreened and tested sperm and ova of their spouse, common-law partner or sexual partner. It makes the reproductive use of all other unscreened and untested human reproductive material illegal on the grounds of health and safety risks.

**Identification of the type of donated sperm and ovum to be tested and screened**

Section 10 amendments introduced by the Jobs, Growth and Long-term Prosperity Act 2012 c.19, Division 56 state: 60

10. (2) Subject to subsection (3), no person shall distribute, make use of or import any of the following for the purpose of assisted human reproduction:
   (a) sperm that has been obtained from a donor and that is meant for the use of a female person other than a spouse, common-law partner or sexual partner of the donor;
   (b) an ovum that has been obtained from a donor and that is meant for the use of a female person other than the donor or the spouse, common-law partner or sexual partner of the donor; or
   (c) an ovum that has been obtained from a donor and that is meant for the donor’s use as a surrogate mother.

10(3) Subsection (2) does not apply if:
   (a) tests have been conducted in respect of the sperm or ovum in accordance with the regulations, and the sperm or ovum has been obtained, prepared, preserved, quarantined, identified, labelled and stored and its quality assessed in accordance with the regulations; and
   (b) the donor of the sperm or ovum has been screened and tested, and the donor’s suitability has been assessed, in accordance with the regulations.

10 (4) No person shall, except in accordance with the regulations, engage in any activity described in paragraph (3)(a) or (b) in respect of any of the following with the intention of distributing or making use of it for the purpose of assisted human reproduction:
   (a) sperm described in paragraph (2)(a);
   (b) an ovum described in paragraph (2)(b); or
   (c) an ovum described in paragraph (2)(c).

10 (5) In this section, “common-law partner,” in relation to an individual, means a person who is cohabiting with the individual in a conjugal relationship at the relevant time, having so cohabited

for a period of at least one year.\textsuperscript{61}

The penalties for failure to screen, test, label, distribute and import as specified in the regulations are set out in s.61.\textsuperscript{62}

61. A person who contravenes any provision of this Act—other than any of sections 5 to 7 and 9—or of the regulations or an order made under subsection 44(1) is guilty of an offence and (a) is liable, on conviction on indictment, to a fine not exceeding $250,000 or to imprisonment for a term not exceeding five years, or to both; or
(b) is liable, on summary conviction, to a fine not exceeding $100,000 or to imprisonment for a term not exceeding two years, or to both.\textsuperscript{63}

**Who is a ‘donor’ and why does this matter?**

The above noted sub-sections 10(2) (a, b, and c) begin by identifying gametes – sperm and ovum – obtained from three different types of ‘donors’. But before we examine who are the ‘donors’ and whether their gametes need to be tested and screened, we need to understand what the AHRA means by the term ‘donor’.

In law, the AHRA situates the act of donation – the giving, granting or conferring of human reproductive material – to the person from whose body the ovum or sperm was obtained. The Act considers **all persons** undertaking IVF treatment to be ‘donors’ even if the ‘donation’ is made to oneself in the form of autologous/own use or when sperm or ovum are to be used by the donor’s spouse, common-law or sexual partner.

The AHRA at s.3, defines ‘donor’ as:

“(a) in relation to human reproductive material, the individual from whose body it was obtained, whether for consideration or not; and

\textsuperscript{61} Jobs, Growth and Long-term Prosperity Act, S.C. 2012, c-19 at s. 718.
\textsuperscript{63} No regulations pursuant to the amended s.10 have been made. Penalties for failure to test and screen human sperm are specified in the Processing and Distribution of Semen for Assisted Conception, SOR/96-254. May 7, 1996.
(b) in relation to an in vitro embryo, a donor as defined in the regulations.”

The Section 8 (Consent) Regulations maintains the broad definition of the term ‘donor’ and the ‘act of donation.’ It specifies permitted uses, including own-use, third-party reproductive use, research and testing all of which must be undertaken with the consent of the ‘donor’ or donors in the case of an embryo. Its goal is to ensure that all fertility patients are enabled to exercise autonomy. However it should be noted that the Section 8 (Consent Regulations) clearly defines the “third-party’ to be separate and apart from the ‘donor’ of the ova, sperm or embryo used in assisted reproduction.

One major difficulty created by the AHRA definition of ‘donor’ applied to the person as ‘donor’ (noun) and the ‘act of giving’ (verb) – donating is that it encompasses in law both concepts: a ‘donor’ who gives to oneself as well as a ‘donor’ who gives human reproductive material to others. In so doing, it confounds and blurs common-use definitions of ‘donor’ and ‘donation’.

The Oxford Dictionary, for example, defines ‘donor’ as the person who is involved in an act of giving. This means that the act of donation is other-motivated and other-directed: “a donor is a person who gives (donates) blood, organs or reproductive tissues to a third-party.”

64 Assisted Human Reproduction Act 2004 c2, s.3.
65 Assisted Human Reproduction (Section 8 Consent) Regulations. SOR/2007-137 state that donor must provide consent for creation and use of an embryo: (i) for their own reproductive use; (ii) use following death; (iii) third-party use; and (iv) research (including IVF instruction). No changes have been introduced to the Section 8 Consent Regulations as a result of the s.10 amendments.
67 Assisted Human Reproduction (Section 8 Consent) Regulations. SOR/2007-137 at s. 1(a) (i) and 1(a (ii).
1. “A person who donates something, especially money to charity.” 1.1 “A person who provides blood, an organ, or semen for transplantation, transfusion.”
AHRA takes a much broader view of who is a donor and the act of giving as it considers the
donor and the act of donation to include giving of a gamete or embryo to oneself as well as to
others, including one’s spouse, common-law or sexual partner in addition to anonymous or
known third-parties for their reproductive uses or for research and training.

To further complicate the matter, the Act’s terminology differs from language adopted by
provincial statutes,69 fertility association recommendations and guidelines,70 and the 2017
CAN/CSA Standard.71 In these instances, the term ‘donor’ refers to the person who donates
human reproductive material or embryos for the reproductive use by a third-party.

When we look at how the term ‘donor’ is defined and used in provincial statutes and judgements,
we see clearly just how different is the AHRA definition of ‘donor’. For example, in a British
Columbia case involving traditional surrogacy, Family Law Act (Re) 2016 BCSC 598, Fitzpatrick
J determined that the petitioner, “K.G. does not come within the definition of a “donor” since his
donation of sperm for the conception was for his “own reproductive use”.72 This ruling is guided
by the British Columbia Family Law Act definition of a ‘donor’:

“a person who, for the purposes of assisted reproduction other than for the person's own
reproductive use, provides:
(a) his or her own human reproductive material, from which a child is conceived; or
(b) an embryo created through the use of his or her human reproductive material.”73

and Related Registrations Statute Law Amendment), 2016. Ontario sidesteps the use of the term ‘donor’ by making
the action of donation of reproductive material a negative action as it concerns parentage. “Provision of reproductive
material, embryo not determinative. 5. (1) A person who provides reproductive material or an embryo for use in
assisted reproduction: (a) is not, by reason only of the provision, a parent of the child; and (b) shall not, by reason
only of the provision, be recognized in law to be a parent of the child.”
Montreal: Canadian Fertility and Andrology Society at 2:
71 Standards Council of Canada, Tissues for assisted reproduction” CAN/CSA-Z900.2.1-17, December 2017 at 17.
72 Family Law Act (Re) 2016 BCSC 598 at 17.
The Canadian Fertility and Andrology Society publication, Guidelines for Third Party Reproduction, adopts a similar definition to one used in the British Columbia Family Law Act. A gamete donor is defined as being: “a person who donates oocytes or sperm to a known or anonymous recipient for the purpose of achieving a pregnancy for the recipient and their partner (if applicable).”

The 2017 CAN/CSA Standards document considers a donor to be a provider of gametes or an embryo for third-party use. This document, which is expected to shape federal testing and screening regulations, defines a ‘donor’ as “an individual who provides reproductive tissues for use in a recipient who is not his or her spouse, common law partner, or sexual partner, in accordance with established medical criteria and procedures.” The 2017 CAN/CSA Standard acknowledges that the AHRA provides a broader definition of ‘donor’: “in relation to human reproductive material, the individual from whose body it was obtained, whether for consideration or not.” However, the 2017 CAN/CSA Standard does not explicitly adopt the broader AHRA definition of donor with the result that the screening and testing procedures it describes would to apply only in the case of third-party gametes and embryos.

74 Jon Havelock et al. 2016. Canadian Fertilization and Andrology Society Guidelines for Third Party Reproduction. Montreal: Canadian Fertilization and Andrology Society. at 2, Glossary; The Province of Ontario sidesteps the use of the term ‘donor’ by making the action of donation of reproductive material a negative action as it concerns parentage. All Families Are Equal Act (Parentage and Related Registrations Statute Law Amendment), 2016, S.O. 2016, c. 23 at: s.5(1) A person who provides reproductive material or an embryo for use in assisted reproduction, (a) is not, by reason only of the provision, a parent of the child; and (b) shall not, by reason only of the provision, be recognized in law to be a parent of the child.

75 2017 CAN/CSA Standards Council of Canada supra note 12 at 17.
Yet, if we look closely at the 2017 CAN/CSA Standard’s definition of donor, we realise that it is more nuanced than it appears on first reading. As the emphasis is on ‘providing’ reproductive tissues for use in a recipient who is not his/her own spouse, common-law partner of sexual partner, the case of sperm provided by the intended father and used to fertilise the ovum provided by the traditional surrogate would need to be screened and tested. But it is not clear that the Standard’s definition fully encompasses the situation of ovum provided by a traditional surrogate as she would be using her own ovum. Yet, the AHRA at s.10(2)(c) mandates screening and testing of the traditional surrogate’s ovum when used in her own pregnancy.

These conflicting definitions of ‘donor’ when applied to the woman who agrees to have an ovum obtained and who also agrees to use this obtained ovum in her own surrogate pregnancy create a number of worrisome implications for conditions of authorised use and for consent to use. Firstly, by making every person involved in assisted reproduction a ‘donor’ regardless of whether the activity involves ‘own use’ or ‘third-party use’ the AHRA situates the obtaining and using of sperm and ovum as a prohibited medical fertility technology unless expressly permitted by regulation.

Second, in the case of traditional surrogates given that they use their own ova in their own surrogate pregnancy, the act of ‘obtaining’ an ovum appears to blur the line between ‘own’ use and ‘third-party’ use. The problem becomes further entangled when one views the concept of ‘use’ through the lens of ‘patient’ rather than ‘donor’. Common law requires that medical patients provide consent to treatment. The AHRA speaks not of patients, but of donors. The 2017 CSA Standard adds another dimension by referring to a ‘donor’ who provides human
reproductive material to be used by a recipient who is not a spouse, common-law or sexual partner. It conveniently omits a reference to the ‘obtained’ ova used by the woman in her own pregnancy, including her own surrogate pregnancy. On a face-value reading of the 2017 CAN/CSA Standard definition, the case of a traditional surrogate who produced the ‘obtained ova’ and who is also the recipient of it appears not to be captured within the scope of the definition. Yet, the AHRA requires her ‘obtained’ ova to be screened and tested.

The definition of ‘donor’ matters for our examination of the changes made to s.10 of the AHRA. It sets the dividing line separating autologous and own-use donation as these are instances where the gametes can be used without the need for screening and testing whereas screening and testing of ‘third-party’ human reproductive material is mandated under the Criminal Code. Failure to test and screen bears a criminal code penalty. I argue that the requirement specified at s.10(2)(c) transforms autologous use into a ‘third-party’ activity, though only for traditional surrogates. In so doing, the AHRA and ensuring regulations situate the traditional surrogate as a third-party donor who poses a health and safety threat, though to whom is not clear.

This sleight of hand whereby the traditional surrogate is both third-party ova donor and surrogate who uses her own ovum distances her from the role of a fertility patient who uses her own gametes. We see this repositioning very clearly in how assisted reproductive data are reported. For example, Canadian and American fertility clinics record gestational surrogates as receiving embryos containing either ‘own use’ or ‘third-party’ ova. In all cases where a gestational surrogate receives an embryo labelled ‘own use ova’ it is in fact the intended mother’s ova that is being used. This occurs because the clinics consider the intended mother to be the fertility
patient not the gestational surrogate.\textsuperscript{76} A similar reimagining occurs in the amendment at 10(2)(c). By turning a traditional surrogate into a third-party donor, I argue, that her ability to determine to decide the use of her obtained ova will be constrained especially if it translates into her formally ‘donating’ her ovum to the intended parents. In this regard, the implications for mandatory screening and testing set out in s.10 and the obligations imposed by the Section 8 (Consent) Regulations given her newly acquired status as third-party donor are significant.

**From which type of donor is sperm and ova to be screened and tested?**

To better understand the implications of the proposed regulatory regime we need to examine which type of donor and donation triggers mandatory screening and testing.

**Sperm donors**

At s.10(2)(a), unless ‘obtained’ sperm is to be used by the donor’s spouse, common-law or sexual-partner, it must be tested and screened pursuant to the criteria established by s.10(3). In principle, the approach represents no change to existing law.

In response to the use of untested sperm that resulted in the unfortunate transmission of HIV\textsuperscript{77} all human sperm used by the person other than the donor’s spouse, common-law or sexual partner or imported for third-party reproductive use must comply with the Health Canada screening and

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\textsuperscript{76} See article written by Kiran M Perkins et al. 2016. “Trends and outcomes of gestational surrogacy in the United States”. Fertility and Sterility 106: 435. The analysis undertaken is conducted from the perspective of the intended parents as they are viewed by the fertility industry to be the patients with the result that very little information is obtained about the surrogate undergoing the embryo transfer or pregnancy.

testing standard instituted in 1996.\textsuperscript{78} The sperm testing regulations were further tightened in 2000 after a woman contracted chlamydia trachomatis from an infected donor.\textsuperscript{79}

The text of the screening and testing amendment at s.s.10(3)(a) and (b) echo the procedures mandated in the 1996 Semen Regulation,\textsuperscript{80} specified in the 2000 Technical Requirements Directive,\textsuperscript{81} and explained in the Guidance\textsuperscript{82} document. It is these technical conditions\textsuperscript{83} for the screening, testing and labelling of human sperm that are under review as part of the Health Canada regulation exercise.\textsuperscript{84} The 2017 CAN/CSA Standard\textsuperscript{85} specifies criteria for donor suitability and sets out the required elements for donor selection and the screening and testing regime to be applied to anonymous and designated reproductive donors. Compared to the 1996 Semen Regulation and related Directive, the restrictions imposed on ‘Designated Reproductive Donors’ have been relaxed and the scope for designating a known donor have been widened. A Directed Reproductive Donor is defined in the 2017 CAN/CSA Standard as:

‘a person who is the source of reproductive cells or tissues [including semen, ova or embryos (to which the donor contributed the spermatozoa and ovum) to a specific recipient, and who knows and is known by the recipient before donation.’

Notes:
1) This term does not include a sexually intimate partner. See Donor.

\textsuperscript{78} Processing and Distribution of Semen for Assisted Conception, SOR/96-254. May 7, 1996.
\textsuperscript{80} Processing and Distribution of Semen for Assisted Conception, SOR/96-254. May 7, 1996
\textsuperscript{82} Health Canada. Guidance on the Processing and Distribution of Semen for Assisted Conception Regulations (Guide-0041).
\textsuperscript{83} The existing standard is controversial especially for male donors who have sex with males and for designated donors. See: Stu Marvel, 2013, “‘Tony Danza. 2013. ‘Is My Sperm Donor?’ Queer Kinship and the Impact of Canadian Regulations and Sperm Donation”. Canadian Journal of Women and the Law 25(2): 221
\textsuperscript{84} See comments in 2018 Health Canada consultation report summary: “What We Heard”.
\textsuperscript{85} Standards Council of Canada. CAN/CSA-Z900.2.1-17 Tissues for assisted reproduction. December 2017 at 10.
2) The terms “designated donor” and “known donor” are also used when referring to a “directed reproductive donor”.86

The designated reproductive donors is not a donor type identified in the AHRA though this type of donation has been a contested feature of the assisted human reproduction landscape since the 1996 Semen Regulations were enacted.87 The 2017 CAN/CSA Standard, like the Act at 10(2)(a), would require in the case of surrogate recipients that the sperm of the intended father be screened and tested for sexually communicable diseases. Given that gestational and traditional surrogates will know the sperm donor (intended father) it is expected that the Designated Reproductive Donor schema for testing and screening would apply. The 2017 CAN/CSA Standard also recommends that surrogates receiving directed human reproductive material (sperm, ova and embryos) be provided with additional counselling about the risk associated with waiving the post-quarantine tests for infectious diseases.88 This is a prudent recommendation given US research findings showing that only 75% of gestational surrogates receive counselling.89 The proportion Canadian surrogates, gestational and traditional, who receive counselling is not known. The Section 8 (Consent) Regulations does not mandate counselling and the provinces would likely assert that counselling of fertility patients falls within their constitutional sphere of responsibilities. Apart from Quebec,90 provinces have not sought to enact fertility treatment

86 Standards Council of Canada, CAN/CSA-Z9000.2.1-17. Tissues for assisted reproduction. December 2017 at 17. This is an interesting definition and it could be argued that it leaves open the possibility artificial gametes and SHEEFS to be created from designated reproductive donors.
87 Marvel, 2013. supra note 5.
88 Standards Council of Canada. CAN/CSA-Z900.2.1-17 Tissues for assisted reproduction. December 2017, section 17.3.1 at 62.
90 An Act respecting clinical and research activities related to assisted procreation, CQLR.C-A-5.01; Bill 20, (2015, chapter 25) An Act to enact the Act to promote access to family medicine and specialized medicine services and to amend various legislative provisions relating to assisted procreation. 10 November 2015. See amendments at s.10 regarding delivery of services and drawing up of ethical and safety guidelines by Collège des médecins du Québec.
legislation though the 2016 Ontario, All Families are Equal Act, requires that surrogates and intended parents had a legal arrangement in place.  

### Ova donors

The 2012 amendments of the AHRA at s.10(2)(b) specify that all human ovum used for human reproduction must be screened and tested unless it is to be used by the ‘donor’ or by the ‘donor’s spouse, common-law or sexual partner’. However, at s.10(2)(c), if the ‘donor’ plans to use her own obtained ovum in her own surrogate pregnancy, it must be screened and tested even though it will be returned by means of a uterine transfer to the donor. It is worth recalling that in Re AHR, Justices Le Bel and Deschamps took the view that not all public health risks should be addressed through criminal law: “it must be found that there is an evil to be suppressed or prevented”.  

What can explain the possible health harm that could occur to a woman using her own ovum in her own surrogate pregnancy that would not also arise when the woman used her own ovum or the ovum of her spouse, common-law or sexual partner in her own non-surrogate pregnancy?

On first inspection, the 2012 AHRA amendment mandating screening and testing of ova used in third-party reproduction corrects a long-standing legislative omission identified by Rivard and

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91 In Ontario, for example, All Families are Equal Act. Chapter 23. Statutes of Ontario. 2016. An Act to amend the Children’s Law Reform Act, the Vital Statistics Act and various other Acts respecting parentage and related registration, see s.2(2) and s.7 where legal advice is required. Counselling is not noted.

Hunter who recommended in 2005 that the government take steps to regulate health and safety measures for human ova used in third-party reproduction. Certainly, changes within the practice of fertility medicine had evidenced strong demand for third-party donated ova along with dramatic improvements in the techniques used to cryopreserve ova. Moreover, preservation of the ova is no longer an unproven or experimental technique with research failing to demonstrate superior outcomes using fresh oocytes (ova) over that of vitrified egg-banked oocytes.

Canadian clinicians have welcomed this long overdue legislative change requiring testing and screening of ova used by third-parties. It is a regulatory modification that the federal agency, Assisted Human Reproduction Canada, could have brought into force prior to its demise in 2012 had it used its mandate to protect the health and safety of Canadians. But it did not.

The Standards Council of Canada 2017 CAN/CSA standard provides guidance for the screening and testing of third-party ova donors: anonymous and directed. It establishes the screening criteria for donation which includes the recording of the donor’s family genetic history, medical

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97 Standards Council of Canada. CAN/CSA-Z900.2.1-17 Tissues for assisted reproduction. December 2017, section 13.2.2.-13.3. Genetic history and testing is specified at section 13.7.
testing for diseases, and establishes the criteria for donor suitability evaluations.\(^{98}\) As noted, it is likely that these elements will be adopted by Health Canada in its upcoming regulatory project.\(^{99}\)

The 2012 amendment at 10(2)(b) also clarifies in law that the use of a partner’s ovum by a woman in same-sex married, common-law and sexual relationships is to be exempt from screening and testing. This type of ova sharing (co-mothering) among lesbian partners is not unknown nor uncommon, though no Canadian data exists as to its prevalence.\(^{100}\) Yet, one needs to ask why Canadian legislators felt it necessary to explicitly specify that this type of reproductive tissue exchange was permitted and that the reason for its non-prohibition is one of health and safety. The AHRA at s.3 states that discrimination in assisted reproduction is prohibited. Surely if heterosexual partners are permitted to exchange sperm and use their own ova, it not clear why the same logic did not automatically apply to the exchange of ova between lesbian spouses, common-law and sexual partners.

For other nations, issues interfering with lesbian exchange of ova have included assisted reproduction access restrictions based on sexual orientation and marital status alongside an ethical discourse suggesting that the medical surgery needed to remove ova from one partner to give to another when both were fertile was unnecessary and as such could be considered

\(^{98}\) The screening and testing parameters noted here also apply to sperm donors.

\(^{99}\) The 2018 Health Canada “What We Heard” report did note that some of the consultation submissions identified concerns with criteria for testing and screening developed by the CSA Standard.

maleficent.\textsuperscript{101} Currently, the legality of the practice varies considerably across Europe, depending on the legal recognition of same-sex marriage and partnership with countries like Belgium, Finland, Ireland, Netherlands, UK, Portugal and Spain permitting it while others such as France or Germany prohibiting or actively discouraging it.\textsuperscript{102} In places where family law has been changed for example, in the UK when the Human Fertilisation and Embryology Act was amended in 2008 to remove the need for a father and lesbian partners permitted to become legal parents, the practice has become more common. In the UK, the issue now revolves on ensuring that all parties exercise informed consent rather than in regulating the health and safety of the practice.\textsuperscript{103}

By not imposing prohibitions regarding the use by a fertility patient of the ova donated by her spouse, common-law or sexual partner,\textsuperscript{104} Canada’s AHRA seeks to normalize same-sex female relationships. It accords the exchange of ova between female spouses, common-law and sexual partners an equivalency status with autologous ova used by a woman in a heterosexual married, common-law or sexual relationship. Specification that the sharing of ova between women engaged in a same-sex spousal, common-law or sexual relationship also serves to note that the federal government considers that the practice holds a no greater health risk to the lesbian recipient than would be experienced to exist for any other woman using her own ova or in the

\textsuperscript{102} Bodri et al., supra n 100 at Table 1, p.130.
\textsuperscript{104} AHRA s.s.10(2)(b)
case of a heterosexual women from receiving a transfer of sperm obtained from her male spouse, common-law or sexual partner.

However, the reason for allowing equal treatment for the use of shared gametes among spouses, common-law and sexual partners regardless of sexual orientation, as noted in the preamble to the screening and testing amendment is a permission reliant on a health and safety rationale\(^{105}\) rather than legal equivalency\(^{106}\) and the right to equal treatment.\(^{107}\) As was ruled by the SCC in Andrews v. Law Society of British Columbia (1989), “discrimination may be described as any distinction, conduct or action, whether intentional or not, but based on a person’s sexual orientation, that has the effect of either imposing burdens on an individual or group that are not imposed upon others, or withholding or limiting access to opportunity, benefits and advantages available to other members of society.”\(^{108}\) Equally, the amendment could have referenced the principle of non-discrimination that underlies Canada’s AHRA: “persons who seek to undergo assisted reproduction procedures must not be discriminated against, including on the basis on their sexual orientation or marital status.”\(^{109}\) But, it did not.

It is unfortunate that the government did not use the 2012 legislative opportunity to indicate that co-motherhood assisted reproduction has been permitted since the inception of the AHRA notwithstanding any stated ethical concerns advanced by those arguing that intra-couple egg sharing for nonmedical reasons could be considered to be ethically non-justifiable, risky, and not

\(^{105}\) AHRA s.10(1)
\(^{106}\) Re Same-Sex Marriage [2004] 3 SC.R. 698; Civil Marriage Act, S.C. 2005, c. 33
\(^{109}\) AHRA s.s.2(e).
cost-effective.  Such argumentation is weak and profoundly dismissive of the reproductive autonomy of lesbians. Moreover little empirical research exists to support claims that the practice is any more risky compared to the harm endured by other female patients undertaking ovarian stimulation related to third-party ova donation or for their own reproductive use. This is an example of where the federal government has embedded a health and safety justification for permitting co-mothering and the exchange of ova between lesbian spouses and common-law and sexual partners rather than adopting an equality-based rationale as enabled by s.3 of the Act.

**Traditional surrogates**

The amendment at s.10(2)(c) created another group of regulated autologous ova users: traditional surrogates. We need to assess whether the supposed health harm of a woman using an unscreened and tested own ‘obtained’ ova in her own surrogate pregnancy warrants prohibition under the criminal code. We also need to question the legal basis whereby the status of the ‘obtained’ ovum has been seemingly transformed from that of an autologous tissue that poses no health harm to the woman from whose body it originated to that of a ‘third-party’ ova which having been ‘obtained’ somehow presents a health and safety risk. In order to situate this discussion, we need to review Canada’s positon on legality of surrogacy especially given that the

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112 Bodri et al., supra n 100.
113 Exchange of emails between P. White and L. Mainland, Health Canada confirming this statutory change, 22 February, 2013.
law views surrogacy when undertaken for payment is seen to constitute a moral evil. Though as Millbank asserts, surrogacy in Canada straddles a non-commercial/commercial boundary.\textsuperscript{114}

**Surrogacy: ‘Moral evil’**

The AHRA establishes that surrogacy is legal in Canada as long as it done altruistically.\textsuperscript{115} Both forms, traditional surrogacy where the surrogate is genetically related to the child she bears for intended parent(s) and gestational surrogacy, where the surrogate is not genetically related to her offspring, are permitted.

The practice of a woman conceiving and carrying a child for an individual or couple who for medical or social reasons are unable to have their own children has been characterised as morally troubling as it disrupts the normative view of motherhood.\textsuperscript{116} It has been a controversial topic for Canadians.\textsuperscript{117} Certainly concerns about commercialisation of human reproduction, the practice of traditional surrogacy, and the ‘moral panic’ raised by the 1984 Baby M incident cast a long shadow over the deliberations of assisted reproduction undertaken by Baird Commission, Parliamentary Committees, and parliamentarians.\textsuperscript{118} The banning of commercial surrogacy by

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\textsuperscript{114} Jenni Millbank. 2015 “Rethinking ‘Commercial’ Surrogacy in Australia” Bioethical Inquiry 12: 477.

\textsuperscript{115} Assisted Human Reproduction Act 2004 c2 at s.6.


the AHRA conformed to the national narrative privileging unpaid donation of blood, organs and tissues and reflected a desire on the part of regulators to avoid an American style approach to the practice of fertility medicine.\(^\text{119}\)

However, considerable social change has taken place in Canada since the 1983 Baird Commission held public consultations on the topic of assisted reproduction, including surrogacy. Twenty-first century Canada has legalised same-sex marriage,\(^\text{120}\) Quebec funded IVF surrogacy costs\(^\text{121}\) and since 2016, Ontario pays for gestational and traditional surrogates to receive fertility treatment.\(^\text{122}\) Gradually provincial governments have been updating family law statutes to reflect parentage made possible by assisted conception, including traditional and gestational surrogacy.\(^\text{123}\)

It is not surprising that there now exists growing evidence that for an increasing number of childless Canadian couples and individuals including gay men, surrogacy may be the only way to have biological children.\(^\text{124}\) For example, a 2012 survey revealed that one-quarter of Canadian

\(^\text{120}\) Civil Marriage Act S.C. 2005, c. 33.  
\(^\text{122}\) In Ontario, surrogates are eligible for IVF and AI under the Ontario Fertility Treatment program. FOI Request A-2017-00-00166 made by Pamela White to Ontario Ministry of Health and Long-Term Care, 1 September 2017.  
childless adult women and 40 percent of childless adult men would consider using a surrogate should they or their partner be unable to carry and give birth to their biological child.\textsuperscript{125} It is not uncommon to read news articles detailing surrogacy experiences told from various perspectives.\textsuperscript{126} Moreover, research with North American surrogates demonstrates, they are typically middle-class, college educated, heterosexual married women who have had non-problematic pregnancies and who undertake the practice for altruistic reasons regardless of the commercial/non-commercial regime in which they operate.\textsuperscript{127}

Given this emerging acceptance of gestational and traditional surrogacy, it is difficult to support the view that a moral evil rationale could be the justification for imposing a prohibition on the use of unscreened and untested obtained own-use ova used by an altruistic traditional surrogate in her own pregnancy. The reason must be the one that as stated in the preamble to the amendment: health evil. The question that needs to be answered: To whom does this harm occur?

**IDENTIFYING THE HEALTH EVIL EMBODIED IN THE ‘OBTAINED’ OVUM ‘DONATED BY A WOMAN AND USED IN HER SURROGATE PREGNANCY**

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The AHRA as amended at s. 10 applies criminal law sanctions to address the ‘health and safety evils’ posed by a woman’s own ‘obtained’ ovum being used in her surrogate pregnancy. Let us now attempt to determine what might be the health and safety risks posed by ‘obtained’ traditional surrogate ovum to ascertain whether use of unscreened and untested obtained traditional surrogate ova warrants criminalisation.

Health and safety risks to the traditional surrogate

Does the use of their own untested and unscreened ova jeopardize the health and safety of traditional surrogate patient? It is illogical to suggest that a traditional surrogate using her own ova in her pregnancy faces a greater health risk than do other women who use their own ova or the ova of their spouse or common-law or sexual partner in their own pregnancy. Recent findings show that gestational surrogates using donor ova appear to experience more adverse prenatal and birth delivery outcomes compared to their previous birth experiences where conception was achieved without use of in vitro fertilization which is the usual situation practiced by traditional surrogates.128

128 Bodri et al., supra n 100 at p.131. See also finding from a recent review article examining risks in surrogacy where the authors note that the risks derive from the fertility treatments. The risks attributable to the women using her own ova in her own pregnancy which is the vast majority of pregnancies world-wide is not the subject of research examining the need for screening and testing. See the following recent review study: M. Simopoulou, K. Sfakianoudis, P. Tsioulou, A. Rapani et al., 2018 “Risks in Surrogacy Considering the Embryo: From the Preimplantation to the Gestational and Neonatal Period” BioMed Research International. Volume 2018, Article ID 6287507 [https://doi.org/10.1155/2018/6287507] See also: Irene Woo, Woo, Irene; Rita Hindoyan, Melanie, Landay, Melanie et al. 2017 “Perinatal outcomes after natural conception versus in vitro fertilization (IVF) in gestational surrogates: a model to evaluate IVF treatment versus maternal effects.” Fertility and Sterility 108(6) 993 which compared gestational surrogate pregnancy and birth outcomes to previous pregnancies where donor ova were not used.
It can be argued that the concern about the health harm to the traditional surrogate of using her own ‘obtained’ ovum in her surrogate pregnancy is misplaced as it is the act of ‘obtaining’ the ova through the application of ovarian stimulation that poses the actual health risk. Ovarian hyper-stimulation syndrome (OHSS) is a serious treatment complication; one which could result in patient death. While it is thought to affect about 1.8% of all IVF cycles it nonetheless represents one the most important concerns in modern IVF practice. It should be noted that little to no study of Canadian fertility patients’ experience of OHSS has been conducted and the annual release of limited information from the IVF Directors’ assisted human reproduction registry (CARTR-Plus) provides minimal insight on the occurrence of this etiology in Canadian fertility clinics.

What is in doubt then is why it would be thought that a more serious health harm would accrue to a traditional surrogate compared with other fertility patients who undergo ovarian stimulation to obtain ova. A matter worthy of our examination I suggest is the potential for confusion about who has the authority to make decisions about the use of the ‘obtained’ embryo. For example, a

131 Between 2001 and 2012, CFAS used to publish a more detailed report on OHSS. This ended with the transfer of the Canadian Assisted Reproductive Technology Registry (CARTR) to Better Outcomes Registry for Newborns (BORN). See CFAS website for annual media announcement on IVF success rates at: http://www.cfas.ca. Considerable research is being conducted elsewhere. See for example: Ruth Howie, Ruth & Vanessa Kay, 2018. “Controlled ovarian stimulation for in-vitro fertilisation” British Journal of Hospital Medicine 79(4) 194; Cindy Farquhar, Jane Marjoribanks , Julie Brown et al., 2017 “Management of ovarian stimulation for IVF: narrative review of evidence provided for World Health Organization guidance” Reproductive Biomedicine Online 35(1) 3
mix up or failure on the part of the IVF clinic to acquire written and informed consent regarding the creation of an embryo containing this ovum and its use could present a moral and legal harm to the traditional surrogate.’

Given the above analysis, one must conclude that the health and safety risk to traditional surrogates of using their own ova cannot be the reason for mandatory screening and testing of obtained ova as it fails to meet the harm test established by the SCC in Reference AHR.

Health and safety risks to clinic staff and patients

Most human sperm, ova, and embryos used and stored in IVF clinics are own use in that they have been provided by the fertility patient and their spouse, common-law or sexual partner and will be used in their fertility treatments.132 Own use gametes and embryos are not subject to mandatory screening and testing though fertility patients, spouses and partners and will undergo a series of medical tests including ones capable of detecting the existence of sexually transmitted diseases and to reduce the risk of transmission of disease.133

All Canadian fertility clinics have been encouraged to follow human reproductive material and embryo labelling, handling and storage protocols designed to prevent cross-contamination and misidentification.134 It appears that Canadian IVF clinics have voluntarily adopted the

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procedures and protocols developed by the Standards Council of Canada to prevent contamination and mislabelling though to date no monitoring information informs Canadian consumers about compliance.\textsuperscript{135} It is recommended that fertility clinics ensure that Standard Operating Procedures are in place to address health and safety requirements regarding sperm, ova and embryo preparation and preservation\textsuperscript{136} and packaging, storage, and the cleaning and maintenance of cryopreservation tank containers.\textsuperscript{137}

In light of the above, it is difficult to sustain the argument that unscreened and untested ova obtained from a traditional surrogate represent a risk to IVF clinic staff and other patients sufficient to warrant criminal law sanctions criminalising a failure to screen and test. Thus, the expectation that ova obtained from a traditional surrogate poses significant health risks to the routine operation of IVF clinics or to other patients cannot be the rationale for the imposition of mandatory testing and screening.

\textbf{Health and safety risks to children born to traditional surrogates}

The preamble to the AHRA includes a section setting out ethical principles guiding the practice of assisted reproduction in Canada. The importance of beneficence and non-malfeasance in the practice of fertility techniques underscores s.2(a) of the Act which states: “The health and well-being of children born through the application of assisted human reproductive technologies must be given priority in all decisions respecting their use.”\textsuperscript{138} In light of this concern, can one sustain

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135 Perhaps the best indicator is Accreditation Canada clinic evaluations conducted at the request of the IVF clinic, a practice encouraged by the Canadian Fertility and Andrology Society.
136 Canadian Standards Association Standard CAN/CSA Z900.2.1-17 Tissues for assisted reproduction, December 2017 at section 15, see 15.4.
137 Canadian Standards Association Standard CAN/CSA Z900.2.1-17 Tissues for assisted reproduction, December 2017 at section 15, see 15.6.
138 AHRA s.2(a).
\end{flushright}
the argument that it is the public good desire to minimize potential health and safety risks to the offspring of traditional surrogates that supports the rationale and justification for mandatory ova screening and testing?

Traditional and gestational surrogates who receive treatment at Canadian fertility clinics are tested to establish their communicable disease status and to assess their ability to successfully conceive and bear children. The voluntary Third-party reproduction guidelines developed by Canadian Fertility and Andrology Society\textsuperscript{139} apply regardless of the fertility treatment a surrogate may receive—ovarian stimulation, IVF embryo transfer, and artificial insemination. However, the federally mandated screening and testing of traditional surrogates triggered by an ‘obtained’ traditional surrogate ova being produced as result of ovarian stimulation, a procedure that carries known risks implies that a different set of procedures, are to apply. This occurs because the Act in effect repositions the status of obtained traditional surrogate ovum and reimagines it to be ‘donated’ third-party ovum, even though it will be used by the traditional surrogate in her own surrogate pregnancy. A missing piece of this puzzle concerns her ability to retain use control over these obtained ova. However, in this discussion we need to recall that the prime reason for screening and testing of human reproductive material is prevent the transmission of disease to a third party; that is, someone other than the person who provided it.

By treating the ‘obtained’ traditional surrogate’ ova as third-party-donated human reproductive material, the amended Act proposes to impose at s.10(3) testing and screening protocols similar to those described in Processing and Distribution of Semen for Assisted Conception

Regulations\textsuperscript{140} and Work-Up of the Directive on Technical Requirement for Therapeutic Donor Insemination.\textsuperscript{141} In the 2017 CAN/CSA Standard we can see how these conditions would be operationalised. For example, the medical, personal and family history information about the traditional surrogate would be obtained and donor suitability screening undertaken.\textsuperscript{142} It would appear that a more intensive set of screening and disease detection tests would be instituted\textsuperscript{143} compared with the voluntary system of screening and testing guidelines proposed by the Canadian Fertility and Andrology Association for traditional surrogates undergoing artificial insemination.\textsuperscript{144}

It should be noted that the AHRA does not mandate that medical, personal and family history information be obtained from a gestational surrogate. Thus, there is a strong likelihood that an uneven collection of personal information is likely to occur as more personal health data and medical history information will be acquired in the isolated and rare instances where ova of a traditional surrogate are obtained.

Regulated screening and testing of a traditional surrogate for communicable health conditions and documentation of medical, genetic and family history would provide additional health and safety assurances to commissioning parents that the surrogate-related child would not be prone to

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\item[\textsuperscript{141}] Health Canada, The Work-up at s.s.3.3.2 (ii) requires a donor consent form. This may be different from the form used pursuant to AHRA Section 8 (Consent) regulations.
\item[\textsuperscript{142}] Canadian Standards Association Standard CAN/CSA Z900.2.1-17 Tissues for assisted reproduction, December 2017 at section 13: Donor screening and section 14: Testing.
\item[\textsuperscript{143}] Some IVF directors have expressed the view that the CSA Z900 be adopted as the screening and testing regulations (A. Leader, CBC Interview, 01.09.2016, http://www.cbc.ca/ottawamorning/episodes/#).
\end{itemize}
serious health or genetic conditions inherited from the traditional surrogate. Acquisition of obtained ova also enables preimplantation genetic diagnosis (PGD) and karyotyping, processes that permit detection of genetic defects and anomalies including trisomy and determination of risks for serious genetic disease.\textsuperscript{145}

If testing and screening documentation obtained as result of screening and testing was made available to surrogate-born children, they would have potentially crucial information about their genetic parentage and medical history. It should be noted that the AHRA does not mandate that medical, personal and family history information be obtained from a gestational surrogate nor when traditional surrogacy is undertaken using assisted insemination, which is the more common practice. Thus, there is a strong likelihood that an uneven collection of personal information is likely to occur as more personal health data and medical history information will be acquired in the isolated and rare instances where ova of a traditional surrogate are obtained.

Without a donor registry there exists no formal means for a donor-conceived child or a traditional surrogate conceived child to learn about their biological parents. Without parental disclosure no mechanism exists enabling them to know that they were a surrogate-born child or that sperm or ova have been provided by persons other than their social (intended) parents. Such information could be of health importance especially as our understanding of the implications of epi-genetic phenomena increases and in cases where inherited biological traits may have medical and health consequences.

\textsuperscript{145} Trisomy 21 is commonly referred to as Downs Syndrome. It is but one of more frequently occurring variants of trisomy.
Canada’s federal donor registry, as envisaged by the AHRA, was ruled ultra vires by the Supreme Court. Provincial gamete and embryo donor registries do not exist. Submissions made to Health Canada as part of the consultation on regulatory change have identified a need for them. Given that no Canadian donor registry exists, no organised and managed system will enable the offspring of traditional surrogates to access the information obtained as a result of a screening and testing regime. As the decision in Pratten v British Columbia demonstrates, knowing one’s genetic history is not a constitutional right. Information indicating that one has been conceived using donor sperm and/or ova is not is recorded on birth registration forms though it could be were Canadian provinces to follow the example set by the US states of Massachusetts, Florida, Michigan and Connecticut. However to do so would involve legislative change. The BC Vital Statistics Act, for example, prevents the birth registration recording of AHR conception. In other provinces, the vital statistics legislation is silent on the matter though the activities of the Uniform Law Commission provide the opportunity to consider this option for Canadian provinces to consider. In the absence of intended parents providing information about donors and surrogates, traditional surrogate-born children, like gestational

146 AHRA at s.19 repealed 2012.
147 Health Canada. What We Heard. January 2018 supra n 13 at 3.
148 This also applies to the off-spring of gestational surrogates. See 2017 CSA Standard at Table 2.
151 Vital Statics Act. [RSBC 1996] c. 479 at 14.1: “If a child is born in British Columbia as a result of assisted reproduction, nothing must appear on any certificate issued by the registrar general that would disclose that the child was born as a result of assisted reproduction.”
surrogate-born children and other donor-conceived children, must look elsewhere to locate donor profile information and siblings; for example, sperm and ova banks, the IVF clinic that performed the treatments, and the Donor Sibling Registry.\textsuperscript{153}

Research shows that surrogates bond with intended parents\textsuperscript{154} and findings from UK studies demonstrate that gestational and traditional surrogates, intended parents, and surrogate-born children can maintain positive and supportive post-birth relationships.\textsuperscript{155} In Canada, given the lack of a donor registry, the maintenance of relationships with intended parents between surrogates takes on heightened importance as this may be a key way for the traditional surrogate-born child to know about its genetic background.

Given that mandatory testing and screening will occur only for ‘obtained’ ova, why does a health and safety ‘evil’ warranting criminal law sanctions benefit only the children conceived using ex utero traditional surrogate ova? If non-malfeasance is the rationale invoked for application of criminal law powers, surely it is owed to all offspring of traditional surrogates, regardless of the location of the ova at time of conception.\textsuperscript{156} The amended AHRA represents, at best, a limited interpretation of compassion for the donor-conceived.


\textsuperscript{156} Zsuzsa Berend, 2016. “‘We Are All Carrying Someone Else’s Child’: Relatedness and Relationships in Third-Party Reproduction” American Anthropologist 118: 24;


\textsuperscript{156} Vincent Couture et al. 2014. “Strengths and pitfalls of Canadian Gamete and Embryo Donor registries: searching for Beneficent Solutions” Reproductive Biomedicine Online 28: 369.
Health and safety harm of an ‘obtained’ traditional surrogate’s ovum

On careful examination, it is difficult to determine how the ovum obtained from a traditional surrogate and used in her own pregnancy represents a health and safety harm so significant as to justify the application of criminal code sanctions on those who would fail to screen and test it prior to its use. This paper’s findings support the conclusion that the application of criminal code sanctions used to penalise those who would fail to screen and test the ova fails to meet the test laid out by the SCC in Ref re AHR.

I argue that not only does the amendment fail to meet the test needed for the application of criminal code penalties, the imposition of mandatory screening and testing imposes a harm: re-imagining of the surrogate’s ova. The amendment functions to transform it from autologous use to third-party use. The implications for consent, reproductive autonomy of traditional surrogate and for fertility patients is considerable.

IMPLICATIONS FOR TRADITIONAL SURROGATES OF AHRA AMENDMENTS CONCERNING THE TESTING AND SCREENING OF OVA

The Act by requiring screening and testing the testing and screening of an obtained ova donated by a woman and used in her surrogate pregnancy appears to transform a traditional surrogate’s ova by means of law and regulation into a ‘third-party’ body part notwithstanding her genetic affinity to it or that once transferred back to her, it will be her decision during the pregnancy and on the birth of the child to fulfil or not to fulfil the surrogacy arrangement. To further muddy the waters, the definition of ‘donor’ adopted by the 2017 CAN/CSA Standard excludes autologous use as it defines ‘donor’ as being “an individual who provides reproductive tissues for use in a
recipient who is not his or her spouse, common-law or sexual partner.\textsuperscript{157} This definition implies that the autologous user is not a ‘donor’. However, the AHRA amendment at s.10 mandates that the surrogate who agrees to have her ova removed from her body by ovarian stimulation must submit herself and the ova to testing a screening as specified in regulation. The obvious workaround the AHRA’s imposition of rigorous screening and testing is to qualify her as a “designated reproductive donor” under the 2017 CAN/CSA Standard even though she does not fit the Standard’s definition of a donor.

It is also important to note that the act of obtaining an ovum from a traditional surrogate is rare. Neither the US nor the Canadian assisted reproduction registries provide information on traditional surrogacy undertaken using assisted insemination or IVF.\textsuperscript{158} The Ontario Fertility Program began funding IVF and assisted insemination for surrogate patients in 2016. Under the program, it is possible for a woman who has been or plans to be a surrogate (traditional or gestational) to receive to receive ovarian stimulation for her own fertility uses. The program does not prevent her from using her own ‘obtained’ ova in her own traditional surrogate pregnancy.

Regrettably the Ontario program does not track surrogate treatments, with the result that no information is available on the uptake of this program by these patients or the outcomes.\textsuperscript{159} Nor is it possible to obtain a count of the number of traditional surrogates undergoing screening and

\textsuperscript{157} National Standard of Canada, CAN/CSA-Z900.2.1-17 Tissues for assisted reproduction. December 2017 at 17.
\textsuperscript{159} FOI Request A-2017-00-00166 made by Pamela White to Ontario Ministry of Health and Long-Term Care, 1 September 2017. Status of the situation verified in July 2018 by the author.
testing using CAN/CSA designated reproductive donor option. Nor is possible to track the transformation of status from ‘own’ ova to that of ‘donated ova’ and to understand the loss of control over its use and change in consenting that such a reimagining of ovum entails. Finally, the Ontario program considers ‘gestational and traditional surrogates to be patients., though the clinic which undertakes the treatment refers to the intended parents as the ‘fertility patients’ and the data collected on the treatments involving the surrogate (traditional and gestational) is recorded from the perspective of the intended parent. I would argue that that the existing data recording system will likely label the ova provided by a traditional surrogate and used in her won pregnancy as a third-party donor gamete regardless of whether she has consented to ‘donate’ it to the intended parents for their reproductive uses.

Twisted and muddled terminology about who is the fertility patient and how this differs in federal and provincial law and clinic practice reveals the potential for problems in the area of consent to use and consent to treatment, especially when roles become interchangeable. While no data are collected on Ontario traditional surrogates using their own obtained ova, the practice can and does occur as the case of a BC traditional surrogate, Ms Chonn, recently revealed.

Ms. Chonn had acted as a traditional surrogate for intended parents. In so doing she had had undergone ovarian stimulation and agreed to have her obtained ova fertilised using the sperm of the intended father. Embryos not used in Ms Chonn’s surrogate pregnancy were cryopreserved and stored by the IVF clinic. Sometime later an embryo containing her ovum and the sperm of the intended father was transferred to the uterus of the intended mother. Ms Chonn has stated that she was not informed that the embryo containing her ovum had been transferred to the
intended mother and that the use of the embryo occurred without her knowledge and written consent. Ms Chonn is genetically related to the child delivered by the intended mother. She has stated that “she couldn't fathom someone else carrying her child.” The outcome has been especially stressful for her given her loss of contact with the intended parents and her genetic offspring.160

This case exhibits a number of characteristics common to assisted reproduction. Roles can be variable and interchangeable. Creation of human life and the intermixing of family and relational bonds are complex and potentially contested. Rules regarding the obtaining of consent are not always followed though in Canada, with the exception of when incident is reported by media, there exists no information on compliance to the Section 8 (Consent) Regulations.161 Whether the Chonn incident is an outlier or indicative of a larger problem, we do not know as other instances have not come to public attention.

I argue that the amendment at s.10(2)(c) requiring screening and testing of the ‘obtained’ ova ‘donated’ by a woman and used in her surrogate pregnancy means that she can be viewed as both ova donor and surrogate. When she is considered to be a ‘donor’ but not viewed by the clinic as a ‘patient’, the door remains wide open for mistakes such as the one encountered by Ms Chonn.

CONCLUSION


161 See Human Fertilization and Embryology Authority. 2017. State of the fertility sector: 2016-17. www.hfea.gov.uk Figure 5: Noncompliance found on inspection at 17. The report reveals that even in a heavily regulated jurisdiction failure to obtain consent is not a non-trivial problem.
“The evil must be real and the apprehension of harm must be reasonable”

When the harm test established by the SCC in Ref re AHR to the situation of a traditional surrogate using her own ‘obtained’ ovum in her surrogate pregnancy is applied, this paper’s findings demonstrate that one encounters considerable difficulty in isolating specific health and safety risks capable of meriting criminal code sanctions being applied to the persons who would use an unscreened and untested ovum obtained from woman and used in her surrogate pregnancy. The paper can identify no health and safety risk posed by an unscreened and untested traditional surrogate’s obtained ovum to the woman herself, the IVF Clinic, its staff, or to stored human reproductive materials and embryos obtained from other patients.

A stronger argument can be found in the benefits to children born of a traditional surrogacy particularly if screening and testing could be applied to pin point the presence or absence of inheritable genetic diseases. But as beneficent as genetic testing and the collection of donor health and medical history information may be, the 2012 amendment at 10(2)(c) will apply to an extremely small subset of traditional surrogate-born children. Yet without the commensurate requirement to maintain a donor registry, failure to screen and test becomes rather a hypothetical harm leading one to ask why genetic and health information is to be collected when traditional surrogate ova are ‘obtained’ via IVF treatment but not when traditional surrogacy occurs as a result of assisted insemination, which is by far the more common practice.

It is important to recall the following summary of the remit of the AHRA as stated by the government when it announced its intentions to bring this section of the AHRA into force: “The Act protects individuals in Canada by setting out prohibited activities related to assisted human
reproduction that may pose significant human health and safety risks or that have been deemed to be ethically unacceptable or incompatible with Canadian values.”

The practice of commercial surrogacy is a prohibited activity as it has been deemed to morally unacceptable and incompatible with Canadian values. An unscreened and tested ovum obtained from a woman and used in her surrogate pregnancy now falls into the category of prohibited activities on the basis of its risk to health and safety. Yet as this paper demonstrates, the ‘health and safety’ test as laid out by the Supreme Court in Ref re AHRA cannot be sustained. What then is the ‘evil’ the government sought to address when it amended the AHRA?

I argue that traditional surrogacy is the ‘moral evil’ that the government wished to regulate under the guise of a ‘health and safety evil’ when it imposed mandatory screening and testing of ova obtained from a donor and used in her surrogate pregnancy. Subsection 10(2)(c) functions as a backdoor means of marginalizing and discouraging the practice of traditional surrogacy enabled by assisted reproductive methods. Requiring that ova obtained from traditional surrogates be treated like other third-party ova discourages the practice, as not all clinics have the expertise or willingness to follow the procedures required to test and screen. This was the situation when the federal semen regulations were adopted in 1996 though some may argue that the testing and screen lite approach set for Designated Reproductive Donors in the 2017 CAN Standard will decrease the burden on IVF clinics.

More troubling is the potential for confusion and mixing of roles of third-party donor, own use and traditional surrogacy that will be created. For example, clinics practices guidelines need to

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be in place that traditional surrogates retain the ability to exercise control over ‘obtained’ ova. The Section 8 (Consent) Regulations need to be significantly robust to ensure that the act of ‘obtaining’ her ova will not infer with her right to determine who can use it for reproductive, training and research purposes. In part, a major source of potential confusion rests with the slipperiness and breadth of the AHRA definition of ‘donor.’ Additional murkiness is created by the 2017 CAN/CSA Standard definition of ‘donor’ which when applied at face value would logically imply that as the ova is being received by the person from which it originated, a traditional surrogate is not a Designated Reproductive Donor. However, once the traditional surrogate’s ova are reimagined to be a third-party ‘donated’ ova, then screening and testing protocols might then apply.

Some may argue that while the traditional surrogate will be the recipient of an embryo comprised of her ovum and sperm donated by the intended father (or some other third-party), she is not the fertility patient as this term had been reserved by the IVF industry the intended parents as they are ones experiencing infertility.\(^\text{163}\) Again we have a difference of usage as the Ontario Fertility program refers to surrogates in receipt of IVF and assisted insemination services as ‘patients’ though as the Ms Chonn incident reveals this may not be the view shared by IVF clinics.

The attempt by amendment to criminalise yet another aspect of surrogacy, in this case those who would facilitate the practice of IVF with traditional surrogates harkens back to the 1993 Baird

Commission, which stated that “surrogacy of any sort is exploitative and unacceptable.”

By recommending prohibition of surrogacy, the Baird Commission sought “to prevent psychological harm to the surrogate who may bond with her unborn child and to save women from the ‘evil’ of surrogacy.” The 2004 Brown Commission Report, Building Families, written in response to proposed 2004 AHR legislation, continued to promote the view that: “Non-commercial (altruistic) surrogacy arrangements can also be socially harmful for the resulting child and place the health of women at risk.” Although the Commissioners agreed with the proposed of prohibition of surrogacy for commercial gain, they stated that “surrogacy for non-commercial reasons should be discouraged but not criminalized.”

The amended 2012 AHRA at section 10(2)(c) seeks to do both. A health and safety argument is advanced to justify a legal reimagining of traditional surrogate’s body. Her ovum once obtained is transformed into a third-party gamete implying that its use will be determined by the intended parents.

The AHRA uses criminal law powers to make it illegal for ‘obtained’ traditional surrogate ova to be used by the surrogate in her pregnancy unless it is screened and tested. The implication of this amendment is that if the ovum is to be used in her surrogate pregnancy she will also need to relinquish control over its use for it becomes transformed through screening and testing into a third-party gamete created for the use of the intended parents. Her sphere of consent will now

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164 Royal Commission on New Reproductive Technologies "Proceed with Care". (Ottawa: Queen’s Printer, 1993) Annex part-9, at 1115.
165 Ibid.at 1115.
167 Supra note 12, Brown at 12.
reside with agreeing to a transfer of an embryo containing an ovum to which she retains genetic affinity but over which she can now exercise only limited control.

The rationale for mandating criminal code powers requiring screening and testing of a traditional surrogate’s ovum is based on a non-existent health and safety concern. The real “evil” in this arrangement is not one of health and safety but that of the use of criminal law powers to restrict autonomy in the practice of traditional surrogacy—a legally permissible practice when conducted altruistically. Once traditional surrogacy adopts reproductive technology practices enabling the removal of ovum from the body of the traditional surrogate, the frameworks of patient (intended parents), treatment options (surrogacy) and spare part provide (traditional surrogate as ova donor) take precedence. An analogy to this situation can found in a recent American anti-abortion legislation, Texas HB2, which was proposed as a patient health and safety protection measure, but which would have seriously transformed the ability of women to access abortion services had it been approved.

Canada’s assisted human reproduction legislation is deeply flawed. Piecemeal amendments and regulatory tinkering serve to further confuse Canada’s fertility laws. Full-scale legislative renewal is required. Indeed had the section of the AHRA requiring parliamentary review of the Act (s.54) not been removed as part of the legislative housecleaning undertaken as part of the 2012 AHRA amendments, one should have already been conducted.

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168 AHRA s.5.
I argue that the federal government cannot apply a health and safety justification to support criminal code penalties for failure to screen and test ovum obtained from a woman and used in her surrogate pregnancy for it fails to meet the test set out by the SCC. More dangerous however are the underlying implications for consent and reproductive autonomy of a traditional surrogate undergoing IVF treatments. Failure to tackle these matters is the ‘evil’ that needs to be addressed.