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Dr. Mark C. McLeod Ph.D. J.D.
Research Associate
NTE: Impact Ethics
Dalhousie University, Halifax, Nova Scotia
E-mail: marcus_c_mcleod@hotmail.com

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VIA EMAIL ONLY

Office of Policy and International Collaboration
Biologics and Genetic Therapies Directorate
Address Locator 0601B, Tunney's Pasture
100 Eglantine Driveway, Ottawa, Ontario
K1A 0K9
Tel: 613-957-2991
Fax: 613-952-5364
Email: bgtd_ahr-dpbtg_pa@hc-sc.gc.ca
Online: https://www.canada.ca/en/health-canada/programs/consultation-assisted-human-reproduction.html

Dear Ms. Ginette Petitpas Taylor,

Re: Submission - Toward a Strengthened Assisted Human Reproduction Act: A Consultation with Canadians on Key Policy Proposals

Please accept my submission with respect to the consultation document — Toward a Strengthened Assisted Human Reproduction Act: A Consultation with Canadians on Key Policy Proposals under the *Assisted Human Reproduction Act.*

If you require further information please contact me as provided.

Sincerely,

Mark C McLeod

Dr. Mark C. McLeod Ph.D. J.D.

SUBMISSION TO THE GOVERNMENT OF CANADA WITH RESPECT TO THE CONSULTATION DOCUMENT REGARDING THE *ASSISTED HUMAN REPRODUCTION ACT*

Dr. Mark C. McLeod Ph.D. J.D.

Dr. Mark C. McLeod is a Research Associate with NTE: Impact Ethics, Dalhousie University, Halifax, Nova Scotia.

NTE: Impact Ethics is an interdisciplinary research team that does research at the intersection of health, bioethics, and public policy. NTE: Impact Ethics advocates for revisions to healthcare guidelines, policies, and laws at the local, national, and international levels. One of our primary aims is to make institutions more responsive, accountable, and just by advocating for public accountability of public officials and institutions.

Dr. McLeod previously worked as a policy analyst at the Assisted Human Reproduction Implementation Office (AHRIO) of Health Canada. Dr. McLeod *developed and identified policy-related issues concerning assisted human reproduction and other related biological sciences* under the *Assisted Human Reproduction Act.* Dr. McLeod is also a Barrister and Solicitor.

1. INTRODUCTION

The Government of Canada has released a consultation document entitled, "**Toward a Strengthened Assisted Human Reproduction Act: A Consultation with Canadians on Key Policy Proposals"**, which indicates plans to enact regulations under the *Assisted Human Reproduction Act* (hereinafter referred to as the 'AHR Act').

2. PROCESS FOR REIMBURSEMENT AND RECEIPTS

Subsection 12(1) of the AHR Act restricts the reimbursement of expenditures directly related to assisted human reproduction (hereinafter referred to as 'AHR') except in accordance with the regulations, explicitly stating:

> "[n]o person shall, *except in accordance with the regulations* … reimburse a donor for an expenditure incurred in the course of donating sperm or an ovum; … reimburse any person for an expenditure incurred in the maintenance or transport of an in vitro embryo; or reimburse a surrogate mother for an expenditure incurred by her in relation to her surrogacy." [1] [*Emphasis Added*]

Subsection 12(2) of the AHR Act addresses the issue of incentivisation and requires that all reimbursements of expenditures under ss. 12(1) are receipted, whereby "[n]o person shall *reimburse* an expenditure … unless a *receipt* is provided to that person for the expenditure.[2] [*Emphasis Added*]

The Supreme Court has upheld this stating that "section [12] also *prohibits reimbursement for expenditures without receipts*[.]"[3] [*Emphasis Added*] Therefore, where a woman, man, couple, surrogate, AHR clinic or storage facility cannot provide a receipt related to AHR, the

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1 See, e.g., *Assisted Human Reproduction Act*, S.C. 2004, c.2. Section 12(1); *Reference re Assisted Human Reproduction Act* 2010 SCC 61, [2010] 3 S.C.R. 457 at [110].

2 See, e.g., *Assisted Human Reproduction Act*, S.C. 2004, c.2. Section 12(2); *Reference re Assisted Human Reproduction Act* 2010 SCC 61, [2010] 3 S.C.R. 457 at [110].

3 *Reference re Assisted Human Reproduction Act* 2010 SCC 61, [2010] 3 S.C.R. 457 at [110].

reimbursement of expenditures is explicitly prohibited.

The consultation document states that under the proposed Process for Reimbursement, a person will only be allowed to reimburse another person for an expenditure incurred as a result of their donation or surrogacy if the following documents are obtained:

- A declaration dated and signed by the person who requests reimbursement (i.e. the donor, the surrogate, or the person who maintained or transported an in vitro embryo);

- The receipt for each expenditure for which reimbursement is sought; and,

- If applicable, the written recommendation from a qualified medical practitioner.

2.1 REIMBURSEMENT OF EXPENDITURE VERSUS EXPENSES

The consultation document repeatedly interchanges between use of the words "expenditure" and "expenses". Importantly, the AHR Act does not use the language of "expenses". Any future consultation documents, policy proposals or resultant regulations should only use the language of "expenditure" to be consistent with the AHR Act.

2.2 EXECUTED DECLARATION

A declaration dated and signed by the person who requests reimbursement is not currently required under the AHR Act.

I submit Health Canada developing a verifiable process by which reimbursement of expenditures may be made, including a declaration, is prudent.

In order to facilitate compliance enforcement activities and to provide clarity and structure to the reimbursement process, it is submitted that the proposed regulations should require that a copy of the aforesaid executed declaration be provided to Health Canada, which describes

the parties to the reimbursement, details the matter being reimbursed, and includes the date of reimbursement, method of payment, and amount reimbursed (including taxes, discounts, credits and other adjustments). Furthermore, the contact information of any associated third party (i.e., vendor) associated with the receipt must be provided. The provision of a copy of the executed declaration to Health Canada may allow the development of a de-facto AHR information registry in order to aid future potential audits by an oversight body and also provide valuable information regarding AHR in Canada.

2.3 RECEIPTS, REIMBURSEMENT AND REASONABLE TIME

It is submitted that the proposed Process for Reimbursement should also consider a requirement for reimbursement of expenditures to be made payable within a reasonable period of time upon provision of a receipt in order to minimize concerns regarding the exploitation of vulnerable women. A reasonable period of time may be no later than 30 days after receipts have been submitted for reimbursement.

A surrogate should also receive reimbursement for expenditures payable within a reasonable period of time upon provision of a receipt, irrespective of whether a child is born. A surrogate may miscarriage, or a decision may be made to terminate the pregnancy. Nonetheless, the surrogate should still be entitled to reimbursement for expenditures.

2.4 QUALIFIED MEDICAL PRACTITIONER

The consultation document also states that under the proposed Process for Reimbursement, a person will only be allowed to reimburse another person for an expenditure, if applicable, upon the "**written recommendation** from a qualified medical practitioner". This proposal relates to provisions such as subsection 12(3) of the AHR Act, whereby

> "[n]o person shall reimburse a surrogate mother for a loss of work-related income incurred during her pregnancy, unless … a qualified medical practitioner *certifies* … that continuing to work may pose a risk to her health or that of the embryo or foetus,

and … the reimbursement is made in accordance with the regulations."[4] [*Emphasis added*]

Subsection 12(3) of the AHR Act presumes that the surrogate is employed at the time that she begins her service as a surrogate.

It is submitted that the text of this proposal be amended from a "**written recommendation** from a qualified medical practitioner" to "**deemed necessary by a legally** qualified medical practitioner". Although to some observers there may be no sharp distinction in common speech between "written recommendation" and "deemed necessary" (or similar language), the difference between the two lies on the priority, reason and will. "Written recommendations" are not bound by a timeframe and are utilitarian in nature. In sharp contrast, "deemed necessary" is a formal need that is framed by time, beyond which there may be negative consequences for the woman, man, couple or surrogate. For example, in the case of subsection 12(3) of the AHR Act, a legally qualified medical practitioner may deem it necessary for a surrogate mother to cease work due to a medical condition. The negative consequence is that continuing to work may pose a risk to her health or that of the developing embryo or foetus. In contrast, a written recommendation implies concern for the well-being of the surrogate mother, but not amounting to a risk to her health or that of the developing embryo or foetus.

I submit that a surrogate in consultation with a legally qualified medical practitioner should determine what constitutes a risk to her health or that of the developing embryo or foetus. As such, the proposed Process for Reimbursement should not be overly restrictive. There are many life situations during surrogacy that may require medical assistance, including, but not limited to, hyperemesis gravidarum (i.e., extreme morning sickness). I submit that as long as the loss of work-related income incurred during her pregnancy is directly related to the risk, and a legally qualified medical practitioner has deemed it necessary for the surrogate to

[4] See, e.g., *Assisted Human Reproduction Act*, S.C. 2004, c.2. Section 12(3). "No person shall reimburse a surrogate mother for a loss of work-related income incurred during her pregnancy, unless (a) a qualified medical practitioner certifies, in writing, that continuing to work may pose a risk to her health or that of the embryo or foetus; and (b) the reimbursement is made in accordance with the regulations."; *Reference re Assisted Human Reproduction Act* 2010 SCC 61, [2010] 3 S.C.R. 457 at para 110 and 112.

have time off work, then reimbursement should be allowed when not covered by an employment contract (e.g., sick leave benefits). As well, there may be legitimate health reasons for time off work after childbirth, such as postpartum (sometimes called postnatal) depression. More about this below.

3. EMPLOYMENT INSURANCE MATERNITY BENEFITS

Employment Insurance maternity benefits may be offered to surrogates who cannot work because they are pregnant or have recently given birth.

I submit that the proposed regulations may allow surrogates to receive additional reimbursement for loss of work-related income from the intended parent(s) above and beyond the Employment Insurance maternity benefit, if said benefit is less than the average weekly wage of the surrogate, in order to negate the surrogate subsidizing the costs of the surrogacy.

The additional reimbursement would still be consistent with the altruistic motivation of surrogacy as the surrogate is not being compensated and there is no fee or profit.

4. REIMBURSEMENT FOR LOSS OF WORK-RELATED INCOME FOR AN OVA DONOR

Subsection 12(3)(a) of the AHR Act allows for reimbursement for loss of work-related income by a surrogate mother, by which

> "[n]o person shall reimburse a *surrogate mother* for a loss of *work-related income* incurred *during* her pregnancy, unless ... a qualified medical practitioner certifies, in writing, that continuing to work may pose a risk to her health or that of the embryo or foetus …"[5] [*Emphasis Added*]

Moreover, said reimbursement for loss of work-related income is time limited to only the

[5] See, e.g., *Assisted Human Reproduction Act*, S.C. 2004, c.2. Section 12(3); *Reference re Assisted Human Reproduction Act* 2010 SCC 61, [2010] 3 S.C.R. 457 at [110].

duration of the pregnancy of the surrogate mother. Therefore, upon a literal interpretation of this provision, payments related to *post pregnancy* work-related income do not constitute a reimbursement under s. 12(3)(a) of the AHR Act and are therefore prohibited. This is problematic insofar as this fails to recognize loss of work-related income after childbirth that is the direct result of the surrogacy.

As s. 12(3)(a) of the AHR Act makes explicit reference to a "surrogate mother", an ova donor engaging in an altruistic medical intervention is not entitled to loss of work-related income and yet, ova donors are at risk of loss of work-related income. Ova donors are required to attend multiple medical appointments prior to donation. These appointments are associated with initial screening, interviews with clinical coordinators and physicians, as well as testing and assessment of general health matters. Thereafter, ova donors may have to undergo suppression of their natural cycle to synchronize their cycle with the recipient, as well as undergo daily injections of gonadotropin to stimulate the ovaries. Subsequently, oocyte maturation and / or oocyte release is induced with an injection of human chorionic gonadotropin (hCG) hormone prior to an ova donor attending an AHR clinic for a retrieval procedure(s) under I.V. sedation. Ova donors may also return to the AHR clinic for a post-retrieval checkup.

During this process, there is a risk that ova donors may suffer from the iatrogenic complication called ovarian hyperstimulation syndrome, which can be mild, moderate or severe and can lead to serious illness or death. It has been associated with symptoms including, but not limited to, abdominal pain, nausea and vomiting, ascites and tense distention, localized or generalized peritonitis, acute abdominal pain, hypercoagulable states and acute renal failure. Ova donors suffering from ovarian hyperstimulation syndrome may require acute or long term medical care.

It is submitted that due to the multiple medical appointments required as part of the donation process leading up to the egg retrieval procedure(s), as well as the possible need to undergo acute or long term medical care due to ovarian hyperstimulation syndrome, ova donors may be required to take time off work. It is submitted that the AHR Act and proposed regulations should expressly allow an ova donor to be reimbursed for loss of work-related income incurred

due to medical appointments, treatment and retrieval procedure(s).

It is submitted that Health Canada should engage ova donors to receive feedback on the issue of loss of work-related income.[6]

5. INDEPENDENT LEGAL ADVICE FOR DONORS AND SURROGATES

The consultation document states:

> "[o]nly expenditures *incurred in the course of* sperm or ova donation … or, for surrogates, *in the relation to* the surrogacy, including the loss of work-related income for surrogates, may be reimbursed." [*Emphasis Added*]

It is common practice for AHR clinics to advise and / or require sperm donors, ova donors and surrogates to seek independent legal advice either before or during donation and medical treatment. This is especially so when donors are identifiable.

It is submitted that the proposed regulations also allow independent legal advice to be a category of expenditure that should be eligible for reimbursement beyond the retrieval of gametes or birth of a child, so that these parties may know their rights and obligations under the law.

I submit it is reasonable to anticipate donors and surrogates may require independent legal advice beyond the retrieval of gametes or birth of a child. It is also reasonable to interpret independent legal advice beyond the retrieval of gametes or birth of a child as being "incurred in the course of" donation or "in the relation to" the surrogacy, respectively.

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[6] The Globe and Mail, *The gift of life* (2015) https://beta.theglobeandmail.com/life/health-and-fitness/health/the-gift-of-life-four-donors-share-theirstories/article27386143/?ref=http://www.theglobeandmail.com& at 8 September 2017. "The recovery was harder than I imagined. I didn't know what I was in for. For about a week after the retrieval, I was extremely bloated. I don't doubt I was mildly overstimulated – they retrieved more than 40 eggs. I did the donation in Toronto, then came back to Ottawa and there was no hand-off to another doctor. *Because my job requires me to be physically active, I had to take about five days off work, until my energy felt back to normal and the bloating subsided. I'm self-employed, so I don't do that lightly*." [*Emphasis Added*]

6. CRYOPRESERVATION AND STORAGE FEES

It is submitted that all expenditures incurred in the maintenance or transport of an *in vitro* embryo should be eligible for reimbursement, including storage, preparing the *in vitro* embryo for transport, the shipping container, preparing the container for transport and for transporting the *in vitro* embryo.

However, and in addition, it is submitted that all expenditures incurred in the maintenance or transport of sperm, ova and human reproductive material may also be a category of eligible reimbursement, which is fact dependent, to the extent that such expenditures are not covered by a Federal or Provincial fertility plan or an insurer and not in contravention of the AHR Act.

There are unknown fact scenarios in life. For example, a man may cryopreserve and store sperm prior to cancer treatment. He may thereafter use said sperm for his own reproductive purposes, but have supernumerary vials in storage after completing AHR treatment. During this time he would have been required to pay a storage fee to an AHR clinic or sperm bank. The AHR Act allows AHR clinics and sperm banks to charge a fee for their services, which may include storage, maintenance or transport. He may then desire to donate said supernumerary vials via a directed donation to a recipient. Consequently, and during this transition period between past AHR treatment and donation, he may have out-of-pocket expenditures directly related to the donation, namely, ongoing storage fees.

Although the AHR Act prohibits payment of ova and sperm donors as their donation must be altruistic, reimbursing out-of-pocket expenditures directly related to the supernumerary vials would not be in contravention of the AHR Act. This fact scenario may also apply with respect to ova and other human reproductive material.

7. CONCLUSION

I appreciate Health Canada allowing the public an opportunity to comment on the consultation document. However, although this form of public consultation is effective for an individual of my professional background (i.e., a legal practitioner and academic in the field of AHR), all

key stakeholders must be engaged in this process. I submit that Health Canada must facilitate participation of all key stakeholders, including gamete donors and surrogates. Moreover, Health Canada should engage in alternate consultation strategies for providing feedback such as discussion groups, roundtables and public forums. This would ensure a robust consultation process.

Sincerely,

Dr. Mark C. McLeod Ph.D. J.D.