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VIA EMAIL ONLY

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Dear Minister Philpott,

Re: Submission - *Notice to interested parties — Intent to develop regulations under the Assisted Human Reproduction Act*

Please accept my submission with respect to the *Notice to interested parties — Intent to develop regulations under the Assisted Human Reproduction Act* that was published on October 1, 2016.

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 REGULATIONS UNDER THE *ASSISTED HUMAN REPRODUCTION ACT*

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

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NTE: Impact Ethics are an interdisciplinary research team that does research at the intersection of health, bioethics, and public policy. NTE: Impact Ethics advocate 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 (AHRA)*. Dr. McLeod is also a Barrister and Solicitor.

1. INTRODUCTION

The CSA Group, who are a third party for-profit organization that “deals with standards development”,¹ have recently published an “informative” Annex entitled “Reimbursement of expenses for donors and surrogates” (hereinafter the ‘CSA Group standards’). Concurrently, the Government of Canada have released a statement indicating plans to enact regulations related to reimbursement of expenses under the *Assisted Human Reproduction Act* (hereinafter the ‘AHRA’).²

Many scholars and social advocacy groups’ suspect that the Government of Canada will enact regulations related to reimbursement of expenses under the AHRA by incorporation by reference of the CSA Group standards.

This concise submission to the Government of Canada will endeavour to address selected apprehensions this author has with respect to incorporation by reference in the development of regulations under the AHRA. This submission contains two sections that address (1) deficiencies in the process of regulatory development, and (2) erroneous content in the CSA Group standards.

2. DEFICIENCIES IN THE PROCESS OF REGULATORY DEVELOPMENT

There are many deficiencies with respect to the process of regulatory development as it relates to incorporation by reference. For example, Liberal MP, Mr. Kevin Lamoureux, expressed lack of support on behalf of the Liberal Party about the use of incorporation by reference in regulations, stating “[t]he Liberal Party has a great deal of concern [and] ... we are not in a position to support the bill [related to incorporation by reference] ... We should ensure there is that parliamentary oversight.”³

¹ CSA Group (2016) <<http://www.csagroup.org/>> at 3 November 2016.

² See, eg, CSA Group, *CAN/CSA-Z900.2.1-12 - Tissues for assisted reproduction* (2016) <<http://shop.csa.ca/en/canada/transplantation/canca-z90021-12/inv/27017722012>> at 25 October 2016; Government of Canada, *Government of Canada plans to introduce regulations to support the Assisted Human Reproduction Act* (2016) <<http://news.gc.ca/web/article-en.do?nid=1131339>> at 8 November 2016.

³ *Bill S-2 (Historical), Incorporation by Reference in Regulations Act* (2015) <<https://openparliament.ca/bills/41-2/S-2/?singlepage=1>> at 8 November 2016. “The Liberal Party has a great deal of concern with regard to Bill S-2. Overall, we are not in a position to support the bill, because we have a number of concerns ... It is important at the get-go to recognize that incorporation by reference enables the federal government or agencies to give legal effect to

2.1 INSUFFICIENT CRITERIA MET FOR INCORPORATION BY REFERENCE

The Government of Canada should utilize incorporation by reference sparingly and only where *essential, necessary and appropriate for purpose*.⁴ As a general principle, incorporation by reference should only be used in a limited number of cases where it is *impracticable to do otherwise*.⁵

It is appropriate to incorporate a document by reference when (1) the incorporated document is *extensive or technically complex* and *affects few persons*, or (2) the incorporated document has been made by agreement between foreign governments with respect to policy that has been approved by Parliament, or (3) the incorporated document has been developed for use in respect of manufactured products, or (4) it is *appropriate* for the incorporated document to be drafted by a specialist agency or third party private sector organisation, rather than by Parliament.⁶

The proposed *Regulations* are (1) not *extensive or technically complex*. The proposed regulations address only a single provision of the *AHRA*, namely, s. 12. Moreover, the CSA Group standards contain only four (4) clauses (i.e., A.1-A.4), which are simply not of the same magnitude as other extensive regulations such as the *Food and Drug Regulations*.⁷

material that has been published elsewhere. We should all be concerned about that. We have talked a great deal within the Liberal caucus and we have shared some different ideas and thoughts in two-way communications with Canadians. Time and time again, and in fact earlier this week, we talked about how Ottawa is broken and how we do not see the type of progress that is important. This is one of the pieces of legislation that I would use to cite that...That is a concern that we should all have. It is something that has caused the Liberal caucus and the *Liberal Party to express our concern, and it is the reason we will not be supporting Bill S-2*...The current government, as I cited, cannot be trusted to use this power responsibly. We have seen that time and time again. Its willingness to abuse oversight mechanisms..." [Emphasis Added]

⁴ New Zealand House of Representative, *Inquiry into material incorporated by reference*, Report of the Regulations Review Committee, Forty-seventh Parliament, (Richard Worth, Chairperson) July 2004 (2004) <https://www.parliament.nz/resource/en-nz/47DBSCH_SCR2794_1/fa349b1c81f369bef6395cf6bcdcd0e4e211a2ec> at 17 November 2016.

⁵ Ibid.

⁶ Ibid.

⁷ *Food and Drug Regulations* C.R.C., c. 870, B.01.045 A food additive shall ... (b) where no specifications are set out in this Part for that additive but specifications are set out for it in the *Food Chemicals Codex*, Fourth Edition, 1996, published by the National Academy of Sciences, Washington, D.C., United States, as amended from time to time, meet those specifications.

The criteria to incorporate a document by reference also cannot be satisfied by the other benchmarks as the proposed regulations have (2) not been made by agreement between foreign governments and (3) it does not involve manufactured products.

It is (4) *not appropriate* for a private sector for-profit organisation to draft a reference document that has serious criminal law consequence for donors, surrogates, fertility clinics and other interested parties.⁸ Health Canada working in consultation with the Department of Justice have extensive expertise and experience at the intersection of health policy and law respectively as it relates to the *AHRA*. For example only, the Assisted Human Reproduction Implementation Office of Health Canada have developed policy documents related to numerous facets of the *AHRA* prior to and following the Supreme Court case of *Reference re Assisted Human Reproduction Act*,⁹ including the *Consent Regulations*. Institutionalized exhaustion at Health Canada is not a justification for delegating their responsibility. In this case, it is *not appropriate* for any third party other than the Minister of Health to develop, consult and promulgate regulations under the *AHRA*.

2.2 INCONSISTENT WITH THE HEALTH CANADA MANDATE LETTER

The possible process of regulatory development utilizing incorporation by reference significantly deviates from the decree of the Mandate Letter that was promulgated by Prime Minister Justin Trudeau, the principles of the *AHRA*,¹⁰ as well as normative frameworks for developing regulations in this country; all to the detriment of donors, surrogates, fertility clinics and other interested parties.

The CSA Group standards may not be informed by extensive public consultation and the best evidence from “professional, non-partisan ... *public servants*”¹¹ [*Emphasis Added*] as

⁸ See, eg, Dalhousie University, *R v. Picard and Canadian Fertility Consulting Ltd* (2016) <https://www.dal.ca/content/dam/dalhousie/pdf/sites/noveltechethics/AHRA_Facts.pdf> at 2 November 2016; thestar.com, *Canada's vague surrogacy laws may be doing more harm than good* (2016) <<https://www.thestar.com/news/canada/2016/09/18/canadas-vague-surrogacy-laws-may-be-doing-more-harm-than-good.html>> at 2 November 2016.

⁹ 2010 SCC 61, [2010] 3 S.C.R. 457.

¹⁰ *Assisted Human Reproduction Act*, S.C. 2004, c.2. Section 2.

¹¹ Justin Trudeau, Prime Minister of Canada, *Minister of Health Mandate Letter* (2016) <<http://pm.gc.ca/eng/minister-health-mandate-letter>> at 22 October 2016 at [17]. “Our ability, as a government, to successfully implement our platform depends on our ability to thoughtfully consider the professional, non-partisan advice of public

well as stakeholders including donors, surrogates, fertility clinics, legal experts, bioethicists, fellow Canadians and the Provinces.¹² Furthermore, by possibly recoiling in its responsibility and bestowing Health Canada's obligation to the CSA Group, the Government of Canada are failing to "*direct [any] resources* to those initiatives that [should have] the greatest, positive impact on the lives of Canadians, and that will allow [the Government of Canada] to meet [their] commitments to [Canadians]."¹³ [*Emphasis Added*] The governments' edict under the Mandate Letter and its suspected way forward on this matter are in direct contradiction.

By possibly incorporating by reference, the Government of Canada will not only fail to "be an essential partner in improving outcomes and quality of care for Canadians[,]"¹⁴ but will not work "through *established legislative, regulatory, and Cabinet processes* to deliver on [this] top [priority]."¹⁵ [*Emphasis Added*] This potential process does not meet the highest ethical standards and Canadians' well-founded expectations of our government.¹⁶

2.3 TRANSPARENCY AND ACCOUNTABILITY TO THE CANADIAN PUBLIC

There are significant pitfalls of collaborative governance utilizing incorporation by reference and the Canadian public should all be concerned about this legal mechanism.¹⁷ Subsection 65(2) of the *AHRA* allows both static incorporation and ambulatory incorporation. This legal mechanism allows the Government of Canada to delegate responsibility and avoid both developing and updating a regulation as the reference

servants. Each and every time a government employee comes to work, they do so in service to Canada, with a goal of improving our country and the lives of all Canadians." [*Emphasis Added*]

¹² Ibid, at [6]. "I expect that our work will be informed by performance measurement, *evidence, and feedback from Canadians*." [*Emphasis Added*]

¹³ Ibid "If we are to tackle the real challenges we face as a country – from a struggling middle class to the threat of climate change – *Canadians need to have faith in their government's honesty and willingness to listen*. I expect that our work will be informed by performance measurement, *evidence, and feedback from Canadians*. We will *direct our resources to those initiatives that are having the greatest, positive impact on the lives of Canadians, and that will allow us to meet our commitments to them*." [*Emphasis Added*]

¹⁴ Ibid, at [13]. "The federal government must be an *essential partner in improving outcomes and quality of care for Canadians*." [*Emphasis Added*]

¹⁵ Ibid, at [14]. "[I] will expect you to work with your colleagues and through *established legislative, regulatory, and Cabinet processes* to deliver on your top priorities ..." [*Emphasis Added*]

¹⁶ Ibid, at [19]. "When dealing with our Cabinet colleagues, Parliament, stakeholders, or the public, *it is important that your behaviour and decisions meet Canadians' well-founded expectations of our government*." [*Emphasis Added*]

¹⁷ Bill S-2, above n 3. As per Kevin Lamoureux, Winnipeg North, MB. "It is important at the get-go to recognize that incorporation by reference enables the federal government or agencies to give legal effect to material that has been published elsewhere. We should all be concerned about that."

document is revised by a third party. This raises significant issues related to (1) parliamentary control over delegated lawmaking, (2) accessibility to Canadian law, (3) participation in agency procedures such as notice and comment, (4) ineffectual policy, (5) judicial review, (6) popular sovereignty, (7) constitutionality, as well as (8) allowing a non-elected body who is not directly and democratically accountable to the Canadian public, as are Members of Parliament, to draft laws that citizenry have to abide by.¹⁸

2.4 LACK OF EXPERTISE

The failure to identify the authors of the CSA Group standards, which are currently confidential, is diametrically opposed to the principle that transparency promotes accountability. The CSA Group have only stated that the CSA Group standards “[were] prepared by a Task Force ...”¹⁹ Stakeholders do not know the identity or qualifications of the “experts” who were part of the Task Force and their knowledge of the legal, ethical and medical issues related to assisted human reproduction, or whether donors, surrogates, fertility clinics or other interested parties were even empanelled. Consequently the Task Force may be overly dependent on or disproportionately receive information from a narrow category of stakeholders.²⁰ At worst, donors, surrogates or fertility clinics may be unrepresented and decision making closed during this pre-notice period.²¹ The legitimacy of the Task Force must therefore be questioned, especially if a donor, surrogate and a fertility clinic, at a bare minimum, were not members.

As the “expert” Task Force do not describe the underlying policy supporting the CSA Group standards, it could be argued that the clauses, which in some case are effusive and bordering on incentivisation (i.e., clauses 3.2.1; 3.4; 3.5.1), were drafted under a partially closed process that lacked context and support. In fact, there is no obligation for the CSA Group to disclose the policy underlying their standards to the public.²² This directly

¹⁸ Nelson, E.L., Comparative Perspectives on the Regulation of Assisted Reproductive Technologies in the United Kingdom and Canada (2006) 43:4 *Alberta Law Review* 1023, 1033; Mendelson, N.A., "Private Control over Access to Public Law: The Perplexing Federal Regulatory Use of Private Standards." (2014) Mich. L. Rev. 112, no. 5. 737, 747.

¹⁹ CSA Group, above n 2.

²⁰ Mendelson, above n 18, 779.

²¹ Ibid 759.

²² Ibid 760.

contrasts the Parliamentary process of rule-making, particularly the development of policy with its underlying basis and purpose.

2.5 ACCESS TO THE LAW

The fundamental concept of an orderly society is that the public has a duty to act in accordance with the law. If the Canadian public have a duty to obey the law, they must know the content of the law.²³ “Rudimentary justice requires that those subject to the law must have the means of knowing what it prescribes.”²⁴ Therefore, the law must be published for public scrutiny, be accessible and must leave in no doubt to donors, surrogates, fertility clinics and other interested parties their rights and obligations. Barriers to accessibility diminish meaningful assurances that regulations will be reasoned and democratically responsive,²⁵ while also undermining agency procedures, political oversight, public deliberation as well as future voting potential as a means of effective accountability.²⁶

The *Incorporation by Reference in Regulations Act* imposes an obligation on the Minister of Health to ensure that documents incorporated by reference, which may include the CSA Group standards, are accessible.²⁷ Nevertheless, the *Incorporation by Reference in Regulations Act* are silent on the statutory definition of “accessibility”, as well as when accessibility to a reference document during the rule making process should be made to the public.

A further barrier to access is the possibility that not only will the law be fragmented between different texts, but the CSA Group may impose a fee for access to review the CSA Group standards, *future amendments* of the standards and *related documents* (i.e., supporting policy documents that are not published publicly) due to restrictions imposed by third party authors of standards under copyright law. In fact, the CSA Group is under

²³ Ibid 774.

²⁴ Antonin Scalia, Essay, *The Rule of Law as a Law of Rules*, 56 U. Chi. L. Rev. 1175, 1179 (1989).

²⁵ Mendelson, above n 18, 777.

²⁶ See, eg, Mendelson, above n 18, 789; New Zealand House of Representative, above n 4; Green, L., *Law and Obligations* (2002) http://digitalcommons.osgoode.yorku.ca/scholarly_works/119 at 18 November 2016.

²⁷ *Incorporation by Reference in Regulations Act* ss. 18.3 (1) “The regulation-making authority shall ensure that a document, index, rate or number that is incorporated by reference is accessible.”

no obligation to continue to provide the CSA Group standards and future amendments at any price and may revoke this access at will. The related CSA Group document entitled "CAN/CSA-Z900.1-12 - Cells, tissues, and organs for transplantation: General requirements" requires a payment of CAD. \$168. This provides a substantial financial obstacle to public participation that is inconsistent with core democratic values.²⁸ Without purchasing this document (i.e., CAN/CSA-Z900.1-12), donors, surrogates, fertility clinics and other interested parties are unaware whether it contains the policy supporting the CSA Group standards, or whether a policy exists at all. Furthermore, requiring the public to purchase this document undermines open discussion of public affairs and accountability of government power.²⁹

In order to address this issue head on, the prime solution is for the Minister of Health to simply avoid incorporating a document by reference, including the CSA Group standards. Considering the Minister of Health recently stated that she is "convinced that we have an obligation as a government of Canada, for example, to do more than simply open up the federal wallet[,]"³⁰ possibly paying the CSA Group to develop the reference document would appear contradictory.

3. ERRONEOUS CONTENT IN THE DOCUMENT THAT MAY BE INCORPORATED BY REFERENCE

This submission will address erroneous clauses contained in the CSA Group standards. These are succinct examples only, and do not describe the multitude of deficiencies in the CSA Group standards.

3.1 PROHIBITION OF REIMBURSEMENT WITHOUT RECEIPTS

Subsection 12(2) of the *AHRA* addresses the issue of incentivisation and requires that all reimbursements of expenditures under ss. 12(1) are receipted, whereby "[n]o person shall

²⁸ Mendelson, above n 18, 769.

²⁹ Ibid 769.

³⁰ CBC, *Health minister vows to do more than just 'open the federal wallet'* (2016) <<http://www.cbc.ca/news/politics/philpott-health-minister-provinces-funding-accord-1.3780633>> at 18 November 2016.

reimburse an expenditure ... unless a *receipt* is provided to that person for the expenditure.³¹ [*Emphasis Added*] The Supreme Court have upheld this stating that “section [12] also *prohibits reimbursement for expenditures without receipts*[.]”³² [*Emphasis Added*] It is unequivocal and unquestionable. Therefore, where a woman, man, couple, surrogate, fertility clinic or storage facility cannot provide a receipt related to assisted human reproduction, the reimbursement of expenditures are explicitly prohibited.

Nonetheless, clause A.2.2.1 of the CSA Group standards indicates that in order for allowable reimbursements of expenditures to be made a receipt or verifiable claim for each expenditure must be presented in addition to a signed declaration.³³ The term “verifiable” is deliberately ambiguous and may include any documents, other information or “other forms of evidence confirming expenditure” relevant to the claim, other than a receipt. Without a freely published policy document that explains the inclusion of the term “verifiable claim”, we can only speculate to their reasoning on this issue.

The *AHRA* also does not contemplate a verifiable claim and a signed declaration to prove expenditure. The disparity between the CSA Group standards based upon a verifiable claim linked to a signed declaration, and ss. 12(2) of the *AHRA* supported by a legal decree from our highest Court creates an unclear obligation, does not protect the interests of donors, surrogates, fertility clinics and other interested parties, and potentially instructs the Canadian public to break the law. No amount of wordsmithing by the CSA Group can amend the substance of the law as promulgated or ruled upon. A Court may require a higher standard than a verifiable claim with respect to the *AHRA* due to the significant risk of incentivisation and commercialization and hold that it is to be expected that a receipt will be retained as the primary purpose of the regulation is about reimbursement incurred during donation or surrogacy.

³¹ See, eg, *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].

³² *Reference re Assisted Human Reproduction Act* 2010 SCC 61, [2010] 3 S.C.R. 457 at [110].

³³ CSA Group, above n 2. “A.2.2.2. In order for allowable reimbursements of expenditures to be made, the following documentation shall be submitted to the person issuing the reimbursement: (a) a receipt or *verifiable claim* for each expenditure; (b) the relevant certificate from the regulated health care professional, where applicable; and (c) with every claim for reimbursement, a *signed declaration* in accordance with Clause A.2.2.3.” [*Emphasis Added*]

3.2 REIMBURSEMENT FOR LOSS OF WORK-RELATED INCOME

Subsection 12(3)(a) of the *AHRA* 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 ...”³⁴ [*Emphasis Added*] As s. 12(3)(a) of the *AHRA* explicitly states a “surrogate mother”, an ova provider engaging in an altruistic medical intervention is not entitled to loss of work-related income. Moreover, said reimbursement for loss of work-related income is time limited to only the *duration* of the pregnancy of the surrogate mother. Therefore, payments related to *post pregnancy* work-related income do not constitute a reimbursement under s. 12(3)(a) of the *AHRA* and are therefore prohibited.

Nonetheless, clause A.3.2.2 (in conjunction with A.2.1.2) of the CSA Group standards expands the eligible recipients of reimbursement for loss of *work-related income* to include ova donors, whereby an ova “donor may be reimbursed for net loss of work-related income due to being unable to work as a result of her participation in the donation process ...”³⁵ It appears that the CSA Group have taken it upon themselves to include a further eligible recipient group for work-related income, which is not promulgated under the *AHRA*. The CSA Group are wordsmithing the *AHRA* as promulgated such that “reimbursement of expenditures” for an ova donor may also mean “loss of work-related income”. It is simply not plausible. This lax interpretation of the *AHRA* by the CSA Group potentially instructs a person that it is permissible to reimburse an ova donor for loss of work-related income, in contravention of the *AHRA* and the stated principle prohibiting financial incentivisation of reproduction in Canada.

³⁴ See, eg, *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].

³⁵ CSA Group, above n 2. “A.3.2.2. A donor may be reimbursed for net loss of work-related income due to being unable to work as a result of her participation in the donation process if a qualified medical practitioner certifies, in writing, that work might pose a risk to her health and safety.”

3.3 DEFINITION OF A PERSON

Subsection 12(1)(b) of the *AHRA* states that “[n]o person shall, *except in accordance with the regulations* ... reimburse any *person* for an expenditure incurred in the maintenance or transport of an in vitro embryo ...” [*Emphasis Added*] A fertility clinic may be, in some circumstances, responsible for maintenance or transport of an *in vitro* embryo. As the term “person” is not defined under the *AHRA*, the *Interpretation Act*³⁶ may be utilized and defines a person to “... [*include*] a corporation[.]” [*Emphasis Added*] Therefore, an incorporated fertility clinic may be defined as a person that is eligible for reimbursement of receipted expenditure incurred in the maintenance or transport of an *in vitro* embryo.

Nonetheless, clause A.1 of the CSA Group standards state “[c]ategories of potential recipients [of reimbursements] ... include ... *donor* of ova ... *donor* of sperm ... *donor(s)* of in vitro embryos; and ... *person* who acts as a surrogate.”³⁷ The CSA Group standards are silent with respect to fertility clinics being eligible recipients, possibly indicating that fertility clinics should not be reimbursed under any circumstance. Whether regulations will state unequivocally that fertility clinics are an expenditure recipient, or whether it is necessary to state it at all, and what controls will be in place to set limitations on possible fee schedules in order to negate abuse is still to be determined.

4. CONCLUSION

The development of regulations related to reimbursement of expenditures are designed for a narrow group of the Canadian public, are not extensively complicated and the government can afford to absorb the costs to develop these standards within Health Canada. Health Canada do not lack the breadth and depth of expertise as well as the resources needed to draft regulations. Health Canada can develop them internally to ensure the principles stated in the *AHRA* are upheld in order to promote the health, well-being, safety, dignity and rights of Canadians.

³⁶ R.S.C., 1985, c. I-21. The *Interpretation Act* is An Act respecting the interpretation of statutes and regulations.

³⁷ CSA Group, above n 2.