DALHOUSIE UNIVERSITY
Inspiring Minds

Novel Tech Ethics
Faculty of Medicine

Office of Policy and International Collaboration
Biologics and Genetic Therapies Directorate
Address Locator 0601B, Tunney's Pasture,
100 Eglantine Driveway
Ottawa, Ontario K1A 0K9

November 25, 2016

Dear Minister Philpott:

Thank you for this opportunity to comment on the prepublication of regulatory proposals to bring sections 10, 12, and 45 to 58 of the *Assisted Human Reproduction Act* (the Act) into force. I am pleased that the federal government is taking steps to develop much-needed regulations to enable the implementation of the Act, and to provide clarity in the governance of this policy field.

I am writing this submission as an academic researcher whose work focuses explicitly on assisted human reproduction in Canada. I am currently a CIHR Postdoctoral Fellow in the Faculty of Medicine at Dalhousie University and my doctoral research traced the interventions of key stakeholders in the policymaking process leading to the passage of the Act. I have also written extensively and continue to publish on the Act's Section 8 regulations, the experiences of egg donors in Canada, and the challenges of regulation in this field to date at the federal and provincial levels.

While I laud the federal government for moving forward with these regulations, I have several concerns related to the (pre)proposed regulations, as well as the circumstances in which they are being drafted that I would like to draw to your attention. They pertain largely to s.12 of the Act and are grouped into three key issues: 1) public engagement; 2) administration; and 3) reasonable expenses. I have additional concerns related to the development of regulations on s.10 which are briefly described at the end of this letter.

1. *Public engagement*

My first concern addresses the process by which these regulations will be drafted. In the years between the 1993 publication of the report of the Royal Commission on New Reproductive Technologies and 2004, when the Act received Royal Assent, there were no fewer than fifteen consultation exercises—between workshops, discussion groups, focus groups—and none focused on the experiences of gamete donors or surrogates. Only one surrogate ever testified before a Parliamentary committee in the hearings on various iterations of the Act, and no egg or sperm donors were consulted.

Alana Cattapan
CIHR Postdoctoral Fellow
Faculty of Medicine, Dalhousie University
P.O. Box 15000, 1379 Seymour St.
Halifax, Nova Scotia B3H 4R2

Tel: 902.494.2936
Fax: 902.494.2924
Email: alana.cattapan@dal.ca
Web: arcattapan.ca

In 2015, the Canadian Standards Association (CSA) recently developed new standards on the "Reimbursement of expenses for donors and surrogates" (Annex A of CAN/CSA-Z900.2.1-12). As Health Canada requested that the CSA develop these new standards (and participated in the process of their development) it stands to reason that Health Canada will be paying particular attention to the new standards in the drafting of the proposed regulations. It is important to note, then, that the consultation process leading to the new standards did not include gamete donors and surrogates at all. Award-winning journalist Alison Motluk noted this absence, writing in the Canadian Medical Association Journal that, "Not a single surrogate or egg donor—or anyone with first-hand experience of providing reproductive tissue or gestation—was invited to sit on the committee…" further stating that "when asked why [CSA subcommittee Chair Arthur Leader] Leader explained that "these people are not easily found."

The excuse that egg donation and surrogacy are ephemeral experiences or that donors and surrogates are not interested in discussing their experiences has too long been used as a way to avoid doing the work of engaging people with embodied experiences of gamete donation and surrogacy in policymaking. Egg donor advocacy group *We Are Egg Donors* is easily found online, and surrogacy agencies in Canada serve as direct points of contact to surrogates, and both groups have long expressed interest in participating in improving the experiences of women in Canada including through legislative and policy reform.

If the intention of the proposed regulations is to "protect and promote the health, safety, dignity and rights of individuals who use or are born of assisted reproductive technologies in Canada," I urge Health Canada to make egg donors and surrogates central the process of making the proposed regulations. This should also extend to people born of reproductive technologies, some of whom have historically participated in policymaking related to assisted reproduction in Canada, although their concerns were not effectively addressed in the Act.

2. Administration

My second concern relates to a lack of clarity about who will be permitted to reimburse gamete donors and surrogates. The CSA standards mention only that a need for a signed declaration from donors and surrogates, and that records "shall be kept for a minimum of six years by the person issuing the reimbursement."

Health Canada needs to be clear about who can issue reimbursements. Intended parents could issue these reimbursements to the donors or surrogate that help them build their family, but this would put individual families in the position of having to scrutinize and assess the receipts provided from their donors and surrogates, and further, it might put them in the position of having to say no to certain expenses or to indicating that they simply do not have the funds to pay for unanticipated expenses. This would also put gamete donors and surrogates in the position of paying out of pocket for their expenses and then having to request funds from people waiting for a new baby, people who have paid extensively for fertility treatments, for reimbursement of their funds. The precarious position of both those seeking expenses and those paying them, in this case, may result in strained relationships and this option is not ideal. And the stakes are high, intended parents who do not follow the regulations and instead pay their donor or surrogate would be subject to the penalties under the Act. Further, as gamete donors are not always known to intended families, alternative approaches would still be necessary.

Another option would be reimbursement from fertility clinics, putting egg donors and surrogates in the difficult position of having both their physiological and financial well-being simultaneously in the hands of their health care provider. People might feel a need not to articulate their concerns about their gamete donation or surrogacy—which they are doing to benefit another patient of that same fertility clinic—when they know that their reimbursements are contingent on those providing care.

What is clear from these examples, however, is that identifying what expenses are eligible for reimbursement is only a small portion of what Health Canada needs to address in the development of s.12 regulations. While the *Intent to Develop Regulations* published in the *Canada Gazette* indicates that there will be a plan to "designate inspectors for the purpose of administering and enforcing the Act and its regulations" this must extend beyond the mere designation of inspectors. Health Canada must work hard to address how reimbursement will occur, who will be authorized to make reimbursements, how they will be inspected, and how complaints will be addressed as these issues will be critical to the successful implementation of s.12. Other jurisdictions including the United Kingdom have dealt with the assessment of reimbursements through the establishment of a set amount for expenses for gamete donation, administered through a state-based agency, namely the Human Fertility and Embryology Authority. Ideally, in Canada, reimbursement (and complaints processes) would occur through Health Canada to ensure that conflict of interests do not occur as money exchanges hands from fertility clinics or intended parents to gamete donors and surrogates.

3. "Reasonable" Expenses

My third concern addresses the nature of reimbursements for gamete donors and surrogates, and primarily ensuring that Health Canada is clear about the intent of these reimbursements. Regulations regarding the reimbursement of expenses should be developed in a way so as to ensure that gamete donors and surrogates experience no financial hardship in the process of engagement (i.e. they should not have to pay out-of-pocket for their expenses), however, they should also be developed in a way so not to provide financial incentives to participate in gamete donation or surrogacy.

If the CSA standards are any indication, Health Canada may be considering a wide scope of potential reimbursements to gamete donors and surrogates. It is important to note that at the time that the Act was passed, many Parliamentarians were generally opposed to comprehensive reimbursement, and saw even reimbursement for missed work as controversial expense. The Act ultimately included a loss of work-related income for surrogates albeit after a great deal of debate. Concerns over the lines between "reimbursement" and "payment" were key issues in the legislative debates leading to the Act with stakeholders willing to acquiesce in part because of the (now-repealed) inclusion of a provision promising Parliamentary review of the Act three years after its passage.

Although the use of reproductive technologies in Canada has increased over time, Health Canada will need to take a cautious approach to ensuring the non-commercialization of reproductive technologies in Canada as per the guiding principles of the Act. Donors and surrogates will need to be reimbursed, for example for missing work to attend medical appointments, but it is unclear what limits will exist on reimbursements. If a donor experiences physiological harm as a result of their donation, for example, how long following the donation should they continue to receive reimbursement for their medical expenses, lost tuition, missed work, home care, etc. If a surrogate, for example, experiences psychological trauma over the course of their surrogacy, will they continue to be reimbursed for counselling expenses in the years following their surrogacy? And to what end

will egg donors whose cycles are cancelled, or surrogates who experience pregnancy loss (or whose fertility treatments are cancelled) be eligible for reimbursement? These considerations are integral to ensuring an effective and comprehensive reimbursement system.

4. Concerns About s.10

Health Canada has indicated that it will develop "draft regulations aimed at reducing the risks to human health and safety arising from the use of donor sperm and ova for the purpose of assisted reproduction, including the risk of the transmission of disease, and bring section 10 of the AHRA into force." My concerns to this end are twofold.

First, Health Canada must recognize that s.10 and the Semen Regulations may provide undue hardship to LGBTQ Canadians. The semen regulations—which derive from regulations governing blood donation--currently impose undue hardship on men who have sex with men seeking to donate their sperm, as they must receive special dispensation from the Minister of Health to do so. Further, lesbian and single women using known donors are faced with more stringent requirements than women using the sperm of their sexual partner to conceive. I urge Health Canada to consult with LGBTQ people and to consider these problematic and disproportionate effects of the Semen Regulations and s.10 on this community.

Second, Health Canada must ensure the highest standards of testing and screening for Canadians using donated reproductive tissues. There have long been concerns about a "shortage" in sperm and a call for either payment or a relaxation of Canada's standards for semen testing. The implementation of the semen regulations—which establish requirements for the testing and importation of sperm that are among the world's most stringent—have been widely cited as the reason for the closure of many of Canada's sperm banks in the early 2000s, resulting in a "shortage" in sperm.

Upholding the commitment to protecting the health and safety of Canadians may raise some challenges in terms of gamete donation. There may be a dearth of Canadians willing to participate in egg or sperm donation as they may have to participate in rigorous screening processes, and further, it is likely that potential donors will be screened out more often than in jurisdictions with laxer standards. This is a price that Health Canada must be willing to pay. Reimbursements (as per s.12) should take account of the time it takes to participate in reproductive tissue donation, and ensure that donors are not paying out-of-pocket to provide tissues.

I am happy to participate further in this process, and would be enthusiastic about providing comments or input on future iterations of these regulations. Please do not hesitate to contact me with questions or comments on this submission. Thank you.

Sincerely,

Alana Cattapan
Postdoctoral Fellow, Novel Tech Ethics
Faculty of Medicine
Dalhousie University

Selected resources:

Cattapan, Alana. "For Love or Money: The 'Shortage of Canadian Sperm Donors." *Impact Ethics* (2015a). https://impactethics.ca/2015/04/23/for-love-or-money-the-shortage-of-canadian-sperm-donors/

Cattapan, Alana.*:* Controlling Conception: Citizenship and the Governance of Assisted Reproductive Technologies in Canada (1989-2004). Dissertation. (2015b). Toronto, ON: York University. http://yorkspace.library.yorku.ca/xmlui/handle/10315/30713

Cattapan, Alana. "Risky Business: Surrogacy, Egg Donation, and the Politics of Exploitation." *Canadian Journal of Law and Society* 29.3 (2014): 361–379.

Cattapan, Alana, and Sara Cohen. "The Devil We Know: The Implications of Bill C-38 for Assisted Human Reproduction in Canada." *Journal of Obstetrics and Gynaecology Canada* 35.7 (2013): 654-656.

Gruben, Vanessa. "Women as Patients, Not Spare Parts: Examining the Relationship between the Physician and Women Egg Providers." *Canadian Journal of Women and the Law* 25.2 (2013): 249–283.

Montpetit, Éric. "Public Consultations in Policy Network Environments: The Case of Assisted Reproductive Technology Policy in Canada." *Canadian Public Policy* 29.1 (2003): 95–110.

Motluk, Alison. "Reimbursement discussions exclude surrogates, donors." *Canadian Medical Association News* 109-5176 (2015). http://www.cmaj.ca/content/early/2015/11/23/cmaj.109-5176

We Are Egg Donors [Website]. See http://www.weareeggdonors.com/blog