DALHOUSIE UNIVERSITY
Inspiring Minds

Novel Tech Ethics
Faculty of Medicine

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Biologics and Genetic Therapies Directorate
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Dear Minister Philpott:

We are writing in response to Health Canada's plan to introduce regulations to support the *Assisted Human Reproduction Act*. We are very pleased to see this initiative as we have long lamented the government's failure to protect and promote the health, safety, dignity, and rights of those who use reproductive technologies by not bringing into force the regulations integral to the *AHR Act*.

> Snow, D., Baylis, F., and Downie, J. (2015). Why the government of Canada won't regulate assisted human reproduction: A modern mystery. *McGill Journal of Law and Health* 9 (1), 1-16.
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> Baylis, F., Downie, J. & Snow, D. (2014). Fake it till you make it: Policymaking and assisted human reproduction in Canada. *Journal of Obstetrics and Gynaecology Canada* 36(6), 510-512; 16.
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> Downie, J. & Baylis, F. (2013). Transnational trade in human eggs: Law, policy, and (in)action in Canada. *Journal of Law, Medicine and Ethics* 41(1), 224-239.
>
> Baylis, F. (2012). The demise of Assisted Human Reproduction Canada. *Journal of Obstetrics and Gynaecology Canada* 34(6), 522-513.

First, a few words about our backgrounds relative to the topic at hand. Françoise Baylis is a philosopher with expertise in women's reproductive health dating back to the mid-1980s. She provided the federal government with an ethics expert report for the SCC Reference on the *AHR Act* and she was a member of the inaugural Board of Directors of Assisted Human Reproduction Canada. Jocelyn Downie is a health law professor also with expertise in women's health. Her most recent policy work in this area was as a member of the Canadian Standards Association Task Force that drafted Annex A "Reimbursement of expenses for donors and surrogates". She resigned from the Task Force prior to the submission of the final version because she believed the proposed standard was inconsistent with the *AHR Act*. For personal and professional ethical reasons, she could not sign onto something that she believed to be contrary to the law.

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As a starting point, we wholeheartedly endorse all of the principles that undergird the *AHR Act*. In discussion of the regulations that are the subject of this consultation, we draw particular attention to the following:

> (a) 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;
>
> (b) the benefits of assisted human reproductive technologies and related research for individuals, for families and for society in general can be most effectively secured by taking appropriate measures for the protection and promotion of human health, safety, dignity and rights in the use of these technologies and in related research;
>
> (c) while all persons are affected by these technologies, women more than men are directly and significantly affected by their application and the health and well-being of women must be protected in the application of these technologies;
>
> (f) trade in the reproductive capabilities of women and men and the exploitation of children, women and men for commercial ends raise health and ethical concerns that justify their prohibition;

In what follows, we focus on the bringing into force of section 12 (on reimbursements for receipted expenditures), and sections 45 to 58 (on oversight and enforcement of the *AHR Act*). Our comments are brief as we do not have draft regulations to which we can respond.

As regards section 12, we have been given to understand that the government will be considering the content of Annex A "Reimbursement of expenses for donors and surrogates" (CAN/CSA-Z900.2.2-12) prepared by the CSA Task Force. As such, our initial comments are organized in relation to this document. We identify substantive problems with Annex A and we comment briefly on problems with the potential strategy of incorporation by reference. Next, we comment on sections 45-58 and insist on the importance of enforcement (which has been lacking since 2004). Finally, we draw attention to matters that are outside the scope of the consultation that we believe should be addressed.

I. Section 12

CSA Standard, Annex A

Annex A includes provisions for reimbursement of "loss of work-related income" for egg or sperm donors. No such provision should be included in the regulations.

- Reimbursement for loss of work-related income for egg or sperm donation is contrary to the *AHR Act*. It cannot be read into s.12(1) as it is explicitly included in s.12(3) for surrogates. If Parliament intended for it to be able to be read into s.12(1), then it would not have included it in s.12(3) (it is unreasonable to assume that Parliament thought they had to include it for one section but could expect people to read it into the other). If the government now wishes to allow for reimbursement for loss of work-related income for egg or sperm donation, they must introduce an amendment to the *AHR Act* (as amendments cannot be made through regulation).

Annex A includes provisions for "loss of work-related income" post-delivery. No such provision should be included in the regulations.

- Reimbursement for loss of work-related income after delivery is contrary to the *AHR Act*. The *Act* states "during her pregnancy". This cannot reasonably be interpreted as including loss after the pregnancy as long as it was arising from the fact of a pregnancy. If Parliament had intended to cover loss of work-related

income after delivery it would have said "during her pregnancy or arising from the fact of a pregnancy". If the government now wishes to allow for reimbursement for loss of work-related income incurred after delivery, they must introduce an amendment to the *AHR Act* (as amendments cannot be made through regulation).

Annex A stipulates what documentation shall be submitted to the person issuing the reimbursement. In the regulations, the "person issuing the reimbursement" should be defined in such a way as to exclude the recipient of the egg, sperm, embryo, or baby.

- The risk of exploitation is significant if the exchange of money is happening directly between the people who are donating and receiving reproductive materials and surrogacy services. For example, if a pregnant woman submits an expenditure for reimbursement to the intended parents which the parents do not consider a legitimate expense, they will be hard pressed to withhold payment and risk having the surrogate negate the contract. The requests for reimbursements and the reimbursements themselves should be managed by an independent third party and preferably one that is subject to professional oversight (e.g., physicians or lawyers).

Annex A stipulates that eligible expenditures for surrogacy are those "incurred on or after the date on which the surrogacy process has commenced and incurred in connection with the surrogacy." Meanwhile, the *AHR Act* states that a surrogate can be reimbursed for "an expenditure incurred by her *in relation to her surrogacy*" (emphasis added)

- A prospective surrogate may require counseling and certainly requires legal advice ***before*** entering into a formal surrogacy agreement. Any regulation should make it clear, insofar as is possible consistent with the Act, that costs for such counseling and advice are eligible expenditures. If a woman cannot be reimbursed for the costs of counseling or legal advice associated with deciding whether to become a surrogate or not there are risks that: (i) she will not seek the counseling or legal advice she needs because she can't afford it and knows she will not be reimbursed, or (ii) she believes that reimbursement is only possible if she consents to surrogacy as then the "initial" counseling and legal advice are part of the "package". These scenarios expose the very real risk of exploitation and coercion. The regulations should seek to minimize these risks. Annex A could be read as narrowing the timeframe within which reimbursement is possible (adding the extra phrase "on or after the date on which the surrogacy process has commenced"). The language from the Act should be used instead (simply "in relation to her surrogacy") and the timeframe permitted under the Act should be clarified through the regulations.
- Further, additional clarity is needed as regards any limits on both of these eligible expenditures in terms of time frame and dollar amount. Consider, for example, a surrogate who is experiencing regret. Can she be reimbursed for counselling, five, ten, fifteen, or twenty years after the surrogacy?

Annex A lists "supplemental insurance" as an expenditure eligible for reimbursement. If this expenditure is to be included in the regulations, more precision is needed.

- Is this limited to health insurance or does this include life insurance? If life insurance is this insurance for 10 years, for 20 years, or for 100 years (Lifetime)?

Annex A lists "household maintenance" as an expenditure eligible for reimbursement. This is potentially over-inclusive insofar as it may be interpreted to include an overly broad range of activities as potentially eligible for reimbursement.

- In the regulations, the meaning and scope of any such potential expenditure should be clarified so that it is clear that this category aims to protect a person from participation in potentially harmful physical labour (e.g., for some women, snow clearing while pregnant might be injurious to their health).

Annex A, consistent with the legislation, makes reference to receipted expenditures. There are some

who suggest that the administrative burden associated with the collection of receipts is such that it is advisable to move to a "flat rate." Neither the legislation nor the regulations should aim to change this feature of the *AHR Act*.

- While keeping receipts for all expenditures may be burdensome for some, this is not a disproportionate burden insofar as it mirrors "usual" practice for claiming reimbursements – consider, for example, the need to collect and submit receipts for work-travel expenses or for taxes. In brief, the collection of receipts is a reasonable burden given the need to tightly link reimbursement of expenditures to the principles in the *AHR Act* that justify reimbursement (i.e., not having people be out of pocket for expenses incurred in the act of non-commercial gamete donation, embryo donation or surrogacy) and the need to avoid creating financial incentives for participating in gamete donation, embryo donation or surrogacy (as flat rates may escalate and cease to reflect the actual out of pocket expenses).

Annex A makes reference to "a verifiable claim" as an alternative to receipted expenditures. No such provision should be included in the regulations.

- The *AHR Act* is explicit in its narrow reference to "a receipt". Reference to a "verifiable claim" extends the scope of the legislation and should not be included in the regulations. Inclusion would require an amendment to the *AHR Act* (as amendments cannot be made through regulation).

Annex A makes no reference to financial limits for any of the categories of eligible expenditures. Some such provisions should be included in the regulations for some expenditures.

- There may be good reason to have upper limits on some categories of expenditures, such as supplemental insurance or household maintenance.
- The government has a travel policy that stipulates economy airfare, accommodations and mileage rates for travel. This could be the standard for all eligible travel expenses.
- Some travel policies require receipts for all meals and in addition have a maximum per diem for meals such that if receipts exceed this amount only the maximum per diem will be paid.

Incorporation by Reference

The *AHR Act* allows for incorporation by reference (s. 65(2) of the *AHR Act*). However, Canada effectively operates with a rebuttable presumption of lawmaking being done directly through statutes and regulations. None of the established bases for using the instrument of incorporation by reference apply to many of the regulations under consideration in this consultation (especially the issue of reimbursement of expenditures under s.12 of the *AHR Act*). To the contrary, the very real need for transparency, accountability, accessibility, etc. means that the regulations should be drafted by government and, as required by the *AHR Act*, be placed in front of Parliament. Obviously it will be necessary to consult widely and to draw upon expertise outside government, as appropriate. However, this does not justify the use of incorporation by reference.

There is also a real danger of failing to respect the legislative intent expressed through the statutory requirement that the regulations be put in front of Parliament (an unusual but very intentional requirement). This risk is particularly acute if the incorporation is ambulatory as that would mean that the content of the regulations could be amended without ever being put back in front of Parliament.

II. Sections 45 to 58

The federal government should commit to meaningful enforcement (within its jurisdiction) of the various provisions in the *AHR Act*. The history of non-enforcement in the face of known non-

compliance has significantly undermined respect for the law and created a grey market in reproductive materials and services.

III. Matters outside the scope of the consultation (either because not federal jurisdiction or not in the regulations that are the subject of the consultation) that should be addressed

The federal government should encourage/facilitate federal/provincial/territorial discussion about ways and means of removing disincentives to gamete donation, embryo donating, and surrogacy. This is a preferable alternative to creating potentially coercive, exploitative, or inducing financial incentives for gamete donation, embryo donating, and surrogacy.

- Many countries around the world prohibit the sale of sperm, egg and embryos as well as commercial surrogacy. Canada should be proud to stand with these countries. People may complain that there is not enough sperm or eggs to respond to demand but this is, even if true, not determinative. Consider, for example, the situation with organ donation. There are not enough organs for transplantation and yet we do not respond to the problem of supply by creating a market in organs. Rather, we try to identify and remove barriers to altruistic donation. The same should be done with reproductive material and embryos. For example, changes could be made to family law to protect the interests of gamete and embryo donors.

The federal government should encourage/facilitate federal/provincial/territorial discussion on the benefits of introducing a licensing system governing those who "obtain, store, transfer, destroy, import or export" gametes and embryos. The goal would be to establish minimum harmonized standards to protect the health and safety of those who use donated human reproductive material and human embryos.

The federal government should encourage/facilitate federal/provincial/territorial harmonization re: data collection. When sections 14-19 of the *AHR Act* were repealed, the ability to collect health information for the benefit of those who use or are born of reproductive technologies was lost. The rationale for such a registry remains and the federal government could play a leadership role in helping to negotiate the creation of some kind of pan-Canadian (F/P/T) registry.

The federal government should amend the *AHR Act* to remove confusion regarding the extraterritorial application of the *Act*.

- For the reasons outlined in our article "Transnational trade in human eggs: Law, policy, and (in)action in Canada," we strongly encourage the federal government to amend the *AHR Act* to make it perfectly clear that the *Act* has extraterritorial application. Canadians should not be free to go to other countries to exploit poor women and to threaten their well-being when they would not be allowed to do so to Canadian women. It is worth noting here that some Australian states have criminalized going to another country for commercial surrogacy. Text similar to that used in the Canadian *Criminal Code* to prevent extraterritorial trafficking in persons and sexual offences against children could be used. For example:

  > 7(4.11) Notwithstanding anything in this *Act* or any other *Act*, every one who, outside Canada, commits an act or omission that if committed in Canada would be an offence against section 279.01, 279.011, 279.02 or 279.03 shall be deemed to commit that act or omission in Canada if the person who commits the act or omission is a Canadian citizen or a permanent resident within the meaning of subsection 2(1) of the *Immigration and Refugee Protection Act.*

In closing, we commend the federal government for taking the initiative to write the regulations required to bring the *AHR Act* fully into force.

Sincerely,

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