

December 16, 2013

Lynn Mainland
Director, Assisted Human Reproduction
Director General's Office
Biologics and Genetic Therapies Directorate
Health Products and Food Branch
Health Canada
2nd Floor, Health Protection Building Room 2170
Ottawa, Ontario K1A 0K9

Dear Ms. Mainland,

We are writing to follow-up (once again) on our letter of October 17, 2013 on the legality of certain practices under the Assisted Human Reproduction Act (AHRA) with respect to transnational payment for eggs and, more generally, with respect to reimbursements under the AHRA, both in Canada and abroad. *(Copy of letter attached)*

It has since come to our attention, in reviewing the 'Agreed Statement of Facts' in *R. v. Picard and Canadian Fertility Consulting Ltd.* that there is a Health Canada policy on reimbursement. The 'Agreed Statement of Facts' includes the following statements: "Health Canada policy permits reimbursement to donors and surrogates of expenses and disbursements related to donation or surrogacy. This cannot involve paying consideration to donors or surrogates for their services or accepting payment for arranging surrogate services or similar financial gain. At all material times, Picard had been advised of and knew and understood the AHRA prohibitions and Health Canada policy." *(Copy of 'Agreed Statement of Facts' attached)*

We well understand the AHRA prohibitions both with respect to payment for eggs and surrogacy, as these are clearly spelled out in the *Assisted Human Reproduction Act*. However, we do not understand the statements re: a Health Canada policy. We have never seen a copy of any Health Canada policy on reimbursement (despite having been in correspondence with you for a number of months now), and moreover, do not understand why we have not been provided with a copy of such policy given our prior correspondence.

We hereby officially request copies of the following documents:

(1) the Health Canada policy referred to in the 'Agreed Statement of Facts'.

(2) the analysis conducted to ensure that this policy was consistent with the *Assisted Human Reproduction Act* – specifically given the fact that s.12 was not and is not yet in force.

We would also like answers to the following questions:

- (1) when did the policy come into effect?
- (2) what process was followed to draft this policy and bring it into effect?
- (3) under what and whose authority within Health Canada was this policy approved?

At this time we would also like to renew our request for a timely response to the six questions in our letter of October 17, 2013. Three of these questions are directly relevant to the issues raised by 'Agreed Statement of Facts' in *R. v. Picard and Canadian Fertility Consulting Ltd.*:

"4) On what basis does Health Canada allow any reimbursement of 'expenditures directly related to their donation'? Section 12 is not yet in force, therefore only s.7 applies and therefore no payments are possible (s. 12 creates an exception to s.7).

5) If Health Canada is acting as if s.12 is in force, then Health Canada must nevertheless conclude that no reimbursement is possible as no regulations are in force. The Act states that 'No person shall, except in accordance with the regulations, (a) reimburse a donor for an expenditure incurred in the course of donating sperm or an ovum.' To repeat, there are no regulations for s.12, therefore it is not possible to reimburse a donor 'in accordance with the regulations'. On what basis does Health Canada conclude that 'donors may currently be reimbursed for their actual expenditures directly related to their donation'?

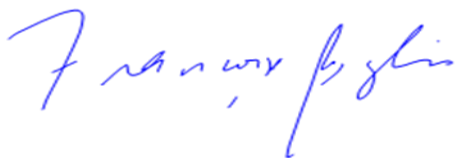
6) On what basis does Health Canada conclude that 'reimbursement ..., *normally occurs* after receipts are required, and may not be paid in advance of anticipated expenses'? (emphasis added) Again, s. 12 is not yet in force. Further, if acting as if s.12 is in force, then Health Canada would have to conclude that a receipt is absolutely required and not accept the lesser standard of 'normally occurs'."

We look forward to your response.

Sincerely,



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