

February 20, 2014

Minister Deb Matthews
Health and Long-Term Care Minister's Office
Hepburn Block
10th Flr
80 Grosvenor St
Toronto ON M7A2C4

Re: Canadian Plasma Resources and Paid Plasma Collection in Ontario

Dear Minister,

We are writing in our capacity as independent academics to express deep concern regarding the prospect of a for-profit plasma collection company, Canadian Plasma Resources ("CPR"), commencing business in the Province of Ontario. Though based in Nova Scotia, we have followed this issue closely and publicly called upon the federal regulator, Health Canada, not to sanction CPR's business model. In light of Health Canada's failure to move on this issue in a timely fashion, we believe there is good reason for the Province of Ontario to take immediate action to stop paid plasma collection in Ontario.

Specifically, we would argue that the Province of Ontario should amend section 10 of the *Trillium Gift of Life Network Act*, R.S.O. 1990, c. H.20, in order to prohibit private for-profit companies in Canada paying donors for blood or blood constituents, including plasma. (See APPENDIX for suggested legislative amendments).

Four concerns motivate a proposed amendment to the Ontario law:

1. CPR (and other for-profit plasma collection entities) poses a serious risk of exploitation.

For example, one of the CPR collection sites is located adjacent to a homeless shelter close to the University of Toronto. The business strategy is plain: locate close to populations for whom a financial incentive to provide plasma is likely to appeal. This exploits the vulnerability of CPR's

surrounding populations and runs directly counter to Canadian legal norms and ethical standards that require biological materials such as plasma to be provided on an informed and voluntary basis.

2. There is no reason to think CPR (or other for-profit plasma collection entities) will enhance the domestic supply of plasma.

According to Health Canada, CPR may help improve Canada's domestic supply of plasma, for which there is growing demand. However, nothing supports this claim. CPR has not agreed to provide plasma to Canadians in need on a priority basis. Moreover, past experience in Canada suggests that for-profit companies operating in this space will prioritize profit on the international market over domestic need. Investigative journalists showed that Connaught Laboratories, the company that played a central role in Canada's tainted blood scandal, exported blood derivative products to the US, earning \$500,000 in 1974 (today: \$ 2,356,321.84) at the very time when such products were in short supply in Canada. Thus, absent a contractual guarantee from CPR to supply plasma to Canadian populations in need first, there is no reason to believe CPR will improve Canada's "self-sufficiency". Available evidence suggests the opposite.

3. CPR (and other for-profit plasma collection entities) poses serious safety risks.

Past experience also teaches us that for-profit plasma collection companies can pursue profit at the expense of patient safety, with tragic consequences. As documented by the Krever Inquiry, Connaught Laboratories acquired plasma from US sources that collected blood from high-risk populations such as prisoners, with inadequate screening measures in place. Connaught later claimed it was unaware of this practice, but it clearly turned a blind eye to these safety risks: Connaught had previously discontinued its inspections of blood collection centres in the US, and failed to review inspection reports provided by the US Food and Drug Administration. Even after news that some of the plasma had been sourced from prison populations surfaced, Connaught entered into joint venture negotiations with the very same company that had collected the blood samples from prisoners.

4. Health Canada provides inadequate oversight.

The current level of federal oversight is much improved as compared with what was in place in the lead up to the tainted blood scandal. It remains woefully inadequate, however, to ensure the safety of blood and plasma sourced by for-profit entities. The National Blood Safety Council, established shortly after the Krever Inquiry, was disbanded in 2003; the implementation of important safety regulations have been repeatedly delayed; and Health Canada is not required to inspect plasma collection sites.

In June 2013, we outlined each of these four concerns in great depth to Health Canada, as part of its public consultations regarding for-profit plasma collection. (We enclose our submission to Health Canada with this letter). Health Canada has yet to publish a report on these consultations despite the consultation closing on July 26, 2013.

Rather than waiting any longer for a decision from Health Canada, we believe the Province of Ontario should proactively protect Ontarians, and indeed other populations, from potential exploitation and serious bodily harm. We propose two possible amendments to the *Trillium Gift of Life Act* (either would achieve this objective).

Sincerely,



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APPENDIX

Background Assumption

The two amendments to section 10 of the *Trillium Gift of Life Network Act* that we propose below are based on the assumption that no hospital (or other health care institution) in the Province of Ontario currently purchases blood or blood constituents. Rather, our assumption is that Canadian Blood Services procures blood or blood constituents, or products generated using blood constituents such as plasma protein products, and distributes the blood, blood constituents, or blood products to all hospitals in the province.

This assumption is based on an email response we received from Canadian Blood Services. The email acknowledged that hospitals may “in theory” buy directly from suppliers but, insofar as this is occurring, Canadian Blood Services is unaware of it.

The accuracy of this assumption is important. If some hospitals do in fact purchase blood, blood constituents, or blood products, then adopting either of the amendments we propose below would render that activity illegal. That is not our intention. Our intention, rather, is to allow Canadian Blood Services to continue its current practices while precluding for-profit companies from paying donors for blood and blood constituents such as plasma.

Proposed Amendments

On the strength of the foregoing assumption, we foresee two ways of amending section 10 of the legislation to achieve the goal of precluding private for-profit companies paying donors for plasma.

The first option preserves most of the current wording of section 10, renumbering it to section 10(1) and removing the phrase “other than blood or a blood constituent”, and then adding an exception in the form of section 10(2) pertaining specifically to blood and blood constituents purchased by Canadian Blood Services. The revised wording of sections 10(1) and 10(2) would read as follows:

10(1). Subject to subsection 10(2), no person shall buy, sell or otherwise deal in, directly or indirectly, for a valuable consideration, any tissue for a transplant, or any body or part or parts thereof for therapeutic purposes, medical education or scientific research, and any such dealing is invalid as being contrary to public policy.

10(2). Subsection 10(1) does not apply to:

- i) blood or a blood constituent;
- ii) bought, sold or otherwise dealt for, directly or indirectly, for a valuable consideration by Canadian Blood Services or Héma-Québec.

A second option is to alter the wording of section 10 as it now stands in order to capture offering to purchase or advertising for the purchase of blood or blood constituents. The language here is broader. Under this second option, section 10 of the *Trillium Gift of Life Network Act* would read as follows:

10(1). Subject to subsection 10(2), no person shall purchase, offer to purchase or advertise for the purchase of any tissue for a transplant, any body or part or parts thereof, or blood or a blood constituent from a donor or a person acting on behalf of a donor.

10(2). Subsection 10(1) does not apply to Canadian Blood Services or Héma-Québec in respect of blood or a blood constituent.

There are other ways to amend the Ontario legislation to achieve the same goal. Section 25 of Québec's *Civil Code*, for example, stipulates that the "alienation by a person of a part or product of his body shall be gratuitous." While this is a simpler provision, it targets the person selling part of his or her body rather than the entity attempting to purchase the same. Thus, in our view, it is preferable to focus the provision on the very actors who, by virtue of offering to purchase blood or blood constituents, are positioning themselves to take advantage of others' vulnerabilities (e.g. Canadian Plasma Resources) as opposed to those who actually may be disadvantaged and vulnerable members of society.