TO: Office of Policy and International Collaboration (BGDT)
FROM: Françoise Baylis, Jocelyn Downie, Matthew Herder
RE: "Round Table Discussion on Payment of Plasma Donors in Canada – Summary Report"

In the Final Report of the "Round Table Discussion on Payment of Plasma Donors in Canada – Summary Report" – a report prepared for Health Canada and available for public comment until July 26, 2013 – a number of safety and ethical concerns are raised about for-profit plasma collection. Below, we elaborate on these concerns.

Our response is in two parts. Part 1 addresses three substantive issues:

> (i) Failure to appreciate the risks associated with relying on the private sector to supply plasma products, as demonstrated by Canada's tainted blood scandal. [PRIVATIZING A PUBLIC GOOD]
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> (ii) Anticipated failure of Health Canada to effectively ensure the screening and testing of plasma providers[1] and the safety of blood products [OVERSIGHT]
>
> (iii) Failure to adequately consider the broad implications of a potential widespread shift in current practice from a single for-profit plasma collection company in Manitoba, to a potentially large number of competing for-profit companies across the country (except for Québec where payment for plasma is legally prohibited) [CONSISTENCY AND COHERENCE]

Part 2 identifies missing data and unsupported value statements in the Summary Report.

PART I

PRIVATIZING A PUBLIC GOOD

Throughout the Summary Report a number of statements are made about the advantages of allowing payment for plasma donation in terms of increasing the "diversity" and "security" of Canada's plasma supply. While becoming self-sufficient (and thus not having to rely on foreign sources of plasma) may be an appropriate policy goal, it is far from clear that endorsing a for-profit plasma collection business model in Canada is the best policy mechanism to achieve that goal. And, in the absence of evidence to support a claim that for-profit plasma collection will facilitate self-sufficiency (the Summary Report provides no such evidence, as outlined below), it appears that the

[1] We eschew the use of the term 'donor' to describe persons who are receiving payments. We reserve use of the term "donor" for those who donate altruistically (i.e., without payment).

goal of self-sufficiency is a pretense for other goals, viz. economic growth, company/job creation, etc. Muddying the first goal of self-sufficiency, which has to do with health, with economic goals, which have to do with prosperity and are independent of health, generates at least two significant problems.

First, according to a number of sources, including the Krever Inquiry and André Picard's book, *The Gift of Death*, the pursuit of economic objectives under the guise of self-sufficiency was a central factor in Canada's tainted blood scandal. Blatant safety concerns were ignored or minimized because of competing efforts to secure lucrative fractionation contracts, create jobs, and attract companies to Canada. The health consequences of this economic prioritization became plain over time. Thus, even assuming a stronger regulatory regime now exists (which we call into question below, see OVERSIGHT), introducing economic objectives into blood donation policy may, over time, undermine the paramount health goal of ensuring a safe blood supply.

Second, even if we assume the current regulatory regime will ensure safety (which, again, we call into question below), past experience in Canada suggests that encouraging for-profit plasma collection companies will not necessarily result in self-sufficiency. For-profit plasma collection companies are in business to turn a profit and there is no reason for them to restrict their customer base to Canada. That is, the business model need not align with the goal of ensuring a sufficient supply of plasma for Canadians. As concerns the issue of safety, the pursuit of business objectives could mean that the company does not take all necessary steps to ensure the plasma is sourced and processed safely.

In support of the above claims, consider, for example, the actions of Connaught Laboratories, which became a for-profit company in the early 1970s. Investigative journalists showed that Connaught exported blood derivative products to the US, earning $500,000 in 1974 (today: $ 2,356,321.84) at a time when such products were in short supply in Canada. In fact, between 1963 and 1976 Connaught sold nearly $7 million worth of blood components to the US. Later, in the early 1980s, Connaught's inability to efficiently use much of the plasma provided by the Canadian Red Cross, led it to begin purchasing plasma on the international market. As documented by the Krever Inquiry, Connaught 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.

Past experience in Canada clearly shows that the pursuit of economic objectives in the name of self-sufficiency can come at the expense of patient safety and supply. Further, there is no guarantee that private companies will deliver plasma products to Canadians in need. The Krever Inquiry emphasized that the blood supply is a public good; ensuring its safety should trump other objectives. Endorsing for-profit plasma collection thus neglects the lessons learned from the tainted blood scandal.

OVERSIGHT

Permitting the expansion of payment for plasma poses risks to Canadians that are not considered in the Summary Report. Specifically, it increases the need for serious oversight (if, for no other reason than that many more people will be put at risk) in a context where there is good reason to distrust the past, present, and future oversight system. For-profit plasma clinics have an inherent conflict of interest as between profit and safety (as outlined above). A robust independent oversight system is therefore necessary. Available evidence suggests that we have not, do not, and will not, have such a system.

Health Canada has a troubling record with respect to oversight. The first example comes from the arena of assisted human reproduction. *The Assisted Human Reproduction Act* established a system for the oversight of the development and use of assisted reproductive technologies. The Assisted Human Reproduction Agency established under this *Act* failed to meet its statutory mandate and was ultimately shuttered through the 2012 budget omnibus legislation *with all oversight responsibilities transferred to Health Canada*. It is widely known that the *AHR Act* continues to be violated (e.g., with respect to sale of human eggs and payment for surrogacy) and yet the *Act* is not being enforced. Regulations needed since 2004 to enable various parts of the *Act* to be brought into force have not been introduced (*a responsibility of Health Canada*). As a result, a field of health care that is largely in the private sector is seriously under-regulated with resultant threats to health and safety, most particularly for the women who use, and the children who are born of, reproductive technologies. Profit-making has threatened, and continues to, threaten the safety of Canadians and the oversight system has been, and continues to be, ineffective.

The second example comes from the blood arena. The National Blood Safety Council (NBSC) was set up in 1998 by the federal health minister to provide oversight of the blood system in Canada. In 2003, it was abruptly disbanded by a different federal health minister -- the members were simply telephoned one afternoon and told that the NBSC had been "consolidated" with the Expert Advisory Committee on Blood Regulation (EACBR). However, as noted by the Chair of the NBSC in the *Globe and Mail*, the NBSC was significantly different from the EACBR. It had a broader mandate (charged with oversight of all “players in the blood system” rather than merely providing

advice to the Biologic and Genetic Therapies Directorate of Health Canada). It was open and transparent while the EACBR was closed and secretive. It was independent of Health Canada while the EACBR was very much tied to Health Canada. The Chair closed his commentary as follows: “On behalf of all Canadians, we ask the Minister to restore independent oversight, transparency, and public participation to our blood system. We believe that these are essential if we are to avoid a repetition of past tragedies."

The NSBC has not been restored. Worse, the EACBR appears to be even less of a functional oversight body than it might have been in 2003. Information about the EACBR, on the Health Canada website, suggests that the committee has not met since the Fall of 2011 (the most recent minutes are from September 29, 2011). Calls and emails to Health Canada to enquire about the status of the Committee revealed that the Committee is still functioning and last met in November 7, 2012. This is not reassuring given the fact that paying for plasma and licensing Canadian Plasma Resources has been (and continues to be) a topic of significant discussion and controversy in public, private and government circles. Furthermore, while initially there was a community representative on this Committee, this is no longer the case. Clearly, the EACBR is not fulfilling the critically important oversight function once performed by the NBSC.

To consider expanding the risks to the blood system in a context within which the oversight system is inadequate is ill-advised.

New blood regulations are not in force. New blood regulations are in the process of being developed by Health Canada. According to the most recent information available on the web, the draft Regulations were published in Canada Gazette I in March 2012. According to the "Fact sheet: Canada's Blood Regulations" on the Health Canada website "the proposed blood regulations will be revised through the drafting process with an expectation for final publication in Canada Gazette, Part II in 2013 and a coming into force date one year later." However, there is reason to be skeptical of this timeline. The history of blood regulations and standards in Canada is one of delay upon delay. For example, the need to revise the plasmapheresis regulations was recognized in 1995, notice of intent was published in Canada Gazette, Part I in 2002, the proposed amendments were pre-published in Canada Gazette, Part I in September 2005, and the final regulations were published in Canada Gazette, Part II in December 2006. This process took eleven years. Thereafter, the official guidance document on these regulations was published in February 2008. In tandem with this, the development of national standards was begun in 1997 and finalized in 2004 (and since updated in 2010).

Further, if we return to the example of AHR, legislation requiring the introduction of several regulations was introduced in 2004. One regulation was introduced in

December 2007. Since then, there has been no progress with respect to the other needed regulations. The most recent information from Health Canada confirms that the drafting of regulations is ongoing and that these may be ready for Canada Gazette I sometime in 2014 or 2015 (another ten year time frame).

Given this history, it seems naive to accept the suggestion that the new blood regulations will be in place very soon and so the safety of for-profit paid plasma will be assured.

Proposed new blood regulations are inadequate to ensure safety of for-profit paid plasma. "Plasma Donation in Canada - Health Canada Fact Sheet 2013" states that "Before a licence is granted, Health Canada inspects the establishment to ensure that it is meeting the safety standards set out under the *Food and Drug Act*. The establishment is then inspected annually to assess that it is following the law." However, the proposed new proposed blood regulations only state that "During the review of an application for an establishment licence, the Minister **may** inspect the establishment's facilities and equipment to assess whether the applicant's activities are conducted in accordance with its proposed authorization and with these Regulations." Furthermore, ongoing oversight under the proposed regulations seems to take the form of an "annual report" that "describes any changes made in the year that are not described in section 9 or 11 and that could compromise the safety of providers or recipients or the safety, quality or efficacy of blood" – in other words, a self-reporting paper-based process.

An optional inspection on application for a licence and self-reporting on an ongoing basis are insufficient oversight mechanisms for for-profit businesses that pose a threat to the safety of Canadians.

CONSISTENCY AND COHERENCE

In the Summary Report, a number of statements are made about plasma products that apply equally to other health care products, including stem cell products once these are viable therapeutics. There is no evidence in the report that due consideration has been given to the policy and practice implications of for-profit plasma collection for for-profit tissue collection for the derivation of stem cell products. Consider the following:

Plasma products are described as "critical drugs needed by Canadians for the treatment of life-threatening disease." It is anticipated that in the near future there will be stem cell products available that could properly be described as "critical drugs needed by Canadians for the treatment of life-threatening disease." In the interim, source tissues for the derivation of stem cell products are needed to develop "critical drugs needed by Canadians for the treatment of life-threatening disease."

The demand for plasma products is said to be increasing globally. There is also an increasing global demand for tissues for the derivation of stem cell products, and this demand will only increase once safe and effective stem cell products are available for therapeutic interventions. We can't know the future, but we can note that the scientific community is championing personalized medicine which suggests a global demand for source tissues.

It is said that a sufficient supply of plasma for the manufacturing of plasma products depends on a paid system. In a number of countries, this sort of reasoning supports the practice of paying for reproductive tissues for the derivation of stem cell products. If the primary justification for payment for plasma is the need to satisfy a demand, pressure may come to change the legal prohibition in Canada on payment for reproductive tissues. This would be a serious negative consequence of moving to paid plasma.

It is said that "to deny access for Canadians to products sourced from paid plasma would threaten the health and lives of thousands of Canadians". Arguably, once safe and effective stem cell therapies are available, the same will be true for the various source tissues. What will (should) happen with respect to payment for tissues to derive stem cell products? Currently, it is illegal to source some, but not all, of these tissues from paid providers. When there are viable stem cell therapeutics, should the source tissues for stem cell products be from paid or unpaid providers? Or both? In which case the legitimacy of payment will depend upon the source tissue (i.e., somatic or germ cells). Here it is important to note that the health and lives of thousands of Canadians are at risk because of legal prohibitions on payment for solid organs. In the near future this may be true with respect to embryonic stem cell products. Thus far, this risk to life has not been of sufficient import to justify a payment system for solid organs or reproductive tissues.

PART II

MISSING DATA

In addition to the above concerns, we note the absence of data to support many of the assertions in the Summary Report. We urge those responsible for future public consultations to be sure to provide relevant, contemporary, Canadian data in support of the assertions referenced below. The relevant data should be made available in a manner consistent with a commitment to an open, accessible and transparent national dialogue.

(i) How do we *know* that "Payment by a private company for plasma donations … will never have any impact on Canada's voluntary system for collecting blood for transfusion" (p.2). On what basis can such a prediction be made about the future?

(ii) How do we *know* that "Collecting enough domestic plasma to be self-sufficient in plasma products is not operationally or economically feasible with a volunteer model" (p.3)? While this may be the experience in other countries (data to support this claim is not provided), this cannot be known to be true in Canada unless a voluntary domestic program has been attempted (and failed). At minimum, such a program would need to include the following key features: improved education; greater collection opportunities; 'rightsizing' demand for blood products.

(iii) How do we *know* that expanding payment for plasma will introduce more diversity of supply into the market? (p. 7)

(iv) How do we *know* that payment for plasma will decrease costs for the health care system? (p. 7) What calculations have been done, based on the introduction of how many additional private clinics?

(v) How do we *know* that paid plasma providers donate more often than volunteer donors? (p. 7)

(vi) How do we *know* that expanding payment for plasma will not contribute to the erosion of the volunteer donor base? On what basis and with what level of confidence can one predict that only 8% of volunteer donors will choose to be compensated instead of continuing with volunteer donations? (p. 9)

UNSUPPORTED VALUE STATEMENTS

In addition to missing data, there are a number of value statements that require justification.

(i) Why is self-sufficiency in plasma products of greater importance than self-sufficiency with respect to other human tissues, and sufficiently so that it warrants payment for plasma? The goal of self-sufficiency does not trump the goal of maintaining a voluntary system for other body tissues, such as reproductive tissues, blood for transfusion, solid organs. Why should it be otherwise for plasma?

(ii) It is said that Canadians "should never be denied access to a product they need – their lives depend on it" (p. 11). Not only is this statement incongruous and out of step with reality, arguably it is also in tension with many Canadian values. It is widely known that Canadians prize their health care system. They do not, however, believe that this is the only value worth promoting and protecting and would not bankrupt the country to make sure that Canadians are never denied “access to a product they need”. There are many needed health care products that Canadian are routinely denied. For example, we do not have a pharmacare program.

(iii) Payment of plasma providers occurs in Manitoba. In sharp contrast, such payments are legally prohibited in Québec. Why refer to Manitoba and not Québec as the precedent worth following?

(iv) Why is contributing to the global supply of plasma products an important consideration?

(v) Why is there no sustained discussion of the risks of exploitation and commodification?