Dear [Redacted]

Re: Your request for access to information under Part II of the Access to Information and Protection of Privacy Act [Our File #: HCS/091/2016]

This is to confirm that on June 29, 2016, the Department of Health and Community Services received your request for access to the following records/information:

“Provide the Canadian Hemophilia Society with any letters sent individually or as part of a letter-writing campaign to the Minister of Health or any of his/her officials in 2016 that mention blood, blood plasma, plasma or paid plasma.”

The Department has reviewed your request in the context of the Access to Information and Protection of Privacy Act (the Act) and is pleased to inform you that access to these records has been granted, in part. In accordance with your request for a copy of the records, the appropriate copies have been enclosed. Some information has been refused in accordance with the following exceptions to disclosure, as specified in the Act:

- Section 40(1) – Disclosure of Personal Information

As required by 8(2) of the Act, we have severed information that is unable to be disclosed and have provided you with as much information as possible.

Please be advised that you may appeal this decision and ask the Information and Privacy Commissioner to review the decision to provide partial access to the requested information, as set out in section 42 of the Act (a copy of this section of the Act has been enclosed for your reference). A request to the Commissioner must be made in writing within 15 business days of the date of this letter or within a longer period that may be allowed by the Commissioner. Your appeal should identify your concerns with the request and why you are submitting the appeal.

The appeal may be addressed to the Information and Privacy Commissioner is as follows:

Office of the Information and Privacy Commissioner
2 Canada Drive
You may also appeal directly to the Supreme Court Trial Division within 15 business days after you receive the decision of the public body, pursuant to section 52 of the Act (a copy of this section of the Act has been enclosed for your reference).

Please be advised that responsive records will be published following a 72 hour period after the response is sent electronically to you or five business days in the case where records are mailed to you. It is the goal to have the responsive records posted to the Office of Public Engagement's website within one business day following the applicable period of time. Please note that requests for personal information will not be posted online.

If you have any further questions, please contact the undersigned by telephone at 709-729-7010 or by email at VanessaMacey@gov.nl.ca.

Sincerely,

Vanessa Macey
ATIPP Coordinator
Dear Health Minister,

Please find attached a copy of a letter sent to Federal Minister of Health Jane Philpott on February 26th, 2016, in support of paid plasma collection.

With the issue of paid plasma in the news again due to the recent opening of a clinic in Saskatoon, the Network of Rare Blood Disorder Organizations (NRBDO) wishes to counterbalance those who are calling for a ban, with feedback from the patient organizations representing the Canadians who actually use and rely on plasma products.

We are happy to provide further information on our position, please do not hesitate to get in touch.

Thank you,

Network of Rare Blood Disorder Organizations (NRBDO)

[Hyperlink to NRBDO website: http://www.nrbdo.ca]
February 26, 2016

The Honourable Jane Philpott
Minister of Health
70 Colombine Driveway
Tunney’s Pasture
Postal Location: 0906C
Ottawa, Ontario K1A 0K9

Honourable Minister,

A company has recently opened a private plasma collection centre in Saskatchewan. The centre has been welcomed by the Government of Saskatchewan and licensed by Health Canada. This has, however, raised the question as to whether the federal government should prohibit the practice of compensating donors for plasma destined for further manufacture into plasma-derived medicinal products (PDMPs).

The patient organizations of the Network of Rare Blood Disorder Organizations take the position that there is a global need for plasma products that can only be met through plasma collection practices such as the one introduced in Saskatchewan. Such centres must, of course, respect the most stringent international standards established by the competent regulatory authorities.

The reality is that thousands of Canadians with chronic hematologic and immunologic disorders currently rely on plasma products manufactured from compensated donors in the U.S. for their health and their lives. Of the approximately 30 plasma products distributed by Canadian Blood Services (CBS) and Héma-Québec (H-Q), only one is manufactured from plasma collected wholly from unpaid Canadian donors. Two more, immune globulin and albumin, are derived from a combination of U.S. paid plasma and CBS/H-Q plasma. All the others are manufactured entirely from the plasma of compensated U.S. donors. More than 70 percent of the plasma required by CBS for the PDMPs they distribute is collected from compensated U.S. donors. This figure approaches 90 percent for Héma-Québec. Every year, demand for plasma for immune globulin is rising faster than the plasma supply from non-compensated Canadian donors.

Since the tainted blood tragedy of the 1970s and 1980s, huge changes have taken place in the regulation and manufacture of PDMPs. Thanks to rigorous donor screening, testing of donations and viral clearance procedures, these products have maintained a perfect safety record with regard to pathogen transmission since 1990. It is false to state that PDMPs from compensated donors are less safe than those from unpaid donors.
We see no evidence to suggest that the establishment of such plasma centres will have a negative impact on CBS’ and Héma-Québec’s capacity to continue to supply Canadians with labile products: red cells, platelets and plasma for transfusion.

Patients who require PDMPs see no merit to the argument that compensation of Canadian donors is unethical, while Canada, and indeed the entire world, rely on paid donors, mainly in the U.S., for the essential raw material needed to produce these life-saving medicines.

We urge you not to prohibit this practice in Canada.

Sincerely,

The Network of Rare Blood Disorder Organizations (NRBDO) is a coalition of national patient groups, formed to share the best practices in health care delivery for people with rare blood disorders such as hereditary angioedema; aplastic anemia, Fanconi anemia, paroxysmal nocturnal hemoglobinuria (PNH), and myelodysplasia; primary immune deficiency; porphyria, sickle cell disease, thalassemia, thrombotic thrombocytopenic purpura (TTP), hereditary hemorrhagic telangiectasia (HHT), hemophilia and von Willebrand disease.
Attached you will find a letter from [REDACTED] as well as an attachment letter addressed to The Honourable Eric Hoskins. The original letter will follow by mail.

Thank you.
May 10, 2016

The Honourable John Haggie, MD
Minister of Health and Community Services
P.O. Box 8700
Confederation Building, West Block
100 Prince Philip Drive
St. John's NL A1B 4J6

Dear Minister Haggie:

I am writing to provide you with the attached letter to the Honourable Dr. Eric Hoskins, Ontario minister of health and long-term care. This letter is in response to correspondence sent by Dr. Hoskins to Canadian Blood Services, outlining his interest in a national approach to addressing increased utilization of plasma protein products, and requesting an update on our plasma strategy. The letter speaks to the many issues surrounding the future of plasma sufficiency and utilization of plasma protein products, and provides solutions for a necessary path forward for mitigating risks to the blood system.

I know this topic is a matter of interest to Canadian Blood Services’ corporate members, the provincial and territorial ministers of health. Please do not hesitate to contact me should you wish to meet to discuss in more detail.

Canadian Blood Services remains committed to further dialogue and collaboration with you and your fellow ministers of health on these key matters of significance for the blood system in Canada.

Sincerely,

Enclosure

c.c.: Beverley Clarke, Deputy Minister of Health and Community Services

Daphne Osborne, Program Manager, Newfoundland and Labrador Provincial Blood Coordinating Program
The Honourable Eric Hoskins
Minister of Health and Long-Term Care
Hepburn Block, 10th Floor
80 Grosvenor Street
Toronto ON M7A 2C4

Dear Minister Hoskins:

Thank you for your letter of April 14, 2016. We are pleased to respond to your call for a national approach to address the growing utilization of plasma protein products (PPPs), and to provide an update regarding Canadian Blood Services' plasma strategy.

With respect to utilization of PPPs, we truly appreciate your comments around the need for a national approach. You may be aware Canadian Blood Services has been proposing a coordinated, collaborative, pan-Canadian approach to utilization for a number of years and provided a written brief to deputy ministers in this regard. To date, jurisdictions have largely attempted to tackle utilization of PPPs individually, with little or limited effect. In fact, many PPPs continue to see year-over-year increases in use, often beyond historical trends.

Canadian Blood Services is well positioned to bring focused attention and national coordination to utilization of PPPs, in partnership with provincial and territorial governments. This approach includes working with transfusion medicine experts and physicians to develop guidelines and help put controls in place to ensure optimum usage and efficiencies. By understanding how blood products can be used more efficiently and effectively — through examining individual hospitals' performance and making accurate comparisons among peer institutions, for example — health systems can gain insights to inform clinical practice, policy-making and funding decisions across the country.

We look forward to collaborating further with governments on a coordinated, system-wide approach to addressing utilization issues. We agree this partnership is essential to managing the major cost pressures for both governments and Canadian Blood Services. Engagement and agreement of all jurisdictions are needed to create and ensure this national collaboration.

In the meantime, Canadian Blood Services has concentrated efforts on areas within our sole purview. For instance, through successful procurement practices, and where a competitive market exists, Canadian Blood Services has obtained significant reductions in product pricing for PPPs. These efforts have been so impactful that prices have been held to, or are even at levels below, those paid in 2009–2010. In recent years, the organization’s procurement success has resulted in annual cost savings and avoidance of approximately $120 million annually ($600 million in total) over five years. This past March we confirmed further savings of approximately $33 million to be applied to the plasma protein products budget in 2016-2017, with an additional $27 million in savings in 2017–2018. Beyond successful contract negotiations, Canadian Blood Services employs other mitigation strategies within its control,
such as hedging practices and denomination of more contracts in Canadian dollars. We expect to see ongoing benefits and risk mitigation in this area.

We also welcome the opportunity to update you on the development of Canadian Blood Services’ plasma strategy. The matter of plasma sufficiency and collecting more plasma from Canadian donors has received much media attention over the past several months, and Canadian Blood Services’ board of directors and executive management have had substantial discussions on this issue. As the publicly funded and publicly accountable steward for the blood system in Canada, Canadian Blood Services has been regularly monitoring and analyzing plasma sufficiency needs in this country. The Canadian Blood Services board has identified this as an urgent matter needing serious, senior-level attention, and we look forward to bringing our strategy to corporate members in the months to come.

Given recent media activity around the question of paying donors for plasma, we want to first assure you Canadian Blood Services is only looking at increasing plasma sufficiency through a non-remunerated model. You will have heard it reported erroneously in the news that Canadian Blood Services is considering paying donors to donate plasma; this is not the case. We have said truthfully that if, at some future point in time, Canadian Blood Services was not able to significantly grow the plasma base in this country with the help of unpaid donors, we would have to consider our options, which could include remuneration. It was a hypothetical question with a hypothetical response. It has never been Canadian Blood Services’ practice, and it is not our plan, to pay donors.

In stating this, we also want to be clear paying plasma donors is not a safety issue. Products made from plasma donated by paid or unpaid donors are equally safe. Three decades of evidence confirms it. Over three quarters of the PPPs Canadian Blood Services buys are made using plasma from paid donors in the United States.

More important than the debate about donor compensation is the looming risk to the security of supply of plasma for fractionation to make lifesaving drugs. There is growing urgency to act to address trends in global markets for PPPs. For instance, our ongoing analysis shows Canada’s, and the world’s, dependence on plasma from the United States is a considerable and growing risk. Currently, North America and Europe make up 70 per cent of the world market for PPPs. To meet projected demand, the global plasma industry is focusing on acquisition and construction of plasma collection centres. North America supplies 63 per cent of the world’s plasma for fractionation into PPPs; more than 80 per cent of these collections occur in the U.S.

This reliance on the U.S. market is causing concern worldwide over the ability of the U.S. plasma collection industry to continue to meet growing global demand for PPPs. It is also prompting countries such as Canada to understand we need to do our part. At the very least, continuing to rely on the U.S. market makes Canada, and Canadian patients, vulnerable in the event of a disruption in supply, should no mitigating actions be taken to increase sufficiency in this country. By 2020, for example, global demand for intravenous immune globulin (IVIG) is expected to double over 2010 levels. Today, the amount of plasma we collect in Canada only meets approximately 25 per cent of the needs of Canadian patients for immune globulins. The other 75 per cent of the products we purchase for patients is made from plasma donated by paid U.S. donors.
As stewards of the blood system in Canada, Canadian Blood Services' role is to ensure safety and security of supply of blood and blood products. All the major patient groups in this country, such as the Canadian Hemophilia Society, the Canadian Organization for Rare Disorders, and immunodeficiency organizations, agree there is no difference between PPPs made from plasma donated by paid donors or plasma donated by unpaid donors, because these products are equally safe. Their main concern, and one that we share, is that there be an adequate supply of safe product for the patients who rely on them.

With respect to Canadian Plasma Resources, it is important to note we do not purchase plasma from this company, we do not have a contract with them to do so, nor do we have an obligation to do business with them in the future. Rather, our plan is to significantly expand our plasma collections to ensure we operate in the most effective way, with the right balance of products derived from Canadian plasma ("toll manufactured products") and those manufactured from the U.S. paid plasma donor pool ("commercial products"). Achieving the right balance is critical to security of supply for Canadian patients.

Our goal will be to more than double the amount of plasma we collect today, from approximately 200,000 litres of plasma per year, to 400,000 to 500,000 thousand litres in the next number of years to diversify our supply and be less reliant on foreign markets. We believe we can do this through voluntary donations and will not be paying donors.

This plan may include building a standalone plasma system with a dedicated and specialized staff, recruiting plasma donors in densely populated locations where it makes the most sense to do so, and investing in new infrastructure to support plasma collections. It will involve taking an incremental approach, as you suggest, in recognition of the fiscal realities of provinces and territories, and to establish a proof of concept. We also see a potential role for the federal government in response to a looming security of supply issue.

In terms of next steps, Canadian Blood Services looks forward to further dialogue and consultations with our corporate members, and with other relevant stakeholders, such as patients groups and clinicians, as we finalize our strategy and business case over the next several months. Together, we will consider and action what is the right and necessary path forward for Canada and Canadian patients.

Sincerely,

Dr. Robert Bell, Deputy Minister of Health and Long-Term Care
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<tr>
<th>From:</th>
<th>[redacted]@blood.ca</th>
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<td>Letter - 2016-05-09 Eric Hoskins.pdf</td>
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Thank you
May 10, 2016

Ms. Beverley Clarke  
Deputy Minister of Health and Community Services  
P.O. Box 8700  
Confederation Building, West Block  
100 Prince Philip Drive  
St. John's NL A1B 4J6

Dear Ms. Beverley Clarke:

I am pleased to provide you with the attached letter to the Honourable Dr. Eric Hoskins, Ontario minister of health and long-term care. This letter is in response to correspondence sent by Dr. Hoskins to Canadian Blood Services, outlining his interest in a national approach to addressing increased utilization of plasma protein products, and requesting an update on our plasma strategy. The letter speaks to the many issues surrounding the future of plasma sufficiency and utilization of plasma protein products, and provides solutions for a necessary path forward for mitigating risks to the blood system.

I hope you will agree these matters merit senior-level attention and consideration as soon as possible. I look forward to meeting with you and your deputy minister colleagues in the near future to discuss and align on next steps.

In the meantime, please do not hesitate to contact me should you have comments or questions.

Sincerely,

Enclosure

c.c.: Daphne Osborne, Program Manager, Newfoundland and Labrador Provincial Blood Coordinating Program

Share your vitality Partagez votre vitalité
May 18, 2016

Canadian Blood Services
1800 Alta Vista Drive
Ottawa, ON  K1G 4J5

Dear [Redacted]

Thank you for your letter of May 10, 2016, and also for sharing your correspondence dated May 9, 2016 to the Honourable Eric Hoskins, Minister of Health and Long Term Care in Ontario. I would like to acknowledge Canadian Blood Services’ commitment to a coordinated, collaborative pan-Canadian approach to utilization of plasma protein products and we look forward to working together with our provincial and territorial colleagues on this initiative. The pending update on the Canadian Blood Services Plasma Self-Sufficiency Strategy will be most welcome as we look for opportunities to mitigate the risk of supply and cost of plasma products from global markets.

I appreciate your clarification of Canadian Blood Services’ position on paid plasma and for articulating the organization’s plans to achieve the goal of more than double current collections in the coming years through voluntary donations.

Newfoundland and Labrador remains committed to collaboration with Canadian Blood Services and with our Provincial and Territorial colleagues to ensure a safe and secure supply of blood components and blood products.

Sincerely,

BEVERLEY CLARKE
Deputy Minister
April 15, 2016

The Honourable Jane Philpott
Minister of Health
70 Colombine Driveway, Tunney’s Pasture
0906C Ottawa, Ontario K1A 0K9

Dear Minister Philpott,

Thank you for your recent reply of March 16, 2016, regarding the federal authorization of payment for plasma collection.

Unfortunately, we remain concerned that Health Canada continues to abdicate its duty to regulate plasma in the public interest. Your letter contains extensive misinformation indicating to us that you, as Minister, are misled and/or misinformed by your Department on key issues.

Some examples of these key issues of misinformation are set out in the appended document.

Much of this misinformation falsely undermines the evidence-based Krever recommendations against paid plasma, and erroneously advances the position of the regulated blood and plasma industry favoring paid plasma collection. We reject the Department’s attempt to re-invent the past and falsely portray as outdated and ill-informed, the realistic, well founded, evidence-based recommendations of Justice Krever, which remain highly appropriate today. Self-sufficiency in voluntary plasma was then and is now an essential and achievable goal for sufficient supply of safe plasma and plasma products in Canada.

Your letter of reply demonstrates Health Canada’s failure in its regulatory duty to challenge the misinformation of the regulated industry, and develop and use its own independent expertise to provide decisions in the public interest. This conduct repeats the root cause of Canada’s past contamination disaster.

As Justice Krever warned, it is crucial that Health Canada maintain its independence and expertise to act in the public interest, in order to avoid repeating Health Canada’s past disastrous regulatory mistakes:
"During the 1980s, the bureau [of Biologics] did not decide independently whether to use its authority to require that measures be taken to reduce the risk of non-A, non-B hepatitis [now 'hepatitis C']. Instead, it relied heavily on information given to it by the Red Cross and, in effect made itself dependent on an organization whose activities it was supposed to regulate (see Chapters 23, 24, 25). The relationship between a regulator and the regulated is often courteous, but it must never become one in which the regulator loses sight of the principle that it regulates only in the public interest, and not in the interest of the regulated. The regulator must develop its own expertise and not rely on that of the regulated." [Volume 3, p 995, Final Report of the Commission of Inquiry on the Blood System in Canada, 1997]

Minister Philpott, we respectfully urge you to perform due diligence in arriving at decisions which serve Canadian citizens, and not the plasma industry, and those benefiting financially from the plasma industry. We urge active regulation of blood and plasma safety in the public interest, not blind acquiescence to industry assertions.

Sincerely,

A package of all correspondence on this topic between the Office of the Federal Health Minister and the Canadian Health Coalition has been sent to each provincial and territorial health minister.
Examples of Misinformation on Key Issues: Assertions by Health Canada in the March 16, 2016 Ministerial Letter to the Canadian Health Coalition.

1. **Health Canada’s duty [para 3, p1; para 2, p3]:**

The Ministerial letter, drafted by Health Canada, states “The decision as to whether Canadian plasma donors can be paid rests entirely with the provincial and territorial governments”. This is not true. There is a clear federal duty, as follows.

The federal enabling legislation, the Department of Health Act, assigns to Health Canada and to you as its Minister the federal duty to uphold the federal legislation, the Food and Drugs Act and Regulations. Health Canada has this statutory duty to assess the safety of drugs, including blood, whole plasma and plasma products. Only Health Canada, and not any province or territory, has the legal authority to protect all Canadians from the inherent health hazard of plasma sourced from a population shown by research evidence to have higher rates of infection, that is, paid donors.

The impact of payment for collecting whole plasma, the raw ingredient of plasma products, is a safety issue. Research evidence demonstrates that payment for collection of blood and plasma does influence the incidence of infectious agents in the resulting collections. Despite this, Health Canada purports that payment is not a safety issue, and is outside Health Canada’s mandate.

"Health Canada’s mandate is to regulate the safety and quality of the plasma that is collected for the purposes of transfusion or use in the manufacture of a human drug, which does not extend to corporate or operational decisions such as compensation to donors.” [Plasma Donation in Canada – Health Canada Fact Sheet 2013, accessed March 1, 2016]

These untrue claims first made in 2013 under the Harper regime demand correction by the new Trudeau government, to restore federal regulatory jurisdiction for the safety impact of payment for plasma.

2. **Misinformation falsely undermines the Krever recommendations against paid plasma collection.**

The letter makes multiple false statements that misrepresent the report of Justice Krever as ill-informed, outdated and surpassed by allegedly new safety systems, undermining Krever’s recommendations against payment for collection of plasma. We clarify but a few examples of misinformation:

2.1 **Modern pathogen reduction measures** [para 4, p2]
The Jetter erroneously states that today's pathogen reduction systems were newly developed, after the 1997 Krever recommendations, portraying the recommendations as now outdated and unnecessary, allegedly now surpassed by new technology, unforeseen by Krever.

"Since the issuance of the Krever Report... actions have since been taken to prevent such a tragedy from happening again. Technological advancements have made plasma products extremely safe. New measures, such as heat treatment, filtration and treatment with chemicals to inactivate viruses and other pathogens have been put into place..." [para 4, p2]

In fact, all the measures cited above were already in place at the time of the Commission's deliberations: heat treatment, filtration and treatment with chemicals [solvent-detergent treatment] were all in use then.

The safety improvement provided by these inactivation processes and their limitations were well known to Krever and are described in the Krever Report, Volume 3, p 957-60. To be clear, Canada's failure to implement heat treatment by 1986 was a central focus of the 1993-97 Inquiry.

Justice Krever made his recommendations against payment for plasma in the full knowledge of the successful impact of pathogen reduction systems used then and still used now to protect against known past pathogens. In his words, these safety measures had "almost eliminated the risk of transmission of HIV, hepatitis C and hepatitis B virus." [Krever Report, Volume 3, p 960.]

His recommendations addressed the inevitable unknown future pathogens. "New and emerging pathogens will always present a risk to the safety of blood and blood products." For example, today, we deal with the new risks of hepatitis E and Zika virus, both transmissible by blood and plasma. To protect against future unknown pathogens, voluntary donation has an evidence-based advantage in selecting for a population of donors shown to have a lower rate of infectious agents.

The letter indicates that Krever's recommendations against payment for plasma are no longer needed because "There have been no cases of hepatitis or HIV transmission by a plasma product in Canada in the last 25 years." i.e., since 1990. [para 4, p2] In fact, this confirms Krever's expectations in 1997 regarding the low incidence of transmission of known past pathogens. It gives no reassurance regarding new, unanticipated pathogens.

2.2 Payment for plasma is a new practice in Canada
[para3, p1 and para1, p2]

The letter's statement that "Payment for plasma is not a new practice...", is a misleading half-truth. It serves to create the illusion that recommendations against paid plasma were long ago abandoned in Canada. The truth is that unrestricted
payment for plasma from general citizens is a new practice and did not occur anywhere in Canada until February 2016, following Health Canada’s February 2016 licensing of the Saskatoon facility of the private corporation, Canadian Plasma Resources.

The letter deliberately mischaracterizes the 30-year Winnipeg experience. The longstanding practice of payment for plasma in Winnipeg was restricted to those few citizens with rare antibodies, relied upon to donate plasma frequently for specific plasma products. Justice Krever cited this rare exception to the general policy against payment for plasma as a reasonable measure to source these rare antibodies not available from the general population.

The letter alleges that Justice Krever accepted the need for paid plasma in general, by misquoting a partial statement from the Krever Report out of context. “...he [Krever] recognized that for some products, ‘it may be necessary to offer compensation to these persons for their time and effort in order to attract a sufficient number of donors’.” [para1, p2] The letter fails to reveal that Krever’s full statement refers specifically to plasma collection in Winnipeg from the few persons with rare antibodies, not to plasma collection in general, known to select for vulnerable populations with higher than average infectious risks.

2.3 Rising need for plasma products, plasma supply issues
[para 1 and 2. p2; para 3, p2]

The letter erroneously attributes Justice Krever’s recommendation against paid plasma and in favor of self-sufficiency in voluntary plasma to his alleged deficient appreciation of multiple plasma supply issues.

The letter falsely states that Krever expected that the need for plasma product would decrease over time. “A key factor to reaching this goal [self-sufficiency in voluntary plasma] was the assumption that the need for plasma products would decrease over time as new alternatives to plasma products were developed. [para 1, p2] The three Volume report contains no such claim.

The letter further purports that the burgeoning industry came as an unexpected surprise, as in “However the demand for life saving plasma products has increased and continues to grow” [para2, p2] This increase was no surprise.

The letter alleges Krever was uninformed on plasma supply issues: “The focus of the Krever Commission was on safety. The report did not include a detailed analysis of plasma product supply issues...” [para 3 p2] On the contrary, Krever addressed product supply issues in Canada, including the possibility of fractionation facilities. See Volume 3, chapter 37.

These false assertions serve to discredit Krever’s recommendations as ill-founded and unrealistic.
In fact, the opposite is true. The three volume Krever report, including specifically the final section on plasma self-sufficiency contains no such expectation of diminishing need for plasma. [See Volume 3, p1047-8, points 2(b) and 2 (c).] For example, non-plasma-based recombinant alternatives had already replaced plasma-based clotting factors in Canada prior to Krever’s Report.

It was well understood in 1997 at the time of Krever’s final report that plasma product production was a burgeoning, lucrative industry, especially regarding IVIG. This added to the urgency for Canada to become self-sufficient, and stop relying on foreign systems of paid plasma production, with their inherent increased risk of infection and insecure supply.

3. Lack of independent regulatory expertise

The Ministerial letter drafted by Health Canada relies extensively on misinformation provided by the regulated industry, unchallenged by Health Canada.

Failure to use independent expertise to provide decisions in the public interest is a chilling repeat of past regulatory failure at the root of Canada’s blood and plasma contamination scandal. Krever specifically warned that the regulator must maintain its own expertise and act independently of the regulated industry:

“The regulator must develop its own expertise and not rely on that of the regulated.”

3.1 Reliance on Canadian Blood Services misinformation
[para 4 and 5, p2; para 1 p3]

Extensive misinformation from CBS provided in the letter [partially detailed in point 2] is blindly accepted by Health Canada as “realities highlighted by the Canadian Blood Services”. Health Canada urges use of the CBS’s recent statements and website, not its own. Health Canada is willingly blind in relying on such plainly wrong CBS misinformation.

3.2 Reliance on Canadian Plasma Resources misinformation
[para 3, p3]

The letter mistakenly repeats the false claim of the private plasma corporation, Canadian Plasma Resources (CPR), purporting that the payment for plasma provided by CPR does not constitute payment, since CPR uses a non-transferable universal gift-card to provide the 25 dollar per visit compensation to the “donor”.

“According to a CPR spokesperson, the gift card ...meets the World Health Organization definition of voluntary non-remunerated donations. As long as the compensation is proportionate to the time involved, is non-cash, and is non-transferable, then the process is considered voluntary and non-remunerated.”

Not so.

In fact, CPR's gift card clearly does not meet the following definition of Voluntary Non-remunerated Donation', endorsed by the World Health Organization:

“Donation is considered voluntary and non-remunerated if the person who gives blood, plasma or cellular components of his/her own free will and receives no payment for it, either in the form of cash or in kind which could be considered a substitute for money. This would include time off work other than that reasonably needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donation”.

This Council of Europe definition of “voluntary non-remunerated donation” (Recommendation No. R (95) 14) is endorsed by the European Union, the World Health Organization, the International Society of Blood Transfusion, the International Federation of Red Cross and Red Crescent Societies and the International Federation of Blood Donor Associations. The CPR gift card does not meet this definition.

Public trust is cancelled when Health Canada officials so readily repeat a convenient fiction put forward by the regulated industry, in this case, a CPR spokesperson.

3.3 Health Canada “working with” industry [para 4, p3]

In closing, the letter states “Health Canada is committed to working with all Canadian blood operators.” This intended assurance is disturbingly inappropriate. This letter itself demonstrates the inappropriate dependent relationship between Health Canada and the regulated blood and plasma industry, specifically the CBS and CPR.
February 19, 2016

The Honourable Jane Philpott
Minister of Health
70 Colombine Driveway,
Tunney’s Pasture
Postal Location: 0906C
Ottawa, Ontario K1A 0K9

Dear Minister Philpott:

The Canadian Health Coalition, on behalf of its member organizations, is writing you to express our strong opposition to the possible licensing of a for-profit clinic that pays clients to donate plasma in Saskatchewan.

Canadian Plasma Resources has set up a clinic in Saskatoon, Saskatchewan after being prohibited from operating in the province of Ontario when that provincial legislature unanimously passed the Voluntary Blood Donations Act in December 2014. The owner of Canadian Plasma Resources stated in a recent interview on CBC’s The Current that his company is within days of receiving a permanent license from Health Canada for his clinic in Saskatoon. He also indicated that his company is in discussions with British Columbia and New Brunswick to expand into those provinces. Quebec is the other province that has passed legislation to ensure donors are not paid for their blood or plasma.

The Canadian Health Coalition believes that the introduction of a pay for plasma clinic in Canada poses a serious safety risk to our blood supply. The Canada Food and Drug Act obligates the Minister of Health to regulate and protect Canada’s blood and plasma supply, and therefore we ask you to immediately prevent Health Canada from issuing a license to this clinic or revoke any license that may have been issued and to do the same for any other clinic that pays donors for blood or plasma.

Allowing this company to pay donors for plasma conflicts with the recommendations of the four-year inquiry into the tainted blood scandal that infected over 30,000 Canadians with HIV and Hepatitis C. The Krever report made unequivocal recommendations that must be heeded to prevent another tainted blood tragedy in this country.
In his report, Justice Krever recommended that:

- "...the Canadian blood supply system be governed by five basic principles, [including] (b) donors of blood and blood plasma should not be paid for their donations, except in rare circumstances. [Krever, Vol.3, p.1047, Recommendation #2].

- "Whole blood, plasma and platelets must be collected in sufficient quantities to meet domestic needs for blood components and blood products." [Vol. 3, Recommendation #2, p. 1047]

- "Canadian plasma should be custom fractionated, in batches consisting only of Canadian plasma, based on specifications negotiated between the fractionator and the national blood service. These specifications should include requirements for the manufacture of the safest and the highest quality products." [Vol.3, Recommendation #5, p. 1051]

There are a number of risks to our national voluntary blood supply system if Canadian Plasma Resources is allowed to operate in Saskatchewan or in any other province:

- **Paying donors for plasma compromises the safety of plasma.** By providing a financial incentive to donate plasma, the clinic could attract donors from vulnerable populations and put the plasma at risk. Saskatchewan has the highest rates of HIV and Hepatitis C in the country, particularly among its aboriginal population which has poverty rates twice the rate of the non-aboriginal population. Blood or plasma donation on a voluntary basis is particularly crucial whenever the collection system is endangered by a new infectious threat, not identifiable by lab testing. The sole means to safeguard against such unknown threats is the voluntary collection of plasma from healthy citizens who have no monetary incentive to lie about their health status.

- **Paying people for their plasma could create competition with our voluntary blood system.** Paying people for their plasma creates a disincentive to donate blood voluntarily, thereby reducing our overall blood supply. The European Blood Alliance has documented that competition between voluntary non-profit blood agencies and for-profit companies that remunerated donors led to a shortage in blood supply in Austria and Germany in 2006 and 2007. Once Canadian Plasma Resources is licensed to collect plasma through payment, other for-profit companies will be able to demand similar treatment and increase the competition for donors.

- **Paying donors for plasma does not create self-sufficiency for the country,** contrary to claims by the company. Instead, it creates a two-tier and fragmented system for the collection of plasma. All of the plasma that Canadian Plasma Resources plans to collect will be exported to the United States and mixed in with large pools of donated plasma. Only plasma collected by Canadian Blood Services that is specifically marked for Canadian use is fractionated in the U.S. and then brought back to Canada. Canadian Blood Services says it has no plans to buy plasma from Canada Plasma Resources.
The Canadian Health Coalition supports a publicly-regulated, not-for-profit voluntary blood and plasma donation system in Canada as recommended by Justice Krever, the World Health Organization, the International Federation of the Red Cross and Red Crescent Society, the International Society of Blood Transfusion, the International Federation of Blood Donor Organizations and the European Blood Alliance.

We urge you to direct Health Canada to:

1) Use its statutory duty to regulate payment for plasma as a safety issue, recognizing that remuneration impacts the safety of the resulting plasma products. The decision to allow or disallow compensation clearly falls within Health Canada's mandate to regulate the safety and quality of plasma products as drugs under the Food and Drugs Act;

2) Abandon the erroneous policy adopted by the previous Harper government, which purported that compensation to donors of plasma is a non-safety "corporate decision" outside of Health Canada's authority;

3) Deny or revoke a license to Canadian Plasma Resources, and any other companies that propose to pay donors for blood, plasma or other blood products; and,

3) Work with Canadian Blood Services to develop a strategy to increase unpaid plasma clinics in Canada and move toward self-sufficiency in plasma supply.

Sincerely,

Cc: Don Davies, NDP Health Critic; Duncan, Saskatchewan Health Minister; Sheri Benson, Saskatoon West MP; Dustin
Dear [Redacted],

Thank you for your correspondence of February 19, 2016, concerning payment for plasma collected in Canada.

I appreciate your taking the time to share your concerns with me. I understand that the Canadian Health Coalition and its member organizations support a safe and sustainable blood supply system. Canada has one of the safest blood systems in the world thanks to its comprehensive regulatory oversight of the collection of blood and plasma. As the federal regulator, Health Canada is responsible for ensuring that Canada’s blood supply for transfusion, as well as its supply of plasma for further manufacturing into plasma products, are safe. The Department takes this role very seriously.

In Canada, blood used for transfusion is collected solely by Canadian Blood Services or by Héma-Québec and only from volunteer donors, while plasma used for the manufacturing of drugs known as plasma products may be collected from paid donors. The decision as to whether Canadian plasma donors can be paid rests entirely with the provincial and territorial governments and, as you have noted, different jurisdictions have taken different approaches. Payment for plasma is not a new practice and is legally permitted in all provinces and territories except for Ontario and Québec. A company in Winnipeg has been operating safely and paying donors for plasma for 30 years. The plasma collected from paid donors is used exclusively for plasma product manufacturing and never enters into the blood for transfusion systems.

Canada does not collect enough plasma to be self-sufficient in meeting the demand for life-saving plasma products, the need for which continues to grow. Therefore, some products, such as life-saving immune globulins, are purchased from manufacturers that use U.S. sourced plasma, mostly obtained from paid donors. In fact, approximately 70 percent of the immune globulin products available in Canada are made in whole or in part from plasma from U.S. paid donors.

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As you highlight in your letter, the recommendations of the Krever Commission were key factors in shaping the structure of Canada's current blood supply system and making it one of the safest in the world. While Justice Krever recommended that "significant efforts be made to ensure that blood components and blood products used in Canada be made from the blood and plasma collected from unpaid donors," he recognized that for some products, "it may be necessary to offer compensation to these persons for their time and effort in order to attract a sufficient number of donors." Justice Krever also emphasized the need to become self-sufficient in plasma and reduce reliance on the U.S. as a source of plasma. A key factor to reaching this goal was the assumption that the need for plasma products would decrease over time as new alternatives to plasma products were developed.

Canada has made significant efforts in this area resulting in a self-sufficient blood for transfusion system based entirely on voluntary donations. However, the demand for life-saving plasma products has increased and continues to grow. Approximately 40 percent of the plasma products currently authorized in Canada came into use after the release of the Krever report.

It should be noted that the focus of the Krever Commission was on product safety. The report did not include a detailed analysis of plasma product supply issues, nor was it possible when the report was produced to envision the number of new plasma products that could potentially be developed. Canadian Blood Services and Héma-Québec have determined that they are unable to collect sufficient plasma to meet today's plasma product needs through the volunteer model.

Since the issuance of the Krever report, almost 20 years have passed. While the lessons of the tainted blood crisis must never be forgotten, actions have since been taken to prevent such a tragedy from happening again. Technological advancements have made plasma products extremely safe. New measures, such as heat treatment, filtration, and treatment with chemicals to remove inactivate viruses or other contaminants, have been put into place in addition to the rigid donor screening and testing requirements necessary when producing products from plasma. Since the introduction of these safety measures, there have been no cases of hepatitis or HIV transmission by a plasma product in Canada in the last 25 years.

These realities have been highlighted again by the Canadian Blood Services who have issued a recent statement on payment for plasma donation, reaffirming that the drugs made from the plasma of paid donors are just as safe as those made from the plasma of volunteer donors, and that a paid plasma market is essential to ensuring enough supply of the lifesaving therapies Canadians need. The statement is available at https://www.blood.ca/en/media/statement-canadian-blood-services-payment-plasma-donation.
As further highlighted in the Canadian Blood Services statement, there is also no evidence that paying plasma donors compromises the safety or weakens a country's volunteer blood donor system. The experiences of other countries suggest both paid and voluntary plasma donation can safely coexist. Additionally and as noted above, the plasma collected by Canadian Blood Services and shipped out of Canada for contract fractionation is only enough to make about 25 percent of Canada's immune globulin needs, and about 60 to 70 percent of albumen needs. The remaining plasma products that Canada requires are manufactured using pooled plasma from U.S. sources, which includes plasma from paid donors and, as noted in your letter, potentially Canadian Plasma Resources.

To this end, you may be aware that Health Canada issued an Establishment License to Canadian Plasma Resources (CPR) for its new Saskatoon facility on February 2, 2016. This licence was issued following a comprehensive evidence-based review and on-site inspection by Health Canada, where product safety was held as paramount. Similar to the other Canadian blood establishments, they will continue to be inspected annually by the Department, and compliance and enforcement actions will be taken in any instances of regulatory non-compliance.

Furthermore, for clarification, CPR’s policy is such that qualified donors will receive a universal gift card valued at $25 for each visit. This card cannot be transferred, cannot be used as cash, and cannot be used to withdraw cash. According to a CPR spokesperson, the gift card approach was selected to be compatible with the World Health Organization definition of voluntary non-remunerated donations. As long as the compensation is proportionate to the time involved, is non-cash, and is non-transferable, then the process is considered voluntary and non-remunerated.

Please be assured that Health Canada is committed to working with all Canadian blood operators to protect Canada’s plasma and blood supply systems, that all establishments that collect plasma for blood products are strictly regulated and in compliance with the Food and Drugs Act and Regulations, and that plasma products sold in Canada are manufactured in accordance with our strict safety standards, regardless of where the plasma comes from and whether or not donors were compensated.

Again, thank you for writing.

Yours sincerely,

The Honourable Jane Philpott, P.C., M.P.
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