Canadian Health Coalition
Coalition canadienne de la santé
251 Bank Street, Suite 212, Ottawa, ON K2P 1X3

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 We reject the Department's attempt to re-invent the past and falsely portray as outdated and ill-informed, the realistic, well founded, evidence-based recommendations of Justice Krever, which remain highly appropriate today.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,

Pauline Worsfold, RN
Board Chair, Canadian Health Coalition

cc: Ms. Genevieve Hinse
Ms. Caroline Pitfield

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.

Attachment 1:

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 [para3, p1; para2, 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 letter 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."
> [Volume 3, p995, Final Report of the Commission of Inquiry on the Blood System in Canada.]

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.