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Nov. 8, 2017

The Honourable Randy Delorey
Minister of Health and Wellness
Barrington Tower
1894 Barrington Street
P.O. Box 488
Halifax NS B3J 2R8

Dear Minister Delorey:

On behalf of Canadian Blood Services' board of directors, I am writing to thank you for our meeting on Oct. 18, [redacted]

Not Responsive

With regards to your questions about our plasma business plan, we are communicating with your officials to provide further background. We are pleased there was consensus at the recent Health Ministers' Meeting that immediate action is needed to improve and expand domestic plasma collection. Our plan to increase Canada's plasma sufficiency for immune globulin (Ig) to 50 per cent will mitigate the looming risk to supply and ensure the blood system remains safe and secure for all patients in need.

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[redacted]

We look forward to continuing our strong collaboration with you and your officials. Thank you for your continued interest in and engagement with CBS as both a corporate member and a committed donor.

Sincerely,

Leah Hollins
Chair, Board of Directors

c.c.: Denise Perret, Deputy Minister of Health and Wellness
Dr. Graham D. Sher, Chief Executive Officer
Jean-Paul Bédard, Vice-President, Public Affairs
Judie Leach Bennett, Vice-President, General Counsel and Corporate Secretary
Lindy McIntyre, Director, Government Relations
Pierre Cyr, Director, Board Relations

Anderson, Wendy

From:	Ashley Haugh <Ashley.Haugh@blood.ca>
Sent:	Wednesday, February 07, 2018 1:41 PM
To:	'minister.he@gov.sk.ca'
Cc:	HLTH.health@gov.bc.ca; 'health.minister@gov.ab.ca'; Health, Seniors & Active Living, Minister (MINHSAL@leg.gov.mb.ca); 'eric.hoskins@ontario.ca'; Benoit.bourque@gnb.ca; Health and Wellness Minister; rjmitchell@gov.pe.ca; hcsminister@gov.nl.ca; pauline.frost@gov.yk.ca; 'glen_abernethy@gov.nt.ca'; pangnakak@gov.nu.ca; Minister_ministre@hc-sc.gc.ca; mel.cappe@utoronto.ca; 'Max Hendricks (Health DM-SK)'; 'judy.hoff@health.gov.sk.ca'; Graham Sher; Corporate Secretariat; Jean-Paul Bedard; Lindy McIntyre; Pierre Cyr
Subject:	Letter from Graham Sher, Canadian Blood Services
Attachments:	2018 02 07 - Min Reiter - re plasma business plan.pdf

Minister Reiter,

Please find attached a letter from Dr. Graham Sher, CEO, Canadian Blood Services.

Thank you

Ashley

Ashley Haugh
Executive Assistant to Dr. Graham Sher, CEO
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Feb. 7, 2018

The Honourable Jim Reiter
Minister of Health
Legislative Building
Regina SK S4S 0B3

Dear Minister Reiter:

I am pleased to respond to your letter of last October to Leah Hollins, outlining your thoughtful questions about Canadian Blood Services' business plan for ensuring the security of Canada's plasma supply for immune globulin (Ig).

I know this has been a complex topic for the past few years, and certainly in recent months. Canadian Blood Services appreciates this is an important dialogue for the public to have, with multiple stakeholders and various experts continuing to offer opinions and positions on what could or should be the best approach for Canada, especially when it comes to plasma collection. It is anticipated the final report from Health Canada's Expert Panel on Immune Globulin Product Supply and Related Impacts in Canada, when released later this winter or early spring, will add to and help further inform this dialogue.

There are also, as you note, divergent views among F/P/T governments, most prominently around the new dynamic of commercial, for-profit plasma collection in Canada. There is absolute agreement patient care is and must be the primary concern for Canadian Blood Services and governments alike, and that we must work together to ensure a sustainable, safe and secure supply of source plasma for the country. However, the lack of consensus among ministers of health as corporate members and the blood system regulator when it comes to the involvement of commercial, for-profit plasma collection operating outside of the national system is challenging and problematic for Canadian Blood Services, and for the country.

As the blood system authority in Canada, Canadian Blood Services is the expert body and authority F/P/T governments and the Canadian public hold accountable and rely on to ensure the safety and security of blood and blood products to meet the needs of patients. In truth, only Canadian Blood Services can determine and declare how the

new dynamic of commercial for-profit plasma collection might impact the current or future health of the blood system in Canada. And only Canadian Blood Services is accountable for ensuring a certain level of source plasma supply for Ig to meet patient needs. And when there is a looming risk to the supply of plasma for Ig, when there is uncertainty over the ability of U.S. suppliers to continue to sustain 80 per cent of the world's plasma collection sites, and when countries around the world are being advised to boost domestic plasma collections, Canadian Blood Services must act on our responsibility to protect and secure lifesaving Ig through the publicly accountable system. This is what we were created to do, and what is clearly expected of us.

With this context in mind, I have tried to be as thoughtful and thorough in the answers to your questions as you have been in your queries. There are also a number of comments made in your preamble I would like to address first. I hope this additional information will aid you and your fellow ministers of health as you continue to review the business plan and make decisions in the best interests of patients and Canada's national blood system.

On the matter of the involvement of commercial, for-profit companies in the collection of plasma, I do understand the points you are making. It is a fact that commercial, for-profit plasma collection in the U.S. has coexisted with not-for-profit blood collectors for decades. You will also appreciate Canada and the U.S. are vastly different countries in most meaningful aspects related to this decades-old coexistence (e.g., population, health care, blood systems, etc.); the experience in the U.S. cannot be easily transferrable or applicable to a Canadian context. More importantly, there are growing concerns in the U.S. that the continual expansion of commercial, for-profit plasma collection from paid donors is impacting whole blood collections from unpaid donors, a concern referred to as "crowding out."

It is worth restating here that Canadian Blood Services has always maintained that, in Canada, a small commercial operation or two, such as the ones in Saskatoon and Moncton, can likely coexist with the national system; it is the emergence of large-scale commercial for-profit collectors that is the concern.

Our plea to F/P/T governments is well known in this area. Canadian Blood Services has been stressing that commercial collectors outside of the national blood system have no responsibility for, or accountability to, the national blood system; they are not concerned with any impact their activities may have on whole blood collections from unpaid donors. There is evidence internationally that when for-profit, paid plasma systems expand rapidly, they can reduce the ability of the not-for-profit blood industry to meet its blood collection targets. For this reason alone, the large-scale proliferation of commercial plasma collection in Canada is a concern. Only Canadian Blood Services can guarantee the collection of plasma and whole blood coexists in harmony to ensure a secure supply of both for Canadian patients.

On this front, we do know the expansion of commercial plasma collection will impact not only Canadian Blood Services' efforts to fulfil our mandate to ensure Canada's plasma

sufficiency level via our plasma collection, but Canadian Blood Services' whole blood collection, as well. Recruiting new donors into the blood system every year is challenging enough, without the impact of commercial entities competing for donors and adding a layer of confusion. Recent polling on the public's views around remunerating donors emphasizes this. As an example, our ongoing monitoring in Moncton and Saskatoon reveals:

- Fluctuations in donations among donors aged 17 to 24.
- Confusion and misunderstanding among donors over the distinction between Canadian Plasma Resources and Canadian Blood Services.
- Additional costs to recruit donors and plan collections above budgeted approaches.

Our main point has been that assigning the control of donated plasma, the essential starting material for the manufacture of Ig, to commercial, for-profit businesses does not mitigate the risk of a supply shortage for Canadian patients. Commercial entities, even if under contract to Canadian Blood Services, could obviously redirect collected plasma to a buyer of their choice once the contract term ended. They are not bound to keep plasma collected from paid Canadian donors in Canada. This has happened in the recent past in the U.S., with the vertical integration approach of large pharmaceutical companies. Grifols, for example, recently purchased 23 plasma centres and intends to redirect the supply of plasma from those centres into its own supply chain. The current buyers of plasma from those 23 centres will no longer have access to that plasma, underscoring the tenuous nature of contracting for the supply of human plasma for fractionation.

You also comment on altruistic plasma collection with respect to the Australian example. I have provided detail about altruistic plasma collection, including in Australia, in answer to your Question 2. However, I did want to quickly clarify that Australia did not have a plasma expansion plan for several years because supply issues and Ig use were not the concern they are today. The rising use of Ig by health prescribers for their patients over the past few years has caused Australia's plasma sufficiency level to drop — this is similar to the experience in Canada and elsewhere. With the looming risk to the global plasma supply, and to ensure a return to a responsible level of plasma sufficiency for the country, Australia's blood operator is now successfully increasing plasma collection from altruistic donors through a planned process. This year, in fact, will see Australia collecting more plasma than whole blood from non-remunerated donors.

You note, too, that commercial plasma collection from remunerated donors has existed in Canada for decades with Prometic Life Sciences (formerly Cangene) in Winnipeg. Cangene/Prometic has indeed collected plasma for manufacture into a niche product for decades. Because of this specificity, there has been no discernable crossover or competition with the national blood system. Such an example cannot reasonably be compared to the situation in the U.S.

In addition to the information and clarifications I have just provided, the following are the specific answers to your four questions.

1. ***In other nations, successful plasma donation networks are operated in a highly-regulated environment by the private sector. CBS recognizes that the source plasma collected from these donors is safe. Why was this approach not considered by CBS in the business case?***

A. As you note, Canadian Blood Services has consistently stated this matter is about security of supply, not product safety. Products made from plasma from paid donors are as safe as those made from plasma from unpaid donors.

With respect to enlisting the private commercial sector to increase plasma collection in Canada, the direct answer is Canadian Blood Services has considered this. We considered it as part of the development of the right plan for Canada, and we considered it as part of the detailed risk assessment applied to this issue. In fact, a partnership to enlist best practices from experienced, reputable and proven plasma collection experts remains part of our path to success as we ramp up source plasma collection in Canada. Partnership, however, is not the same as contracting with any commercial business that wishes to open up in Canada, as this would essentially be delegating the "security of supply" equation to independent, commercial, for-profit collectors. This is not a solution or responsible mechanism for ensuring Canadian control over the security of the plasma supply to manufacture drugs to meet the needs of Canadian patients.

In short, the plasma sufficiency level for the country can and should only be determined and secured by the same entity that owns and operates the plasma collection infrastructure. In Canada (outside Quebec), this is Canadian Blood Services, which operates the publicly owned blood system in Canada on behalf of ministers of health. This includes the ability and agility to make informed and holistic decisions about where, when and how to collect plasma to ensure the supply needs of Canadian patients are met into the future.

Again, we agree this is not about paying or not paying donors. This is why Canadian Blood Services is necessarily exempt from the legislation recently enacted in Ontario and Alberta. Canadian Blood Services has operational independence to do whatever is necessary to ensure patients have access to lifesaving products. I did, in fact, address this with health ministers in 2016 when asked during the Annual General Meeting of members in Toronto. Patients come first, and we understand that options for some form of remuneration for plasma donation is something the publicly accountable national blood operator might one day need to consider should available supply to meet patient need be in jeopardy. Rather, this is about the system in Canada, and Canadian Blood Services, as the publicly owned and accountable entity, controlling where, when

and how to collect plasma, in harmony with whole blood collection, to ensure an adequate supply of both for Canadian patients.

2. ***It is our view that the evidence and experience from other jurisdictions suggests an altruistic plasma collection model has not provided for a stable, sustainable supply of source plasma. Based on polling conducted by CBS, there seems to be a change in the public's view of remunerating donors. What is different in Canada or the CBS business plan that would lead to a reasonable expectation that an altruistic model would be sustainable and successful?***

A. I want to first make a point about the polling. Such data points, along with our own monitoring in Saskatoon and Moncton, highlight the confusing and complicated world of recruiting donors for both whole blood and plasma, and the need for ensuring these are done in harmony with each other. This is a main reason we have been asking F/P/T governments for a pause in further expansion of commercial, for-profit plasma collectors. We need consensus among health leaders in this country on how the national system can be supported to ensure successful collection of both plasma and whole blood for Canadian patients.

In terms of sustainable and successful models of plasma collection from altruistic donors, there are a growing number of examples. Australia, as mentioned, is a leading example of successfully increasing plasma collection via non-remunerated donors. Australia has a very high growth rate in the demand for Ig, and is now targeting a sufficiency level of 70 per cent for the country to be achieved by the national blood system. In 2015–2016, Australia collected 601,000 litres per year (about three times more than Canada), and was targeting 921,000 litres by the end of 2018–2019. More importantly, this year, 2018, will see Australia collecting more source plasma than whole blood, and doing so using a non-remunerated model.

Several European countries are also making plans to significantly increase plasma collection, again via non-remunerated donors. Denmark, Belgium, Netherlands, France, Spain and Italy are all increasing domestic plasma collection to meet patient need, as outlined below:

- In France, the national blood operator, Établissement français du sang, currently collects 800,000 litres of plasma, giving France a 50 per cent sufficiency level to ensure security of supply to meet patient requirements. In addition, EFS has plans to increase its apheresis plasma collections as part of a dedicated source plasma strategy. At EFS collection sites, both whole blood and apheresis plasma are collected; careful monitoring of the donor base is conducted to ensure targets for both programs are met.

- The Dutch blood operator, Sanquin, currently collects 335,000 kilograms of plasma annually, which meets 100 per cent of the Ig needs of the

Netherlands. With the decline in red cell collection, Sanquin has increased its apheresis plasma collections to meet the Ig demand. Sanquin recruits all of its donors into the whole blood program and then moves donors as appropriate into the plasma program. Sanquin is exploring options to expand its plasma collections program so as to increase the volume of plasma to be manufactured into derivatives at its fractionation plant in Amsterdam.

- In Denmark, the Organisation of Transfusion Centres is responsible for supplying blood and plasma for that country, and it now has a goal to collect enough plasma to achieve 100 per cent of the Danish population's requirements for Ig (from the current 50 per cent). This means increasing plasma collections from unpaid donors from 30,000 in 2015 to 230,000 by 2020. This goal will be supported by the fact the Danish blood service is among the most efficient in the world, having applied Lean concepts and significant automation to its process design.

- Other European blood operators (e.g., Spain, Italy) have been mandated to meet 100 per cent of Ig needs through voluntary, unpaid plasma collection. In Belgium, the government has decreed the national blood system must collect sufficient plasma to meet 50 per cent of the country's Ig needs.

To help blood operators achieve the plasma collection goals, organizations such as the International Plasma Fractionation Association and the European Blood Alliance have developed recommendations on how to increase donations from voluntary, unpaid donors.

Even in the U.S., in the epicentre of the commercial, for-profit remunerated system, there are now non-remunerated source plasma collections in the not-for-profit sector. For instance, the Blood Source (recently acquired by Blood Systems Inc.) not-for-profit plasma operation collects approximately 10,000 litres annually in Northern California. This program started as a niche part of the overall Blood Source operation but, as demand for whole blood began to decline, blood donors were moved to the plasma program so as not to lose them from their donor base. Blood Source closely monitors the donor bases of the two programs to ensure that both have sufficient numbers of donors appropriate to the program.

In terms of Canadian Blood Services' plan in Canada, as stated in the answer to Question 1, we will be using key learnings from these examples and others with success in plasma collection, including the option of partnership to enlist best practices from experienced, reputable and proven plasma collection experts.

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In terms of Ig utilization, it is worth noting here that Canadian Blood Services does everything within its purview to save or avoid costs on Ig and other expensive drugs for our government funders. The significant savings of the recent RFP for plasma protein products is an excellent example of this. Canadian

Blood Services is also a willing partner in helping governments reduce product utilization within their jurisdictions, as outlined in our plan. Utilization is a major factor in the plasma sufficiency equation for Ig. Increasing the supply of plasma for Ig and tackling Ig usage go hand in hand as we manage costs and ensure the security of Canada's plasma supply. Addressing Ig utilization in partnership with governments is a purpose only the publicly funded and accountable national blood operator would have. Commercial, for-profit operators would not have an interest in curtailing the use of product by health systems, for obvious reasons.

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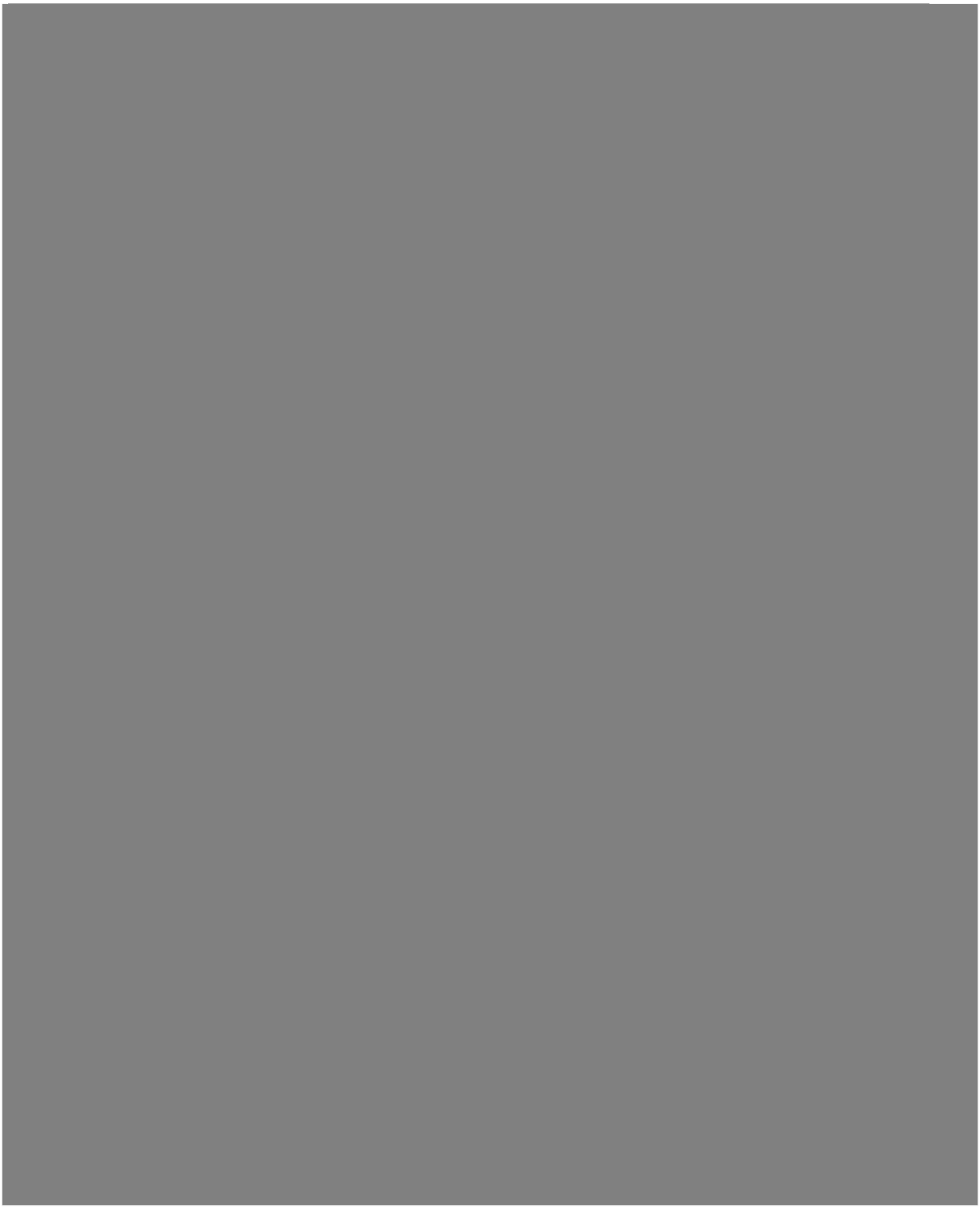

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These and other examples highlight how important it is address the security of the plasma supply for Ig now. We know the demand for Ig (and other proteins) is growing and will grow for years to come. Clearly, commercial plasma collectors would not be looking to enter new markets such as Canada if this was not the case. Rather, the world is seeing rapid plasma collection expansion, in both the commercial and public sectors. And, as mentioned, even the for-profit sector is warning they may not be able to meet global demand. The World Health Organization and other authorities are, therefore, calling for countries to collect more plasma domestically to ensure security of supply.

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Canadian Blood Services is answering this call for Canada on behalf of F/P/T governments, and we will do so via a sustainable, responsible and affordable approach. [redacted]

Our plasma collection plan is very transparent in laying out a total plan over multiple years to reach 50 per cent domestic plasma sufficiency via plasma collection from non-remunerated donors (as a reminder, 50 per cent sufficiency is the minimum level needed in Canada to ensure security of supply to meet the needs of those patients for whom Ig is a lifesaving therapy with no alternative).

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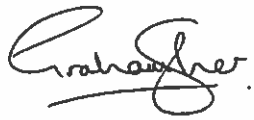
I hope this information is helpful. I welcome further dialogue as we work through these issues and find consensus on how best to support the national blood system and the Canadian patients who depend on it.

Sincerely,



Dr. Graham D. Sher

c.c.: Federal/Provincial/Territorial Ministers of Health
Mel Cappe, Chair, Board of Directors
Max Hendricks, Deputy Minister of Health
Judy Hoff, Director, Transfusion Services
Jean-Paul Bédard, Vice-President, Public Affairs
Lindy McIntyre, Director, Government Relations
Pierre Cyr, Director, Board and Stakeholder Relations