



**Canadian
Blood
Services**

BLOOD
PLASMA
STEM CELLS
ORGANS
& TISSUES

**Senate Submission: S-252
Voluntary Blood Donation
Act**

March 13, 2019

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Who we are

Canadian Blood Services was established through a memorandum of understanding between the federal, provincial and territorial governments following the Royal Commission of Inquiry by Justice Horace Krever into Canada's blood contamination crisis. We opened our doors in September of 1998.

As the national blood authority in Canada (except in Quebec, which has Héma-Québec), Canadian Blood Services is responsible and accountable for ensuring the safety and security of the supply of blood and blood products, including plasma, for Canadians.

Recognizing blood as a public resource, Canadian Blood Services acts in the best interest of Canadians according to the ministerial principles upon which the national system was founded. Included among these principles are the following:

- Donors should not be paid.
- A national blood supply program should be supported and maintained.
- Access to blood and blood products should be free and universal.
- The safety of the blood supply system is paramount.

Canadian Blood Services' funding comes largely from provincial and territorial (P/T) governments. P/T health ministers are the members of the Canadian Blood Services corporation and appoint our board of directors. Health Canada is the system regulator, and also provides funding for research and development, and for national organ and tissue donation and transplantation activities.

Canadian Blood Services operates within a broader national network of Canadian health-care systems, and provides health services, including blood and blood products, as well as transfusion and stem cell registry services, on behalf of all provincial and territorial governments.

We work with patient groups, clinicians, health-care organizations and governments to improve patient outcomes, help health systems operate more effectively and derive the best quality and value from our collective public investments. In collaborating with this diverse community of stakeholders, Canadian Blood Services is an active contributor to both national and international networks focused on transfusion and transplantation in the following key areas:

Blood for Life

We collect, test and manufacture blood and blood products, including red blood cells, platelets and plasma. We also provide diagnostic laboratory testing services. Our research efforts yield new knowledge, processes and technologies for the manufacturing environment, while



helping to improve quality and efficiency in the blood supply chain — and indeed across our entire scope of operations.

Plasma for Life

We collect plasma from volunteer, unpaid donors in Canada for two purposes: first, to meet the transfusion needs of Canadian patients, and second, to ship to contract manufacturers where the plasma undergoes a process called fractionation and then is returned as biological therapies called plasma protein products (PPPs) for Canadian patients. These products treat patients with a variety of life-threatening conditions. While over 20 specific proteins are purified from human plasma, the main category we are concerned about within this context is immune globulin (Ig). Canadian Blood Services is responsible for ensuring an appropriate level of plasma sufficiency in Canada to secure Ig for Canadian patients. We also bulk purchase (tender) PPP drugs, including Ig, manufactured by the global pharmaceutical industry and then distribute these products to hospitals across the country.

Stem Cells for Life

We operate several programs that support better outcomes for patients living with the many diseases and disorders that can be treated with stem cell transplants. We collect umbilical cords to manufacture stem cells through our cord blood bank. We operate a robust national registry of adult stem cell donors and participate in an international network of donor registries. And we provide human leukocyte antigen (HLA) typing services to ensure the best possible matches between stem cell donors and patients.

Organs and Tissues for Life

We manage a national transplant registry for interprovincial organ sharing, as well as related programs for donation and transplantation. Working with partners across the organ and tissue donation and transplantation (OTDT) community, we develop leading practices, support professional education and public awareness activities, and collaborate on new ways to share data on the performance of the OTDT system in Canada.

Ensuring plasma for Ig sufficiency

Canadian Blood Services is responsible to Canadians and accountable to governments for ensuring an appropriate supply of Canadian plasma to make immune globulin for Canadian patients.

Canada's sufficiency strategy has evolved over the years. National self-sufficiency was originally encouraged in the founding memorandum of understanding between the federal and provincial and territorial governments, primarily due to the safety and security of supply concerns that were prevalent during the tainted blood crisis.

In the years that followed, in Canada and internationally, significant technology improvements changed the safety paradigm and regulatory oversight for fractionated plasma products, making these products inordinately safe, no matter if the plasma was sourced from a non-remunerated or paid donor.



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In 2003 and 2004, Canadian Blood Services consulted with patient groups, clinicians, F/P/T governments, industry and other blood operators. This consultation resulted in a consensus recommendation that Canada should move away from the pursuit of self-sufficiency. Informed by the vCJD (mad cow) experience in the U.K., and from lessons learned in Canada when there were interruptions to the supply of domestic products, Canadian Blood Services and blood system leaders understood total self-sufficiency to be riskier to security of supply than a diversified approach.

Based on this consensus, Canadian Blood Services established a target of 40 per cent Ig sufficiency, meaning 40 per cent of Canada's Ig needs would be made from plasma collected by Canadian Blood Services, with 60 per cent of Ig products purchased on the international market. (These products are largely made by the commercial industry from U.S. sourced plasma from paid donors. Every country purchases these drugs on the global market as part of ensuring these life-saving products are available to their patients.)

By 2009, we had secured the services of two fractionators to process Canadian plasma and had diversified the vendor base for commercial Ig products. This reduced the risk of a supply interruption. As a result, the previous Ig sufficiency target of 40 per cent was lowered to a range of 28 to 30 per cent.

In the ensuing years, the growth in demand for Ig in Canada did not slow (despite utilization controls), and the amount of recovered plasma we shipped for fractionation declined as whole blood collections declined, due to reduced hospital demand for red blood cells. These two factors effectively reduced the proportion of Ig made from Canadian plasma, a concern we have been drawing attention to for the past five years. To help mitigate concerns, we also purchased recovered plasma derived from the blood donations of non-remunerated donors at FDA licensed non-profit centres in the U.S., to supplement our plasma sent for contract fractionation. We have not and do not purchase plasma from for-profit plasma collectors. This has helped ensure Canadian Blood Services' control of its PPP supply chain on behalf of Canadians and is also aligned with founding ministerial principles which state donors should not be paid.

Currently less than 14 per cent of Canada's plasma supply for Ig is protected through the collection of plasma by Canadian Blood Services, and yet approximately 50 per cent of the demand for Ig is for patients whose lives depend on it. The critical supply of Ig for these patients must be protected in the event of a prolonged shortage of product arising from ongoing growth in global demand, and a limited supply.

Risk to global supply of plasma for Ig

Canadian Blood Services, in its role as national blood authority and operator responsible for ensuring safety and security of Canada's plasma supply for Ig, has been alerting F/P/T governments to emerging risks to global security of supply.



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With a steady increase in the global use of Ig, and the predicted growth of Ig use in emerging health systems like China, India and Eastern Europe, the demand for PPPs, including Ig, will go up. The plasma fractionation industry estimates that worldwide demand for Ig will double over the next 10 years. In Canada, an annualized seven per cent increase in Ig usage is the current trend. At the same time, there is declining availability of Canadian plasma to make into the Ig needed by Canadian patients.

While the risks are not immediate in Canada, other countries around the world have already experienced Ig supply constraints. There are concerns and evidence from commercial plasma collectors in the U.S. that at some point, the market in the U.S. will begin to reach capacity. Even these commercial plasma collectors are urging all countries to do more to mitigate this concern.

At the recent European Directorate for the Quality of Medicines (EDQM) Plasma Sufficiency Symposium in January 2019, information was presented that the global demand for plasma derived products will continue to increase internationally through 2023. There was also discussion that countries around the world are becoming increasingly attentive to the growing risks of dependence on the U.S. and Europe for products. The United Kingdom, France, Netherlands, Romania, Cyprus, Greece, Hungary, Latvia, Portugal and Lithuania have all reported experiencing supply tensions, supply instability or insufficient supply to meet their needs at given times.

The critical supply of Ig for patients who depend on this product to live must be protected in the event of a prolonged shortage of product arising from ongoing growth in demand globally and a limited supply. The question is not if we will see product shortages, but when.

With several years needed to ramp up collections to address a future risk, the time to act is now.

Other countries have been increasing domestic plasma collection to mitigate risk. Within Canada, Quebec has already substantially increased its plasma collection capacity. Canadian Blood Services has been acting by maximizing plasma collections within its existing infrastructure and will soon implement a program of three plasma collection centres to test a new plasma collections model to ensure operations are as cost-effective and efficient as possible.

Canadian Blood Services' plan to collect more plasma

In January 2017, Canadian Blood Services submitted a business plan to federal, provincial and territorial governments, which outlined the looming risk to the security of the plasma supply for Ig. The plan detailed how this risk could be mitigated by significantly increasing the plasma it collects via non-remunerated donors.

Since the tabling of the 2017 plan, our thinking has evolved, both in response to changing dynamics in the collection environment, and as a result of many international knowledge exchanges.

For instance, Canadian Blood Services has learned a great deal from international plasma collection industry expertise and from partner organizations like the Australian Red Cross Blood



Service, Sanquin in the Netherlands, and Plasmavie (Hema-Quebec), who are all further ahead in this area. We continue to work with these organizations, and other operators who have successfully implemented programs to increase domestic sufficiency using non-remunerated donors, to learn their best practices for employing an efficient and effective strategy.

To this end, we have developed and will be implementing a program of three proof-of-concept plasma collection sites — a test-and-learn model for changing the way we collect source plasma. The proof-of-concept program will demonstrate that the new design concept needed for source plasma collection is achievable and operationally efficient and effective.

This new model is different from the way we collect source plasma today, but its foundational elements are still firmly premised on the principles underlying the blood system in Canada. With the proof-of-concept program, we intend to be as cost-effective, efficient and price proximate to commercial plasma collectors as possible.

Commercial plasma collection in Canada

Throughout our planning and efforts to mitigate supply risks and increase plasma collection, Canadian Blood Services has been continually asked about commercial plasma collection in Canada, and if we would purchase plasma from commercial, for-profit entities, such as Canadian Plasma Resources, who choose to set up in provinces where they are allowed to operate.

Canadian Blood Services recognizes there are divergent views about the new dynamic of commercial, for-profit plasma collection in Canada. While there is absolute agreement that patient care is, and must be, the primary concern for all — and that we must work together to ensure a sustainable, safe and secure supply of source plasma for the country — there is lack of consensus regarding the involvement of commercial, for-profit plasma collection operating outside of the national system.

For Canadian Blood Services, the considerations are many. For one, purchasing raw plasma collected by for-profit, commercial plasma collectors who pay their donors is not aligned with the founding blood system principles that remain in force today. And while commercial plasma collection in the U.S. has coexisted with not-for-profit blood collectors for decades, we are aware of growing concerns in the U.S. that the continual expansion of commercial enterprises that pay donors is impacting whole blood collections from unpaid donors, a concern referred to as “crowding out.”

Within this context, we have 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. This must be considered carefully and responsibly by Canadian Blood Services and health system leaders as to consequences and impacts. Internationally, it has been discussed 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.



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Most significantly for Canada, 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 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.

Further, 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, as the publicly owned and operated national blood system, on behalf of ministers of health. Our purview includes the ability and agility to make informed, responsible and responsive decisions about where, when and how to collect blood and plasma to meet needs of Canadian patients now and in the future.

Conclusion

As the blood authority in Canada, Canadian Blood Services welcomes discussion on these and other issues affecting the blood system. Canada (except Quebec) has fallen below the international standard of care necessary for mitigation of supply disruptions. The current dialogue is an important one for the country to have, as Canadians support our efforts to increase the country's plasma collection and ensure security of supply of life-saving products for the patients we serve.