

Considerations related to repeal of the Voluntary Blood Donations Act, Alberta

Who we are

Canadian Blood Services was established through a memorandum of understanding among the federal, provincial and territorial (P/T) governments following the Royal Commission of Inquiry led by Justice Horace Krever into Canada's tainted blood crisis. We began operations in September of 1998.

As the national blood authority in Canada (except in Quebec, where Héma-Québec operates), 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 set out in the memorandum of understanding which founded the national blood system. Included among these principles are the following:

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

We collect blood and plasma donations through an integrated collections strategy which seeks to balance supply and demand across the country.

In 2019, governments reaffirmed Canadian Blood Services' role as the national blood authority, with responsibility for the safety and security of the national blood supply in a National Accountability Agreement. This agreement outlines the accountabilities, roles and responsibilities of Canadian Blood Services and P/T governments.

Canadian Blood Services' funding comes largely from P/T governments. P/T health ministers are the corporate members of Canadian Blood Services and appoint our board of directors. We are regulated by Health Canada as a biologics manufacturer. Health Canada also provides funding for research and development, and for national organ and tissue donation and transplantation activities.

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

We work with health-care organizations, clinicians, governments and patient groups to improve outcomes, ensure the blood supply system operates effectively and to derive the best quality and value from 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, process, test, store and distribute 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 across our entire scope of operations.

Plasma for Life

We collect plasma from nonremunerated 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 (separation into specific plasma proteins for therapeutic purposes). These contract-manufactured plasma protein products (PPPs) are licensed by Health Canada as biological therapies. Once manufactured, these PPPs derived from our plasma are returned to Canadian Blood Services for distribution to Canadian patients. They are exclusively licensed for this use and cannot be sold elsewhere. 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).

In addition to distributing these contract-manufactured PPPs, through competitive tenders we also bulk purchase PPP drugs, including Ig, manufactured by the global biologics industry and then distribute these products to hospitals across the country. Through these procurement processes, we provide brand diversity, product choice and state-of-the-art products while obtaining highly favourable pricing. Having a portion of the PPP supply derived from our collected plasma and purchasing a portion from the global plasma industry offers a diversified supply and is an important risk mitigation strategy for Canada. The power of bulk purchasing for all the provinces and territories (except Quebec) also ensures significant price and therefore cost advantages for the health systems we serve. For example, as a result of two rounds of procurement, we have delivered cumulative value to corporate members (in terms of both savings and cost avoidance) that will be more than \$1.2 billion between 2013–2014 and 2020–2021.

Stem Cells for Life

We provide stem cell products and services for patients living with the many diseases and disorders that can be treated with stem cell transplants. We collect umbilical cord blood stem cells through our cord blood bank. We operate a national registry of adult stem cell donors and participate in an international network of donor registries to identify potential stem donors for patients requiring stem cell transplants.

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.

Canadian Blood Services' footprint in Alberta

For more than 20 years, provincial governments like Alberta's have been investing in, and benefiting from, Canada's national blood and plasma supply chain. Our model means provincial governments in Canada can cost-share and achieve together what no one province can do alone. Today, our footprint in and relationship with Alberta is substantial. Currently, we:

- serve more than 100 hospitals in the province
- welcome over 75,000 whole blood donors annually
- are home to approximately 600 employees
- are privileged to engage with over 1,300 volunteers
- and work with more than 1,200 corporate and community partners across Alberta.

In addition to the hundreds of donor events held across the province each year, we recently completed construction on a state-of-the-art, national biologics manufacturing, production and testing facility in Calgary. This is the most modern, purpose-built blood manufacturing and testing centre in Canada. Each day we process 25 per cent of the national volume through that facility, and test 40 per cent of all samples on a daily basis.

We also have a new donor centre in Calgary, a production and donor centre in Edmonton (the best performing donor centre in the country), and a donor centre in Red Deer. Our donor centre in Lethbridge will be relaunched later this year as a dedicated plasma collection site.

Most importantly, however, when Albertans need us, we are there. One integrated supply chain across Canada managed by a single system operator means that we can respond to any range of circumstances — from moving inventory regionally or nationally when bad weather, a natural disaster, or a pandemic keeps donors away — to calling on donors across the country to show their support and replenish reserves should there be a substantial human trauma.

Ensuring plasma for Ig sufficiency

Canadian Blood Services is responsible and accountable to governments for ensuring an appropriate level of plasma sufficiency in Canada to make into Ig. Plasma sufficiency means the percentage of plasma collected and controlled by a country's national blood system to be made into Ig for its patients.

Throughout the past twenty years, Canadian Blood Services has ensured a secure supply of Ig through a balanced, diversified and cost-conscious approach: we collect a percentage of plasma which is sent to manufacturers (fractionators) contracted by us to make Ig, and we bulk-purchase the rest of the Ig needed for Canada's patients on the international market. As per our mandate, we collect blood and plasma donations through an integrated collections strategy which seeks to balance supply and demand across the country – something not required of commercial plasma collectors.

In recent years, we have been alerting governments to an emerging global security of supply risk related to plasma for Ig. In doing so, we have often noted that assigning control of plasma to commercial, for-profit businesses does not mitigate supply risk for Canadian patients. This is because 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.

Further, most large commercial plasma collectors are vertically integrated with the global fractionation industry. The raw plasma they collect from paid donors is directed to their own manufacturing sites, and not to entities outside their own supply chain. Once fractionated into finished PPPs, these companies then sell the end products on the international market. There are also a small number of for-profit plasma collectors that are not vertically integrated in this way, which sell their plasma to manufacturing sites within the global industry to make into plasma therapies that, again, are sold on the international market. One such commercial plasma collector operates in Canada in Saskatoon and Moncton.

Plasma collected in Canada by commercial collectors outside the national blood system does not, therefore, contribute directly to security of plasma supply for Ig for Canadian patients. Even if the system in Canada changed, and commercial plasma collectors were under contract to sell plasma to Canadian Blood Services, once the terms of the agreement end, the commercial collectors would be free to sell their plasma to the highest bidder on the global market.

Growing risk to global supply of plasma for Ig

There continues to be a steady increase in the use of Ig in developed nations, as a result of growing clinical indications for which it is the preferred therapy. This rate of growth has been between 6 and 8 per cent per year for many years now. In addition, there is a rapidly rising use of Ig in emerging health systems like China, India and eastern Europe, as health systems in these countries expand and adopt novel therapies.

Prior to the pandemic, the plasma fractionation industry had been estimating that worldwide demand for Ig will double over the next 10 years. In Canada, an annualized seven per cent increase in Ig usage has been the trend over many years. While the global plasma industry had largely kept pace with the demand growth, in the last few years there have been concerns around the ability of the commercial sector to sustain its collections growth capacity, and many countries are implementing strategies to collect more plasma via the publicly accountable systems to meet domestic sufficiency needs.

As of early 2019, countries around the world were experiencing Ig supply constraints, with concern that the U.S. market would begin to reach capacity. In August of 2019, the U.S. Food

and Drug Administration declared an Ig shortage. During this time, no patients served by Canadian Blood Services went without acceptable and effective treatments due to the strengths of the country's blood system supply chain, and our diversified approach to product acquisition.

Since the COVID-19 pandemic, risk to the supply of plasma for fractionation has increased significantly. In Europe, some manufacturing plants are operating intermittently because of staff absenteeism due to the pandemic, and there are sustained and serious indications of a decreased ability to collect plasma in the United States and resulting product constraints to come in the next six to twelve months.

In the U.S., beyond growing infection rates, the principal drivers for this pending supply chain impact are both economic and operational:

- the federal COVID-19 financial programs in the U.S. have removed the financial incentives of many who use plasma donation as an added source of income; and
- the physical distancing implications and related adjustments needed to the commercial service delivery model are having an impact.

There is also the potential for additional collection and supply constraints as further large volumes of plasma are needed to support hyperimmune globulin production for the global market as a COVID-19 treatment.

U.S. protectionism may also become a factor in the future. Since the onset of the pandemic, the U.S. move to retain or secure essential supplies and drugs, including a move to secure the world's supply of remdesivir, has been a challenge for Canada and other countries. Given this context, it is not unreasonable to apply this concern to global Ig supply constraints.

Canadian Blood Services' plan to collect more plasma

Given this elevated risk environment, it is more important than ever that the supply of Ig for patients who depend on this product be protected. To ensure this critical need is met, Canadian Blood Services has been advising governments that we must increase Canada's domestic sufficiency target to a 50 per cent level. This would mean that 50 per cent of Ig needs in Canada are met through Canadian Blood Services' collections of plasma for fractionation into Ig products. The remaining 50 per cent would continue to be met by purchasing Ig products on the international market. This approach:

- reduces reliance on the international market, and in particular a single geographically concentrated region (the U.S.) by increasing Canadian collections of plasma for fractionation,
- ensures domestic supply for patients who have a critical product need,
- increases the blood operator's ability to negotiate even better prices for Ig products by contributing more raw plasma for their fractionation, and
- diversify risk by drawing appropriately on both Canadian and international capacity.

Canadian Blood Services is taking steps to significantly expand source plasma collections. In 2019, we received approval and funding from P/T ministers of health to begin measures to increase Canada's plasma supply with three new plasma collection centres. The first two will open in 2020 in Sudbury, Ontario and Lethbridge, Alberta, and a third in Kelowna, B.C. in 2021. We look forward to our success with these centres and the investments they will make in the communities within which they operate.

These dedicated plasma collection sites will implement a new, leaner approach for collecting plasma from non-remunerated donors, with an operating model that is price proximate to commercial plasma collection. To help ensure we achieve this goal, we are enlisting commercial sector expertise and best practices from international colleagues in the not-for-profit sector. This model will bring together the best of the commercial sector's efficiency, productivity and market savvy, while leveraging Canadian Blood Services' trusted brand and ensuring all outputs are under the stewardship and public accountability of Canada's blood system.

Commercial plasma collection in Canada

The appearance of commercial, for-profit plasma collection in Canada has created a debate and divide in the country in the past few years. Commercial collection is a relatively new dynamic and paradigm shift for the country. It is appropriate to review and assess what this does or could mean for the national blood system, and to carefully examine the potential impacts and implications for the security of supply of blood and blood products for Canadian patients. This debate requires resolution, particularly in the face of critical Ig sufficiency challenges and the escalated global shortage risk due to COVID-19 impacts.

The main points for Canadian Blood Services around the matter have been the following:

- Large-scale growth of commercial plasma collectors, without adequate controls, is the major concern; a limited number of small collectors can likely co-exist with national system with minimal harm in terms of encroachment.
- While the evidence for encroachment (or “crowding out”) is hard to prove conclusively, executives of larger American blood system operators continue to express grave concern about impacts to their operations from the rapid growth of the commercial plasma sector across the U.S. Market intelligence provides suggestive evidence of encroachment in approximately 40 per cent of U.S. markets examined.
- Canadian Blood Services does not “buy back” plasma once it has been processed by international fractionators, nor does it purchase raw plasma from commercial, for profit collectors in the U.S. With regard to plasma for fractionation, we do two things:
 - We collect plasma from nonremunerated donors to ship to contract manufacturers where the plasma is fractionated into PPPs, which are licensed by Health Canada as biological therapies. Once manufactured, the PPPs derived from our plasma are returned to Canadian Blood Services for distribution to Canadian patients. They are exclusively licensed for this use and cannot be sold elsewhere.
 - Through competitive tenders, we also bulk purchase finished PPP drugs, including Ig, manufactured by the global biologics industry and then distribute these products to hospitals across the country. Via these procurement processes, we provide brand

diversity, product choice and state-of-the-art products while obtaining highly favourable pricing for the jurisdictions we serve.

- Having a portion of the PPP supply derived from our collected plasma and still purchasing a portion of these medicines from the global plasma industry is not hypocritical. It offers a diversified supply and is an important risk mitigation strategy for Canada.
- Canadian Blood Services is not among the highest bidders for Ig globally. The power of bulk purchasing for all the provinces and territories (except Quebec) ensures significant price and, therefore, cost advantages for the health systems we serve. As a result of two recent rounds of procurement, we have delivered cumulative value to corporate members that will total more than \$1.2 billion between 2013–2014 and 2020–2021.
- Canadian Blood Services is not against the commercial plasma industry. We recognize that patients around the world rely on the commercial industry for these needed therapies. Products from the sector form an important part of our strategy

Conclusion

Canadian Blood Services recognizes this is a complex topic. We know we must collect more plasma in this country. We have been seeking support for this for the past number of years and are opening new dedicated plasma collection sites beginning this summer. In addition, we have been calling for dialogue with ministers of health to reach consensus on how as a country we should or could approach the emerging paradigm of commercial plasma collection expansion in relation to the national blood system principles and operations.

Currently, Ontario, British Columbia, and Alberta have laws prohibiting payment for donations (Quebec also prohibits payment for donations). This legislative landscape recognizes the principles underpinning the national blood system established by federal, provincial and territorial ministers of health.

The private member's bill in Alberta to repeal the Voluntary Blood Donations Act adds urgency to the need for solutions and consensus. Canadian Blood Services has continued to respectfully ask for a pause on any legislative interventions in this sphere until such time that ministers and Canadian Blood Services have discussed and determined the conditions that should govern commercial plasma collection so that it does not jeopardize the voluntary blood and plasma system in Canada.

Attachments:

- Attached is Canadian Blood Services' response to MLA Tany Yao after he requested input on his intention to introduce a private members' bill relating to the Voluntary Blood Donations Act.

February 20, 2020

Tany Yao
MLA for Fort McMurray-Wood Buffalo
Federal Building 9820-107th Street
Edmonton, AB T5K 1E7

Dear Mr. Yao:

Thank you for your letter of February 3 informing Canadian Blood Services you are investigating the possibility of amending *The Voluntary Blood Donations Act* in Alberta and for the opportunity to comment. This is an important area of our mandate from health ministers and we want to work with you to ensure a thoughtful approach to blood system matters.

As you may know, Ontario, British Columbia, Alberta, and Quebec have laws banning payment for blood donations, which include donation of red blood cells, platelets and plasma. In recognition of our role as national blood authority and system operator in Canada (except in Quebec, which has its own publicly funded and accountable blood operator, Héma-Québec), Canadian Blood Services is exempt from these laws.

This legislative landscape recognizes the principles underpinning the national blood system established by federal, provincial and territorial ministers of health through a memorandum of understanding in 1997. It also responds to a relatively new dynamic in Canada, the emergence of commercial, for-profit plasma collection with payment to donors. We believe this landscape provides the country with an appropriate forum and opportunity for a needed dialogue among ministers of health and Canadian Blood Services to reach consensus on key matters, including:

- how as a country we should or could approach this new dynamic;
- under what conditions should or could commercial plasma activity take place; and,
- what considerations should be assessed to ensure no negative impact or encroachment impedes national blood system operations.

From our perspective, given our mandate, the question is not whether donors should be paid, but rather how should Canada, as a country, best manage the supply of plasma and plasma protein products. While we would not interfere with legislative matters, until the country's health system leaders have had this essential, collective dialogue, Canadian Blood Services would necessarily express concern with legislative change deemed to have the potential to impact the national system and our ability to collect blood and plasma from non-remunerated donors.

To be clear, Canadian Blood Services is not against paying for plasma donations, and not against the commercial plasma industry. Patients in Canada and internationally rely on access to the commercial industry for the products they need, so much so that some patient groups have been calling for repeals of any bans on paying donors. That said, in Canada, the responsibility and accountability for the national system of blood and blood products for Canadian patients rests with Canadian Blood Services. We fulfill this mandate according to founding principles from ministers of health, which include the following:

- the safety of the blood supply is paramount;
- a fully integrated approach is essential;

- voluntary donations should be maintained and protected;
- adequacy and security of all needed blood, components and plasma should be encouraged;
- gratuity of all blood, components and plasma fractions to recipients within the insured health services of Canada should be maintained;
- a cost-effective and cost-efficient blood supply program for Canadians should be encouraged;
- a national blood supply program should be maintained.

Within this context, a main focus of our mandate is ensuring an appropriate level of plasma sufficiency in Canada to make into a life-saving product called immune globulin or Ig, for Canadian patients. Plasma sufficiency means the percentage of plasma collected and controlled by a country's national blood system to be made into Ig for its patients.

Throughout the past twenty years, Canadian Blood Services has ensured a secure supply of Ig through a balanced, diversified and cost-conscious approach: we collect a percentage of plasma which is sent to manufacturers contracted by us to make Ig, and we bulk-purchase the rest of the Ig needed for Canada's patients on the international market. As per our mandate, we undertake plasma collections in harmony with blood collections to ensure they are integrated and not in conflict with each other – something not required of commercial plasma collectors.

In recent years, we have been alerting governments to an emerging global security of supply risk related to plasma for Ig. In doing so, we have often noted that assigning the control of plasma to commercial, for-profit businesses does not mitigate supply risk for Canadian patients. This is because 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.

In 2019, Canadian Blood Services received approval and funding from provincial and territorial ministers of health to begin measures to increase Canada's plasma supply with three new plasma collection centres. The first two will open in 2020 in Sudbury, Ontario and Lethbridge, Alberta, and a third in Kelowna, B.C. in 2021. We look forward to our success with these centres and the investments they will make in the communities within which they operate.

Alberta, in particular, has always played a critical role as a dedicated blood and plasma donor base for the country. Canadian Blood Services also just completed construction on a state-of-the-art, LEEDs certified, national biologics manufacturing, production and testing facility in Calgary and a new modern "Donor Centre of the Future" collection site in Edmonton. We would be pleased to host you on a tour of any of our Alberta facilities to further aid in your understanding of our operations and Alberta's importance to the national system.

Thank you, again, for informing us of your investigation regarding *The Voluntary Blood Donations Act*, and for the opportunity to comment. We recognize this is a highly complex issue and have attached a question and answer document to help aid your review. We look forward to speaking with you, and with the Minister of Health, who is a corporate member of Canadian Blood Services, to address this matter further and to answer any questions you may have.

Sincerely,

Pauline Port, (Acting for) Dr. Graham D. Sher
Chief Executive Officer, Canadian Blood Services

Q: What is Canadian Blood Services' mandate in Canada? Who are its funders?

A: 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 by separating it from donated whole blood units (recovered plasma) at our processing facilities, as well as through a specific plasma donation procedure called apheresis (source plasma) where only the plasma is collected from a donor and all other blood components are returned to the donor via an apheresis machine (source plasma). We collect plasma from volunteer, unpaid donors 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.

Q: How did the country's plasma strategy evolve?

A: 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.

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. (There were no Canadian fractionators licensed by Health Canada at this time.) 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.

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. It is within this context that governments in Canada have now supported Canadian Blood Services to collect more plasma, started with three new centres in Sudbury, Lethbridge and Kelowna, starting in 2020.

Q: What are Canadian Blood Services' views on commercial plasma collection in Canada?

Canadian Blood Services recognizes there are divergent views about commercial, for-profit plasma collection in Canada. We are not against payment for plasma or the global commercial plasma industry. Both of these dynamics form a part of our strategy for a secure supply.

Canadian Blood Services is the blood authority and operator in all provinces and territories except Quebec. It is our mandate to manage the supply of plasma for transfusion and fractionation and to purchase plasma protein products on behalf of our corporate members, the provincial and territorial ministers of health. From our perspective, the question is not whether donors should be paid, but rather how should Canada, as a country, best manage the supply of plasma and plasma protein products.

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.

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 growth 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.

Most significantly for Canada, assigning the control of 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 a 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, the national blood operator acting 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.

Q: Why did Dr. Sher speak out against a prohibition on paid plasma in 2013?

A: In 2013, emerging risks to the global security of supply for Ig were not yet fully known. Rather, the key concern of many stakeholders with regard to growing commercial plasma collection in Canada was that plasma collected from donors who have been paid was unsafe. Within this context, Dr. Sher spoke out to clarify that this is not true. At that time, the organization felt it was essential to communicate that a broad prohibition against importing commercial plasma protein products based on a mistaken understanding that plasma from paid donors is not safe would harm patients.

Like blood operators in many other countries, Canadian Blood Services and Héma Québec purchase plasma protein products made by international pharmaceutical companies from the plasma of donors who have been paid (typically American donors). These drugs are essential for the health of thousands of patients in Canada. If these drugs were unsafe, they would not be approved by the country's drug regulator, Health Canada, and Canadian Blood Services would not import them as part of its strategy to maintain a secure supply.

Q: Why doesn't Canadian Blood Services buy plasma from Canadian Plasma Resources?

A: Canadian Blood Services does not buy raw plasma from commercial collectors; we buy finished drugs on the global market.

Further, Canadian Plasma Resources could only provide limited volumes, in limited markets, and therefore does not offer domestic security of supply. More to the point, assigning control of plasma collection to a commercial for-profit collector that is free to sell their plasma anywhere in the world does not offer long-term sustainability of security of supply for the country. Should Canadian Blood Services secure volumes of plasma from a for-profit company that then exited the market or chose to sell their plasma outside of Canada, it would be extremely difficult to fill the void because of the time it takes to ramp up plasma collections under any model, remunerated or non-remunerated.

Q: Would a compensated model of plasma collection in Canada not contribute to assuring a safer supply for the country?

A: We've assessed the experience of many of our peers and believe it is possible to substantially increase plasma sufficiency in a non-remunerated model. In Quebec, immune globulin (Ig) sufficiency, the measure by which blood operators assess security of supply, has grown from 15 to 21 per cent in a non-remunerated model in recent years. In Australia, Ig sufficiency is currently at 55 per cent in a non-remunerated model, with a target of 70 per cent. We have experience in recruiting donors in a non-remunerated environment. We are also

leveraging the expertise and operating efficiency of the commercial plasma sector to understand how they do their operations efficiently. We don't believe, at this point, there is a need to emulate their remunerated donor recruitment strategy.

Q: Is it hypocritical to buy plasma products made from the donations of American who are paid for their plasma? If we can't justify compensating plasma donations here, in Canada, how can we continue to buy products that are made from plasma collected from companies in the United States, who compensate their donors?

A: As per the principles and the mandate under which Canadian Blood Services operates, we are seeking to grow our donor base in a non-remunerated model. Within this model, we purchase finished pharmaceutical products on the international market, as is the practice in most developed nations. Rather than being hypocritical, this approach is a matter of diversification of risk. Understanding that there is no safety issue with products made from the plasma of paid donors, many countries buy finished plasma products on the global market, even those in Europe and Australia, where remuneration is prohibited by law, in order to take advantage of risk diversification.

Q: What is Canadian Blood Services' target in increasing Ig sufficiency?

A: Outside of Quebec, Canadian Blood Services maintains responsibility for 100 percent of Canada's plasma supply for both transfusion and for fractionation into plasma products such as Ig. The recommended target is that Canadian Blood Services collects 50 percent of the plasma needed to meet Canadian Ig demand, balanced with its contracting of U.S. suppliers for the purchase of commercial products to meet the other 50 per cent of patient need.

This approach provides a diverse, secure supply for Canada. Under this scenario, in the event of a supply crisis external to Canada, such as a protectionist U.S. market, there would be enough Canadian-sourced plasma to create Ig for patients who depend on this product to live. And should Canada experience an emerging pathogen that compromises its plasma supply chain, the country would have the appropriate commercial relationships in place in the global community to continue to meet the needs of patients.

Q: Does Canadian Blood Services have a role in building plasma processing facilities in Canada?

A: Canadian Blood Services has always partnered with the fractionation industry to manufacture products from Canadian plasma. Canada has not had a fractionator in the past, but, Green Cross, a Korean-based pharmaceutical manufacturer is set to begin operations in Montreal Quebec in the near future.