



Report to the Senate Committee on Social Affairs, Science and Technology

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Date: Wednesday, February 27, 2019

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Presentation:

Thank you, chairperson, Senator Petitclerc and senate committee members for the invitation to provide testimony regarding impact of Bill S-252, Voluntary Blood Donations Act on plasma product availability for Canadian patients. If the bill were passed today as written it would essentially shut down the collection of speciality plasmas in Canada. Shortage of this plasma, used to manufacture hyperimmune plasma medicines, would impact on availability of Anti-D Immune Globulin as well as impact development of other speciality plasma medicines. I will provide background on the Winnipeg Plasma Collection center, past and present, its contribution to plasma derived medicines and lessons learned during my 38 years in the Canadian plasma industry.

During my career in the plasma collection/fractionation industry starting with Winnipeg Rh Institute, I worked in quality, development and manufacturing operations of blood plasma products. I was fortunate enough to serve on the Canadian Blood Safety council, an initiative established as a result of the Krever report. I am currently employed by Prometic Plasma Resources, a wholly owned subsidiary of Prometic Life Sciences Inc (Appendix A).

Prometic Plasma Resources was established in 2015, when Prometic purchased the Winnipeg Plasma Collection center from Emergent BioSolutions, formerly Cangene Corporation. The plasma collection center has a long-standing history in the supply of speciality human source plasmas used to manufacture speciality plasma products. The center originated with the Winnipeg Rh Institute in 1969, founded by Dr Jack Bowman, a pioneer in Rh disease research, who led to the development of WinRho, Anti-D Immune Globulin. This product, licensed in 1980, has saved over 4 million lives by preventing Rh disease. Throughout its history the center has paid donors for their program donation time. Many donors had contributed for over 20 years contributing thousands of liters to the program. WinRho was not only a success in Canada but over 20 countries globally. In the early days of the program, their plasma supported products in Sweden, Spain and the United States. It is my experience that plasma donations would drop off significantly without donor compensation.

There has been significant media attention around paid donation in Canada being unsafe with references to Justice Krever's report and recommendations for corrective actions to address the 1980's blood scandal in Canada. HIV and Hepatitis C viral transmissions in patients that were treated with unsafe blood and plasma products at that time was a tragedy. Lessons from that time should never be forgotten. The Winnipeg center plasma and the products made from the compensated donor plasma has never transmitted any blood borne illness. This long safety track record is attributed to the quality of the donors, strong selection programs to verify donor suitability, and ongoing improved plasma screening programs. Additionally, development of state-of-the-art plasma protein separation systems with highly evolved virus inactivation as well as virus retention systems greatly enhanced product safety. The Krever inquiry reviewed the Winnipeg special plasma collection program and deemed it to be appropriate and safe (Appendix B).

Today the center operates at the University of Manitoba, Smart Park, an industrial park adjacent to the South Winnipeg campus. It has grown from its origin at the Winnipeg Canadian Red Cross facility and has embraced not only Health Canada compliance standards but US FDA and European Medicines authority standards. Additionally it has been certified by the Plasma Protein Therapeutic Association (PPTA) voluntary standards for plasma collection, international Quality Plasma Program, iQPP (<https://www.pptaglobal.org/safety-quality/standards/iqpp>). These standards were created to address critical past issues in the industry and continue to evolve today.

When the plasma center was relocated to the university campus and expanded, CBS was consulted with efforts to not negatively impact their blood collections. The center has operated on campus without "crowding out" CBS blood donors. I personally feel that PPR raises awareness of the need for blood and blood protein products. Not many donors become 20-year anti-D donors, but all are introduced to the impact that their blood/plasma can make a difference with patients and could save lives.

The plasma center currently collects plasma to support a number of hyperimmune and speciality plasma protein programs (Appendix C):

With licensure of the new products more Source Plasma will be required. While the center has been a long-term supplier of plasma to support Canadian hyperimmunes distributed in Canada like anti-D and Hepatitis B it is a global supplier with licenses in Canada, the USA and in the future Europe. The reason for this is simple. Rare diseases have fewer patient populations and require global efficiencies to be commercially viable.

PPR is developing a plasma collection center in Buffalo, NY with twice the capacity of the Winnipeg center. Equipped with a fully automated donor and plasma management system it will become the model for future PPR collection operations.

Prometic supports the 50% plasma supply goal of CBS and will continue to support its efforts towards achieving this goal. Refer to Appendix D for an example.

The Bill S-252 has been written to protect CBS from private competition for plasma and plasma donors in Canada. I personally believe that industry can work in harmony with the blood operators with the ability to provide safe and secure plasma products for patients that are reliant on this unique source of biological products. The Health Canada report on IVIG supply speaks to Canada stepping up to contribute more plasma for patients that are reliant on plasma products. I feel that both sides can contribute synergistically to increasing overall plasma supply for the betterment of Canadian patients.

Appendix A Prometic Life Sciences Background

Prometic is a publicly traded on the Toronto Stock Exchange global biotechnology company headquartered in Laval, Quebec. Prometic's leverages its experience in bioseparation technologies used to isolate and purify biopharmaceuticals from human plasma as a drug discovery and development platform. Prometic's primary goal with respect to this platform is to address unmet medical needs with therapeutic proteins not currently commercially available, such as Ryplazim™ (plasminogen). We are also leveraging this platform's higher recovery yield potential to advance other novel and established plasma-derived therapeutics. Plasminogen, the lead product is expected to be licensed in the United States and Canada in the near future, is used to treat patients with a rare genetic disease and expected to be used in a multitude of acquired and acute plasminogen deficiencies. The follow-on plasma-derived therapeutic, IVIG, has been used to treat primary immunodeficiency patients (PID) that lack antibodies to fight disease. Prometic has a manufacturing facility in Laval, Quebec and plans to expand manufacturing into Winnipeg in partnership with Emergent BioSciences as well as Belleville, Ontario.

Appendix B Canada- Debunking the Krever Commission Report in 2018, Bill Bees, V.P Plasma Technologies, Prometic, Presented at PPTA June 2018 Plasma Forum (see Attached).

Appendix C Plasma Programs at PPR

Plasma Program	Product Supported	Country
Anti-D Source Plasma	WinRho Rho(D) Immune Globulin (Emergent BioSciences) and A Second Supplier of Anti-D	Canada and International
Source Plasma for Fractionation	Human Plasminogen for Injection and Intravenous Immune Globulin both having completed phase 3 clinical development with Prometic Life Sciences	Canada and USA pending license filings
Influenza Source Plasma:	Clinical stage Flu-Immune Globulin for Emergent BioSciences in Winnipeg, MB	Clinical Trials
Future collection of Zoster Source	Varicella Zoster Immune Globulin (Emergent BioSciences) distributed in Canada.	Canada and International

Appendix D -Support for Canadians

As an example and according to Hema Quebec and CBS annual reports, 2015/2016 Canada's costs for plasma proteins were \$ 976 million. ~66% of costs are derived from the purchase plasma-derived proteins; 34% from the purchase of recombinant proteins. With ~ 45% of the total costs, IgG represents the single most important product. Today only 17% / 17.7% (rest of Canada/Quebec) of plasma-derived protein therapeutics come from Canadian sourced plasma, provided through toll manufacturing of such plasma by fractionators situated abroad.

It is expected that the use of IgG in Canada will continue to grow at average of 6-8 % / year as it has done over the past years; by 2020 resulting in >\$ 900 million of annual costs for plasma-derived proteins being purchased to the largest extend from fractionators situated outside of Canada where paid for plasma donations are the norm.

ProMetic not only efficiently manufactures proteins abundantly present in plasma, but is an innovator in the plasma protein market, developing new products for unmet medical needs, specialized in the Orphan Disease market.