



Submission to the Standing Committee on Social Affairs, Science and Technology in regards to Bill S-252: the Voluntary Blood Donations Act (an Act to Amend the Blood Regulations)

November 5, 2018

CIPO, Canadian Immunodeficiencies Patient Organization

The Canadian Immunodeficiencies Patient Organization (CIPO), is a registered charity representing patients and those affected by Primary Immunodeficiency Diseases (PI) across Canada. We would like to thank the Standing Committee on Social Affairs, Science and Technology for accepting our submission on Bill S-252, the Voluntary Blood Donations Act (an Act to Amend the Blood Regulations).

Primary Immunodeficiency (PI) is a group of rare genetic disorders in which the immune system is either malfunctioning or missing from birth. It can affect just one cell or many parts of the immune system.

There are roughly 30,000 PI patients in Canada. Of these, only a fraction (13.5%, 4,000 patients) are currently receiving treatment. Plasma-derived therapy is the **only** treatment option currently available to PI patients.

There are over 300 different types of PI, varying in degrees of rarity (some with only 2 known cases). The average PI patient will suffer complications including: chronic infections, hospitalizations (95%), pneumonias (90%), certain cancers (50% increased risk), GI disease (60%), respiratory diseases (over 90%) and autoimmune issues (50%). (Elizabeth Tough, 2016) Without proper treatment and monitoring there is increased morbidity and mortality rates. (Elena S. Resnick, 2012)

To completely understand this issue, it is important to distinguish the separate parts of human blood: red cells, platelets and plasma. Plasma makes up roughly 55% of our blood. From plasma certain plasma derived products (PDPs) are made, including immune globulin (IG).

IG in the form of either intravenous immune globulin (IVIG) infused in hospital every 3-4 weeks, or subcutaneous immune globulin (SCIG) infused in home is a necessary and life-sustaining treatment. The recent Health Canada report on IG stated: "It is appropriate for Canada at a minimum to be able to provide sufficient plasma to meet the needs of the one group who are truly life dependent on IG – those patients with primary immunodeficiency." (Health Canada, 2018, p. 63)

Safety

The safety of Canadian patients has to remain the first priority. We will never forget the tragedy of the 1980s and are thankful to our friends in the rare blood disease world who fought to bring life-saving changes to the blood system.

The world of today is not the world it was twenty years ago, and safety and technology have made incomparable advances. Pathogen inactivation technology along with other stringent testing and safety measures to PDPs surpass rigorous regulations. We cannot continue to cite safety concerns of the past, when medicine, technology and innovation continue to move forward for the betterment of the patient. Without the innovation of the past 20 years, we would not have the HPV vaccine, the PET scan, antiretroviral therapy (HAART) for HIV patients, or a treatment and cure for Hepatitis C, just to name a few.

The last known viral transmission of HIV through a PDP in Canada was in 1987 and of HCV was in 1988. Thanks to the advancements in technology and the stringent safety measures put in place by the manufacturer, Health Canada and Canadian Blood Services, today, as patients, we are able to use PDPs with certainty, and know that our lives are safe.

Supply

Canada is currently self-sufficient in its production of plasma for transfusion, red cell and platelet needs. I am sure this committee is aware that Canada is currently only producing 17% of its source plasma needs. Canadian Blood Services purchases the remaining, through tender process, from the US market. The 83% of PDPs purchased from the US are made using paid donors.

Canadian Blood Services unveiled a plan to the provincial governments in 2017 to increase source plasma collection by 2023 to 50% self-sufficiency. The plan, similar to Héma-Quebec's Plasmavie, in which plasma collection centres will be opened in select locations across Canada, has yet to be funded by the ministries and requires the recruitment of more than 145,000 new plasma donors. This is in addition to the 100,000 new blood donors Canadian Blood Services needs to continue to recruit every year to meet Canada's red cell and platelet needs.

Recently, I sat on a panel at the European Society for Immunodeficiency (ESID) and International Patient Organization for Primary Immunodeficiency (IPOPI) conference in Lisbon. The question regarding the compensation of donors was addressed to the panel. I spoke with physicians, nurses, patient organizations and blood operators from around the world. I heard similar concerns about supply, access and pricing again and again. While we are looking at it from a directly Canadian view, it is very much a global issue.

At the moment, we are looking at how Canada can become more self-sufficient, and how Canada can contribute in greater quantity to their own supply of IG. We, as a global economy, are over-reliant on US plasma. "like most of the world, we are too dependent on one jurisdiction (US) for the supply of the vital raw material used to make these products. Canada needs to do more to collect plasma and take other steps to enhance our self-sufficiency in meeting the needs of our citizens for PDP's." (Health Canada, 2018, p. xi)

We know that the demand for PDPs continues to grow in Canada by 9% every year. We know that PI is underdiagnosed in Canada by 70%. Efforts are underway to change this and better diagnose PI patients, which would increase IG usage in Canada. A 2016 study from McMaster University looked at the incidence of PI in Canada. With new education and awareness efforts, more than 525 new PI patients were diagnosed in 2015. With the number of PI patients growing year over year, and the demand for IG steadily increasing, the strain on supply is apparent. According to the Dublin Consensus: "An insufficient supply is a major safety risk to patients" (Dublin Consensus Statement, 2011, p. 1.1)

Donors

It takes roughly 130 plasma donors to treat 1 PI patient for 1 month. It takes between 3,000 to 15,000 donors for each lot of IG produced. Where an average blood donation takes between 30-60 minutes, an average plasma donation takes 1 ½ to 2 hours. Plasma donors have to make at least two donations for the plasma to be used and the needle is substantially larger.

There have been media reports in the past few years regarding plasma collection centres opening doors across from homeless shelters. These reports have been met with public outcry, bringing memories of the tainted blood scandal to forefront. Obviously, the industry needs to collect plasma to manufacture PDPs. However, it will not accept just any plasma. It needs plasma that will pass Health Canada, FDA and in some cases European regulations. In order to do this, they need low-risk plasma donations, not plasma from vulnerable adults, as media reports have suggested. Donor screening is rigorous.

We feel that it is important that donors should not be exploited by any organization, individual or regulating authority. Donors should be able to make an informed decision about their donation.

Compensation

In regards to whole blood - red cells and platelets - we feel that this system should remain voluntary and non-remunerated. There are no supply issues, and this system is not at risk.

In regards to the plasma component and PDPs, this is a for-profit sector globally, in which Canada buys 83% of its current needs from the US market. We have heard from other countries (UK, South Africa, Romania, Puerto Rico) of IG shortages in the last year. Experts agree that the IG shortages from 1998 are doomed to be repeated, “[seeing] the growing global demand and the list of indications currently being studied, and it’s not a matter of if there will be a shortage, but when.” (Rhodes, 2015)

Former Federal Health Minister, Jane Philpott, felt that the issue of compensation was provincial, allowing the Health Canada expert committee to review the situation. Upon release of the expert report, the Nova Scotia legislature dropped all discussion of paid plasma, indicating that “There are feasibility challenges to actually meeting collection targets for source plasma from volunteer donors” (Health Canada, p. 64)

There is a coexistence of the voluntary and compensatory models already proven in Canada. In Manitoba, Prometic (previously Cangene) have been collecting plasma and compensating donors near the University of Manitoba for over 30 years. This has never conflicted with Canadian Blood Services donation efforts in Manitoba. Although there have been claims of “crowding-out” in blood donations in Saskatchewan recently, due to the opening of a private collection centre in Saskatoon, all information is currently anecdotal.

Ethically, Canadians are happy to be compensated for plasma donations. More so than to be paying for US plasma, whose donors have been paid. A 2017 joint study from the University of Toronto and Johns Hopkins University looked at the willingness of Canadians to be compensated for plasma donation. 72.6% of respondents were in favour of compensation for

plasma donations. (Nicola Lacetera, 2018) The study showed that no moral or ethical argument could be made to ban compensation in Canada.

With no ethical or moral justification and no scientific reasoning on the grounds of safety to impose a ban on remuneration of donors, we ask this committee to consider the future of patient needs in Canada “A requirement for unpaid or non-remunerated donors would create major supply problems and product shortages without any justification on grounds of safety” (European Agency for the Evaluation of Medicinal Products, 2002) A federal ban, even with an allowance for Canadian Blood Services, is could prove catastrophic for the patients at most risk.

On June 5, 2018 we wrote to Senator Pamela Wallin, as well as several other Senators in regards to Bill S-272, the Voluntary Blood Donation Act. We attach the letter to this submission.

As end users of plasma-derived products, key concerns remain the same. These are:

1. Currently, our patients are safe with their products. We want them to continue in this regard.
2. CIPO feels that maybe this Bill is in reaction to public opinion or certain plasma collection centres, and not what is best for the future of this country. As a patient group, we hope this senate makes a decision based on science rather than history and politics.
3. Patients with Primary Immunodeficiency are the only disease state identified by Health Canada as users of IG as a life-sustaining product. We would like to ensure that our patient demographic has continued access to their products.

We at CIPO will continue to work with Canadian Blood Services and Héma-Quebec to encourage blood and plasma donations and to make the most complete use of all components. We feel that just as in life, this is not a black and white decision. Plasma is the only therapy option available to PID patients, at CIPO we are asking the Ontario Government not to cut off our life line.

References

(2011). *Dublin Consensus Statement* .

Elena S. Resnick. (2012). Morbidity and mortality in common variable immune deficiency over 4 decades. *Blood, Journal of the American Society of Hematology*, 1650-1657.

European Agency for the Evaluation of Medicinal Products. (2002). *CPMP Position Statement, Non-Remunerated Donors and Remunerated Donors: Safety and Supply of Plasma Derived Medicinal Products*.

Health Canada. (2018). *Protecting Access to Immune Globulins for Canadians: Final report of the Expert Panel on IG*.

Nicola Lacetera, M. M. (2018). Moral NIMBYism in Contested Commodities. *Law & Contemporary Problems*, 83-105.

Rhodes, R. T. (2015). Immune Globulin, Controlling Supply and Demand. *BioSupply Trends Quarterly*, 14-18.

Whitney Goulstone, E. T. (2016). *A Survey of Canadian Patients with Primary Immunodeficiencies*.

Senator Pamela Wallin

June 5th, 2018

RE: Proposal to Ban Compensation of Plasma and Blood Products in Canada

Dear Senator Wallin,

The Canadian Immunodeficiencies Patient Organization is national charity providing support, education and advocacy to patients and families living with primary immunodeficiency disease (PID) in Canada. The recent Health Canada report recognized our disease state as the one group truly life dependent on immune globulin (IG).

It has come to our attention that you have introduced a bill that would ban the compensation for donation of plasma and blood products in Canada. We believe that any such legislation would be ill-advised and negligent to the needs of the hundreds of thousands of Canadians in need of these products.

For patients living with PID, of which there are approximately 30,000 in Canada, IG therapy is the **only** treatment option available. This life-sustaining treatment helps prevent infections, lower antibiotic usage, increase quality of life, lower hospitalizations, and prolong life expectancy. These improvements in the health in patients are shown to drastically cut costs to provincial and regional health care.

We sincerely hope that you would not propose any legislation based on claims from a fringe group which has no medical or scientific basis, and unfairly targets all compensated plasma and blood donation on alleged basis of safety citing the Krever Commission report. This issue is not an ethical issue, and the last few decades has proved it is no longer one of safety.

These claims have been refuted in the recent Health Canada report: "Protecting Access to Immune Globulins for Canadians". This report from the expert panel on IG, found that there was no evidence to suggest that safety was of concern, as there have not been any cases for transmitted disease in blood and plasma products for over two decades.

With developments in testing technology, donor assessment methods, and manufacturing processes, significant advances have been made in product safety and quality in the industry. Over the past twenty years, there has not been a single reported transmission of HIV or hepatitis documented by Health Canada, the FDA, Australian, and European authorities and is available for review in both regulatory policy statements and peer-reviewed scientific literature.

The Government report also found that there was no evidence to support the private donor system for any "crowding out" of the public system, and indeed suggested that a dual private/public model would be beneficial to Canada in order to ensure continued access to a safe and secure access of supply. In fact, there have been compensated donations in Winnipeg for over 20 years and there have been no drop in Canadian Blood Services donations in the area. There are models globally as well of a paid/unpaid systems co-existing. There is no proof that compensated donation would have a direct effect on volunteer donations.

Compensated plasma donations would allow products designated as Canadian plasma products to be more readily available to Canadians.

Presently, Canada only produces roughly %17 of the plasma it requires through voluntary donations, purchasing over %80 from the United States (through compensated donors). The United States currently supplies %91 of the world's plasma needs, with the global demand growing every year. If Canada can assist in ensuring the supply of a product it utilizes, we can help supply meet demand and eventually become more self-sufficient. If legislation is passed to ban compensation, we will never become more independent and continue to rely heavily on US paid donors and global industry at increased cost.

Given the current trade climate, the need for Canada to increase its plasma and blood production are ever greater. Now would not be the right time to introduce legislation such as this.

I would like to say that CIPO in no way or form condones or endorses the business practices of the company currently collecting compensated plasma donations in Ontario and New Brunswick. The sole purpose of this letter is to ask for consideration of facts and consultation with stakeholders and end user before introducing legislation.

Thank you for your time and consideration in this vital matter.

Sincerely,

Whitney Goulstone

Executive Director

CIPO National

www.cipo.ca

info@cipo.ca

1(877)607-2476