Plasma Protein Therapeutics Association

Bill S-252 – Senate of Canada Standing Committee on Social Affairs, Science and Technology

OTTAWA, Wednesday, December 5, 2018

Penrod - Opening Remarks

Good afternoon and thank you Madam Chair and honorable Senators.

I am Josh Penrod, Senior Vice President at the Plasma Protein Therapeutics Association or PPTA. We are a trade association representing more than 700 source plasma collection centers in North America, including here in Canada, and in Europe, as well as the manufacturers of life-saving plasma protein therapies.

I'd like to start by noting the most important fact here: plasma is the primary building block of many life-saving therapies that treat patients with chronic and rare diseases including immune deficiencies; Guillain-Barre Syndrome; CIDP; alpha-1 antitrypsin deficiency; hereditary angioedema; and clotting disorders such as hemophilia and von Willebrand disease. Canada is a world leader in the treatment of these diseases and in the level of access it provides to patients in need of plasma protein therapies. In considering policies, we would urge you to enact those which maintain or further improve the existing high standard of care that Canadian patients currently enjoy. As a corollary to this, the need for a system to be in place to collect the source plasma needed to provide life-saving therapies for patients, in Canada and around the world, has never been more important.

Plasma is collected from human donors through a process called plasmapheresis which collects only plasma, leaving the other components of blood behind. This is usually called source plasma and is only used as the starting material for many therapies; it is never used for transfusion, which is a critical distinction. Around 75% of the source plasma in the world comes from compensated donors. To emphasize, the process we are talking about today is completely different from blood donation, which takes around 20 minutes and can only be done every 8-12 weeks. No one here is talking about paying whole blood donors; I want to be very clear on that point. A dual system of compensated plasma donation and non-compensated whole blood and plasma donation does and should coexist.

Health Canada's own Expert Panel on Immune Globulin Product Supply and Related Impacts in Canada, the findings of which were released in 2018, takes the position that compensated plasma donation is necessary to meet the needs of patients, noting in its Report that [quote] "jurisdictions that permit payment of source plasma donors have a significantly higher plasma collection capacity on a per capita basis compared to those jurisdictions where compensating source plasma donors is prohibited."

You will hear from the proponents of this bill that private plasma collectors take advantage of donors or are somehow unethical. These concerns are misplaced. One can still be motivated to donate one's plasma in order to help patients, while at the same time receiving a fair and modest compensation for the time commitment. I have a letter here, which I believe you have received, from 31 ethicists and economists, including two Nobel Prize winners and several Canadian intellectuals, which stresses the ethical compatibility between plasma donation and compensation. It notes that the amounts of money in question make a meaningful impact on a household budget, but are not so great that a donor would feel compelled to donate. In addition to this, in 2011, the UK's Nuffield Council on Bioethics declared compensated plasma donation to be ethically acceptable, given the rarity of the diseases, the importance of treatment, and the quantities of source plasma needed to create the finished products. Depriving a

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donor of a safe and legal way to augment their income while at the same time helping patients does not seem like a more ethical position to take.

You have heard about the concept of self-sufficiency, or the idea that a country should be able, completely on its own, to collect the enormous amount of plasma required to treat those patients. To date, the only countries in the world that have achieved self-sufficiency are those that compensate donors. Some countries will claim to be approaching "self-sufficiency," but that is often due to a smaller amount of product used in the country because of restrictions placed on access or a lower standard of care; these are hurdles that Canadian patients do not face. I'd suggest that self-sufficiency does not need to be a goal at all. Patients who rely on access to plasma protein therapies are in turn reliant on countries to facilitate the safe and plentiful collection of plasma. The more plasma that is available worldwide for manufacture into these therapies, the more that will be available to Canadian patients.

Over the last decade, our industry has collected over 300 million donations from healthy, qualified donors, an enormous undertaking representing the vast majority of plasma used to make these therapies, and one that could not have been achieved without compensation. To give some context to the number of donations needed, it requires 900 plasma donations to treat one Alpha-1 patient for one year, and 1,200 to treat one patient with Hemophilia A. Third-party estimates suggest that in order to meet clinical need, around 75 million liters of plasma need to be collected per year by 2024; roughly a 50% increase. This is not a time to limit the options available to meet this need.

In her testimony, Senator Wallin referred to the Krever Commission, which investigated the tainted blood scandal in Canada. We recognize the important role that the findings of the Commission played in modernizing the blood system here. That said, the report was written using the facts of the day; the facts as they stood over 20 years ago. The industry has changed radically in that time. Safety processes that were just beginning to be understood then are standard fare today. Plasma donation – whether the donor is compensated or not – is heavily regulated, in addition to voluntary industry standards adhered to by all PPTA member companies. Current measures in Canada for quality assurance and safety are rigorous and effective. As a result, there has been no viral transmission of any kind through a Health Canada or US Food and Drug Administration-licensed product in over a quarter century.

Reference has been made to this committee of compensated donation impacting non-compensated collections. There is no evidence that the use of compensated sources are crowding out voluntary donation. Germany has had great success collecting plasma from compensated donors with no effect on non-compensated collections. Just two weeks ago at a meeting of the European Directorate on the Quality of Medicines, German transfusion experts showed data which further illustrated the fact that plasma donors and blood donors are two separate populations with very little overlap. In another example, the U.S. collects the majority of the world's source plasma from compensated donors while still maintaining a world-class whole blood supply. Finally, Health Canada's Expert Panel found no evidence of such an adverse effect on non-compensated donation.

I understand why some may be inclined to support this bill at face-value and based on a belief that they are doing so for altruistic reasons. However, that reasoning is not based on evidence. Certain provinces have fallen into this trap – we are urging the federal government not to do the same. As Senators, you have a unique opportunity to look at this bill through an evidence-based lens. Please do so, because the evidence shows that the current system is keeping patients alive and healthy, with a superior quality of life.

Thank you. I would be happy to answer any questions you may have.