



Compensation for Plasma Donation in Ontario: A CAUTIONARY TALE

BY DAVID PAGE

In July 2014, the Government of Ontario re-introduced legislation to prohibit payment for donation of whole blood and blood constituents in that Canadian province. The proposed Bill came after more than a year of public controversy over the planned opening of three plasma collection centres by Canadian Plasma Resources (CPR) in Toronto and nearby Hamilton. The legislation will be debated and likely passed by the Legislative Assembly this autumn.

In Canada, regulation, licensing, and inspection of blood establishments is a federal responsibility of Health Canada. The agency is currently evaluating the CPR submission to open the three centres. Policy on compensation of donors, however, is up to Canada's ten provinces and three territories. Currently, only one province prohibits payment for blood or plasma donation. Quebec's Civil Code stipulates that the donation of any body part must be made without compensation. In Manitoba, on the other hand, Cangene, purchased in 2014 by Emergent BioSolutions, has been manufacturing a variety of immune globulins from compensated plasma donations for three decades, licensed by both Health Canada and the U.S. Food and Drug Administration (FDA).

Canada is largely dependent on the U.S. for both plasma-derived medicinal products and the plasma required to manufacture them. According to Canadian Blood Services (CBS) and Héma-Québec, the two blood establishments that collect blood from non-compensated donors in the country

and that distribute both labile and stable blood products to Canadian hospitals and patients, 27 of the 30 plasma-derived products are made entirely from U.S. plasma. Of the other three, CBS collects only 30% of the plasma needed to manufacture the immune globulins it distributes from non-compensated donors; Héma-Québec only 10%. Nor is Canada self-sufficient in plasma from non-compensated donors for the manufacture of albumin or factor VIII/von Willebrand factor concentrate.

When CBC Television reported on the opening of the three Ontario plasma centres in February 2013, the outcry was immediate. It was led by individuals who had lived through Canada's tainted blood tragedy and the ensuing Royal Commission of Inquiry (the 1993-97 Krever Commission). More than 1000 Canadians were infected with HIV through blood and blood products before 1987, including 700 people with hemophilia through factor concentrates mainly from compensated donors in the U.S. More than 20,000 people were infected with hepatitis C before 1990, the vast majority infected from transfusions from voluntary non-compensated Canadian donors. Many have since died. Government compensation programs for the Canadians affected have cost more than two billion dollars in public funds. The proceedings of the Krever Commission were front page news for years. Its final recommendations changed blood establishments around the world. One of those recommendations was that "donors of blood and plasma should not be paid for their donations, except in rare circumstances."

Soon joining the activists protesting the opening of the centres were physician groups, nurses groups, unions, prominent ethicists, opposition members in the federal

[Continued on page 8 >](#)

Parliament, and all parties in the Ontario Legislature. A statement by the Opposition Health critic in Ottawa was typical of the reaction: “In the 1980s, blood from for-profit brokers was a significant contributor to the tainted blood scandal where 20,000 Canadians were infected with HIV and hepatitis C,” said New Democratic Party (NDP) Health critic Libby Davies (Vancouver East). “It is our responsibility to ensure that that sad chapter in Canadian history is never repeated.”

The concerns of those who wanted to block the opening of the centres were primarily these:

- » Paid donors are less safe than non-paid donors;
- » Compensating plasma donors will undermine Canada’s voluntary donor system;
- » It is unethical to pay for a human body part.

In addition, opponents objected to the location of the centres, which, while close to universities, were also next door to homeless shelters or drug rehabilitation centres.

Tension soon grew between the federal government, which had been licensing paid plasma collection centres for decades (Cangene) based on regulations similar to those in the U.S., and the Ontario government, intent on finding a way to block the opening of the centres. The federal Minister of Health initiated a consultative process to collect information and perspectives.

Interestingly, the only groups not jumping on the anti-payment bandwagon were the blood establishments and patient groups whose members rely on plasma-derived medicinal products.

Dr. Graham Sher, chief executive officer of Canadian Blood Services wrote in the *Toronto Star*, on March 13, 2013: “Prohibiting pay-for-plasma would harm patients. Part of operating a safe system is ensuring security of supply. The reality is that thousands of patients depend on these life-saving fractionated products, and without those produced using plasma from paid donors we would not be able to meet patients’ needs ... A prohibition on paying donors for plasma for commercial fractionation use would deny patients access to these products, both here in Canada and around the globe. When lives are at risk, that’s simply not an option.” Dr. Sher also maintained there was no evidence from countries with both paid and non-paid systems that whole blood and platelet donors would stop donating.

The Canadian Hemophilia Society, whose policy had acknowledged the role of compensation since 2001, wrote in the *Toronto Star* (March 18, 2013): “Thousands of Canadians with chronic blood disorders rely on plasma products from paid donors for their health and their lives ... These plasma products have a 20-year safety record of never transmitting pathogens like HIV, hepatitis B and hepatitis C... In the 1970s and ’80s, blood system authorities ignored the facts,

Policy decisions of this nature should not be made without hearing from those who are affected the most by the legislation: that is, the recipients of plasma-derived medicinal products represented by their associations.

followed accepted dogma and imperiled the lives of thousands. In 2013, decisions should be based on current knowledge, not on misconceptions.”

Hereditary Angioedema Canada published its position on March 20, 2013: “HAE Canada shares the stated positions of the Canadian Blood Services and the Canadian Hemophilia Society that support the long-held practice of using plasma products that were sourced from paid blood donors in treatment of rare blood disorders. HAE Canada considers these products safe and essential.”

The debate has raged on in Ontario now for more than a year. Strangely, the draft Bill exempts Canadian Blood Services, presumably because CBS offers “incentives” to donors, and passage of the Bill could threaten the importation of products from paid donors, which would be catastrophic.

Ironically, in Quebec in 2014, where payment is banned, the Government announced an agreement with a fractionator whereby it would provide generous subsidies and loan guarantees to build a plant using U.S. compensated plasma. The Ontario Government itself had only two years earlier promised subsidies to attract a major fractionator to the province. The project fell through.

Patient groups continue to express their objection to the proposed legislation. In July 2014, the Network of Rare Blood Disorder Organizations (NRBDO), a coalition of more than ten associations whose members use blood and plasma products, wrote to the Ontario Minister of Health. The letter said: “There is merit in contributing to the world supply of plasma for the production of plasma derived medicinal products. Global over-reliance on the U.S. plasma supply is risky ... Paying Ontarians is no more or less ethical than paying Americans, as we do today for almost all products used in Ontario and elsewhere in Canada ... Policy decisions of this nature should not be made without hearing from those who are affected the most by the legislation: that is, the recipients of plasma-derived medicinal products represented by their associations.”

The NRBDO will appear before the Social Policy Committee studying the draft legislation this autumn. ●

DAVID PAGE, *National Executive Director, Canadian Hemophilia Society*