



## DRAFT POLICY ON PAID PLASMA DONATIONS

The Canadian Hemophilia Society (CHS) Draft Policy on Paid Plasma Donations was approved by the CHS Blood Safety and Supply Committee on March 11, 2013, and is an addition to the complete CHS Policy on Blood, Blood Products and their Alternatives ([www.hemophilia.ca/en/about-the-chs/public-affairs/chs-policy-on-blood--blood-products-and-their-alternatives](http://www.hemophilia.ca/en/about-the-chs/public-affairs/chs-policy-on-blood--blood-products-and-their-alternatives)) adopted in 2002 and reviewed annually. The CHS invites questions and comments from stakeholders ([chs@hemophilia.ca](mailto:chs@hemophilia.ca)).

**A final draft will be proposed to the CHS Board of Directors for adoption on May 25, 2013.**

Given that 80% of the Canadian and world supplies of plasma derived-products are manufactured from the plasma of paid donors, mainly from the U.S.;

Given that Canadian Blood Services and Héma-Québec are increasingly dependent on U.S. source plasma from paid donors for the supply of plasma-derived products and that they have no plans to become, at best, more than 30% sufficient in plasma for immunoglobulin (Ig) supply from Canadian non-paid donors;

Given the worldwide shortage of plasma for plasma-derived products, a shortage that could increase dramatically with the approval of Ig for Alzheimer's disease;

Given that many plasma-derived products used in the treatment of bleeding disorders (von Willebrand disease, rare clotting factors, inhibitors) are already manufactured from U.S. source plasma from paid donors;

Given that plasma-derived products are life-saving therapies for a number of other rare blood diseases that affect thousands of Canadians;

Given that, with the exception of factors VIII, IX and XIII, there are no recombinant alternatives for these products;

Given that effective donor selection and testing technologies are applied to both paid and non-paid donations;

Given that, in addition, highly effective viral elimination/reduction steps are applied to plasma-derived products;

Given that plasma-derived products from paid donors have not been shown to transmit HIV, HBV or HCV in more than 20 years;

Given that plasma collection sites in Canada where donors are paid have operated under Health Canada and U.S. FDA regulation and oversight for many years;

### **The Canadian Hemophilia Society takes the position that...**

1. Plasma-derived products in adequate supply from both paid and non-paid sources are essential to the health of thousands of Canadians and, indeed, hundreds of thousands of people around the world;

2. Plasma-derived products manufactured following Standard Operating Procedures and Good Manufacturing Practices are of equally high quality from both paid and non-paid donors;
3. The collection of source plasma from paid donors in a properly regulated environment is not a patient safety issue;
4. CBS and Héma-Québec should make all reasonable efforts to increase the quantity of Canadian plasma for fractionation from non-paid donors and the number and quantity of plasma-derived products made from this plasma;
5. In the absence of any realistic strategy to significantly increase the Canadian contribution to the world supply from non-paid donations, and when Canada relies almost entirely on paid donors from the U.S. for life-saving plasma-derived products, it is not defensible to reject paid donor practices on ethical grounds;
6. Any endeavour to collect plasma for plasma-derived products from paid donors in Canada must respect the highest regulatory standards. Health Canada should make these standards known to Canadians and report to Canadians on a regular basis the results of their collection site inspections, including transfusion-transmissible infection rates among donors;
7. Any endeavour to collect plasma for plasma-derived products from paid donors must not affect the ability of Canadian Blood Services or Héma-Québec to collect whole blood, platelets and plasma from non-paid donors to meet the needs for fresh blood components. Canadian Blood Services and Héma-Québec should report to Canadians on a regular basis the impact of paid plasma collections on their ability to meet the needs of Canadian patients;
8. The health of donors should not be compromised by their donations, paid or non-paid. Donors should not be exploited by any individual or organization. Measures and initiatives taken to encourage blood and plasma donations should not overwhelm the capacity of the donor to make an informed decision about whether to donate;
9. Patients whose continued health is dependent on the use of blood components or plasma-derived products have a right, through their representative organizations, to be consulted on any issue which may have an impact on the safety, efficacy or supply of the treatment they receive. Health authorities should ensure that robust mechanisms are in place to ensure that this happens.

Approved by the Canadian Hemophilia Society Blood Safety and Supply Committee.  
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