



RESPONSE TO PETITION

Prepare in English and French marking 'Original Text' or 'Translation'

PETITION No.: **421-00533**

BY: **MR. DAVIES (VANCOUVER KINGSWAY)**

DATE: **JUNE 16, 2016**

PRINT NAME OF SIGNATORY: **HONOURABLE JANE PHILPOTT**

Response by the Minister of Health

SIGNATURE

Minister or Parliamentary Secretary

SUBJECT

Health Care Services

ORIGINAL TEXT

REPLY

The Government of Canada recognizes that some Canadians have concerns regarding the issue of paying donors for plasma, much of which stems from the painful impact of the tainted blood tragedy of the 1980s. Fortunately, regulatory oversight and technology have evolved significantly and plasma products used in Canada now have an excellent safety record.

Canada has one of the safest blood systems in the world thanks to its comprehensive regulatory oversight of the collection of blood and plasma. As the federal regulator, Health Canada is responsible for ensuring the safety of Canada's blood supply for transfusion, as well as its supply of plasma for further manufacturing into plasma products. The Department takes this role very seriously.

The issuance of establishment licenses by Health Canada to companies that collect plasma or other blood components is based on a scientific evaluation that focuses on the safety of the companies' procedures. Health Canada's review of any establishment licence application is based on sound science and will put the safety of Canadians first.

The decision as to whether Canadian plasma donors can be paid rests with the provincial and territorial governments, and different jurisdictions have taken different approaches. Payment for plasma is not a new practice and is legally

permitted in all provinces and territories, except for in Ontario and Québec. For example, a company in Winnipeg has been operating safely and paying donors for plasma for 30 years. The plasma collected from paid donors is used exclusively for plasma product manufacturing, and never enters into the blood for transfusion systems.

Canada is self-sufficient regarding plasma used for transfusion, relying 100 percent on volunteer donations from Canadian Blood Services and Héma-Québec. However, Canada does not collect enough plasma to be self-sufficient in meeting the demand for life-saving plasma products, the need for which continues to grow. Therefore, some products, such as life-saving immune globulins, are purchased from manufacturers that use U.S.-sourced plasma, which is mostly obtained from paid donors. In fact, approximately 70 percent of the immune globulin products available in Canada are made in whole or in part from plasma from U.S.-paid donors. To this end, patient groups, including the National Chapter of the Canadian Hemophilia Society and the Canadian Organization for Rare Diseases, have expressed their support for a paid plasma model and have stated that the supply of plasma-derived products from both paid and non-paid sources is essential to the health of thousands of Canadians.

The recommendations of the Krever Commission were key factors in shaping the structure of Canada's current blood supply system, and in making it one of the safest in the world. While Justice Krever recommended that "significant efforts be made to ensure that blood components and blood products used in Canada be made from the blood and plasma collected from unpaid donors," he recognized that for some products, "it may be necessary to offer compensation to these persons for their time and effort in order to attract a sufficient number of donors." Justice Krever also emphasized the need to become self-sufficient in plasma, and to reduce reliance on the U.S. as a source of plasma.

Almost 20 years have passed since the issuance of the Krever Report. While the lessons of the tainted blood crisis must never be forgotten, actions have since been taken to prevent such a tragedy from happening again. Technological advancements have made plasma products extremely safe. New measures, such as heat treatment, filtration, and chemical treatment to inactivate viruses or remove other contaminants, have been put into place in addition to the rigid donor screening and testing requirements used when producing products from plasma. With the introduction of these safety measures, there have been no cases of hepatitis or HIV transmission from a plasma product in Canada in the last 25 years.

Canadian Blood Services have issued a recent statement on payment for plasma donation, which affirms that the drugs made from the plasma of paid donors are just as safe as those made from the plasma of volunteer donors, and that a paid plasma market is essential for ensuring enough supply of the lifesaving therapies Canadians need. As also identified in the statement, there is no evidence that paying plasma donors compromises the safety of, or weakens, a country's volunteer blood donor system. The experiences of other countries suggest that both paid and voluntary plasma donation can safely coexist.

Health Canada is committed to safeguarding Canada's plasma and blood supply systems, ensuring that all establishments that collect plasma for blood products are only licensed following a comprehensive evidence-based review and on-site inspection where product safety is held as paramount, that they are strictly regulated and in compliance with the *Food and Drugs Act* and its Regulations, and that plasma products sold in Canada are manufactured in accordance with our strict safety standards, regardless of where the plasma comes from, and whether donors were compensated.