

Securing & Protecting The Canadian Blood Supply

Why We Need
A Legislative Ban On
Paid-Plasma In Canada

BloodWatch

Senate of Canada & House of Commons **Brief**

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“Plasma, just like whole blood, is a public resource that must be safeguarded for Canadians. Long-term security of the plasma supply for Ig (plasma-mediators) can only be achieved through increased plasma collection by the publicly funded and publicly accountable not-for-profit blood system operated by Canadian Blood Services.”

Canadian Blood Services (Canadian Blood Services, 2017)

“Payment for the donation of blood (including donations of plasma and cellular components) not only threatens blood safety, it also erodes community solidarity and social cohesion which, on the contrary, can be enhanced by the act of voluntary non-remunerated donation.”

World Health Organization Expert Consensus (Expert Panel, 2012)

“In countries with dual systems (where unpaid and paid collection coexist), blood establishments who collect components for transfusion encounter increasing difficulties in recruiting and retaining unpaid donors.”

European Blood Alliance (EBA, 2016)

The Krever Commission

Recommendations

During the tainted blood crisis of the 1980s and 90s, over 30,000 Canadians were infected with HIV and hepatitis C from contaminated blood and blood products. It is estimated that over 8,000 Canadians died or will die as a direct result.

The subsequent Krever Inquiry exposed the systemic failures of the Red Cross, Health Canada, and the Federal and Provincial Governments to protect Canadians and the blood supply from tainted blood and blood products. The inquiry established that these failures caused the tainted blood crisis: the largest single public health disaster Canada has ever experienced.

Justice Krever concluded that Canada failed to take precautionary screening and testing measures to protect our blood supply. The inquiry also uncovered cost-cutting attempts, which favoured for-profit paid-plasma schemes, cover-ups and widespread political interference, as well as negligent importation of blood collected from high-risk American donors. Krever's discoveries were clear: this was a preventable tragedy. (Canadian Encyclopedia , 2006) (Krever, 1997)

The exhaustive federal report issued by Justice Horace Krever has become the foremost health document on how to manage the safest public blood system. The Krever report recommended that the Canadian blood system be fundamentally guided by these principles: (Krever, 1997)

- › Blood is a public resource.
- › Donors should not be paid.
- › Canada should be self-sufficient in blood and blood products.
- › Access to blood & blood products should be free and universal.
- › Safety of the blood supply is paramount.
- › No part of the national blood operator's duties should be contracted out to others.

Is Justice Krever's Report Still Relevant Today?

Yes. Justice Krever's robust study of the Canadian blood system investigated every aspect of blood system management. His investigation was evidence-based and apolitical. It was truly an arms-length inquiry that set out the path to preserving and protecting the

The licensing of paid-plasma clinics in Canada contravenes every single fundamental recommendation of the Krever Commission.

public blood system for generations to come. To this day, the Krever Report is still considered the guiding document internationally on best practices of blood system management.

Krever's recommendations, which continue to guide our blood system, serve the interests of the Canadian public and promote the life-saving national blood system. They underscore the vital importance of the strict government oversight and regulation of our integrated public blood system and the elimination of profit-making incentives that create insecurity in our blood supply. Krever

concluded that for-profit blood procurement created disparity within blood system management. Organizations in the global community including the World Health Organization (Expert Panel, 2012) and the European Blood Alliance (EBA, 2016) echo this finding today. To this end, Justice Krever made it clear that Health Canada must not engage in any measures that would undermine the national blood authority, Canadian Blood Services. Health Canada's role is to regulate for the sole benefit of the Canadian public. (Krever, 1997)

Why Is Protecting the Canadian Blood System an Issue Today?

From 2012 to 2014, Canadian Plasma Resources (CPR), a blood broker, attempted to open three cash-for-blood plasma collection clinics in Ontario. These clinics contravened the recommendations of the Krever Inquiry and the Memorandum of Understanding on the creation of Canadian Blood Services, signed by the provinces, territories and federal government. (MOU, 1996) CPR's plan was (and remains to this day) to open ten cash-for-blood plasma collection sites across Canada in order to sell the blood plasma of Canadians on the international market for a profit. (CPR, 2016) Despite opposition from the province, Health Canada issued CPR's operating license. (The Canadian Press, 2014)

In response, the government of Ontario used legislation to shut down the clinics. The Ontario **Voluntary Blood Donations Act** was passed in December of 2014. It received unanimous support from all parties in the Legislative Assembly of Ontario. (Ontario Government, 2014)

After being shut out of Ontario, CPR began a cross-country lobbying effort to secure support and generate business opportunities in other provinces. In December 2015, CPR revealed that Health Canada had quietly worked with CPR and the government of Saskatchewan to launch CPR's operations in that province. The Saskatchewan government claimed that CPR would increase plasma availability to patients in the province. (The Star Phoenix, 2016) In the years since, this claim has proven to be false: All of the plasma collected from CPR's Saskatoon facility is being sold on the international market. (Macleans, 2017)

In 2016, Health Canada proceeded to approve a second CPR facility in Moncton, New Brunswick. Neither the public nor stakeholders in that province were properly consulted or informed of this major policy decision before it was made. (Canadian Press, 2016)

What is most troubling is that Health Canada's decision to license CPR clinics in Saskatchewan and New Brunswick was undertaken **despite warnings by Canadian Blood Services not to do so**. (Globe & Mail, 2017)

Health Canada argues that their only responsibility to the Canadian blood system, as a regulator, is to ensure the CPR clinic facilities are safe. This has the effect of offloading the final decision to the provinces, since the only way to prevent cash-for-blood plasma sites from opening is for the provinces to step in and implement legislation banning them.

In response to Health Canada's position, Ontario (Ontario Government, 2014), Alberta (Alberta Government, 2017) and British Columbia (BC Government, 2018) have all implemented their own version of the Voluntary Blood Donations Act in order to block CPR, and other companies like them, from accessing blood donors in their respective provinces. Quebec has had a similar law in place since 1994, following the tainted blood crisis. Provinces that have adopted this legislation have done so with the explicit intention of protecting the security of the Canadian blood supply by safeguarding the integrity of the national voluntary blood donor system. (Canadian Press, 2018)

Health Canada's Role in Creating Disparity in Our Blood System: **Roles & Responsibilities**

Currently, Canadian Blood Services and Health Canada are at odds. By licensing paid-plasma clinics, Health Canada has permitted the emergence of a disparity in our national blood system. This amounts to supporting a private competitor to the detriment of the publicly accountable blood operator—Canadian Blood Services. Meanwhile, as the regulator of the blood system, Health Canada has no ability to ensure that the blood plasma collected by private brokers goes to Canadian patients in need.

CBS has made it clear to the Federal Government and to provincial/territorial Health Ministers that **only the national blood authority can secure and protect the national blood supply**. (Canadian Blood Services, 2018)

Four of the largest provinces in Canada, who have studied this issue in detail, concluded that upholding Justice Krever's recommendations and protecting the voluntary blood system was in the best interest of Canadian patients and the public. Yet, Health Canada continues to defend the licensing of paid-plasma schemes in provinces that are struggling economically and have smaller populations: Saskatoon, Saskatchewan and Moncton, New Brunswick.

Why Do We Need A Federal **Ban On Private For-Profit Plasma?**

Today, 80% of Canada's voluntary blood system is protected due to the provincial bans in place in Quebec, Ontario, Alberta and British Columbia. However, Health Canada has made it clear that since the practice of licensing paid-plasma is not illegal at the federal level, there is nothing restricting the agency from issuing more licenses to CPR and other companies alike: currently, **there are a whopping 18 private paid-plasma license applications in the queue.** (Health Canada, 2018) This would mean that the smaller provinces would end up being hosts to the private paid-plasma industry. This is a fundamentally flawed approach to securing our blood and plasma supply in Canada.

In order to protect Canadian Blood Services as our national blood authority, safeguard blood and plasma as a public resource, and ensure the Canadian blood system is never compromised—we need a federal law in place.

A Federal Voluntary Blood Donations Act Would:

- › Protect blood and plasma as a public resource.
- › Protect Canadian Blood Services as our sole national blood authority.
- › Protect and secure domestic plasma supply for Canadian patients.
- › Keep competitive, profitmaking blood collectors out of Canada's blood system.
- › Protect the integrity of the pan-Canadian voluntary blood system.
- › Ensure that Canada maintains control over our life-saving resource.
- › Protect donors and vulnerable populations from being exploited.
- › Ensure greater control of the cost of blood and blood products
- › Ensure that foreign companies or corporations never control our blood supply.

Reframing the Debate

On “Paid-Plasma”

The debate around “paid-plasma” has been fueled by the question: should we pay donors to sell their blood plasma? Within the context of this debate, a “paid” donor is a donor taken from the public system—that serves Canadians—and is drawn to the private blood-brokers that export the blood-plasma out of Canada and sells it for a profit to pharmaceutical companies.

Canadian legislators and policymakers should be asking the following questions instead:

- › Should the Federal Government protect the Canadian blood system and treat blood and plasma as a public resource in order to secure supply for Canadians?
- › Should the Federal Government dismiss the fundamental recommendations of the Krever Commission?
- › Should the Federal Government create disparity in the pan-Canadian voluntary blood system, which has taken two decades to rebuild after the tainted blood crisis, merely to support a private paid-plasma enterprise?
- › Should the Federal Government take a “wait and see” approach to determining how much more harm paid-plasma schemes will do to our voluntary blood system, or should they take preventative measures as Ontario, Alberta, British Columbia and Quebec have done?
- › Should the Federal Government allow foreign ownership of blood and plasma in Canada, and risk the loss of sovereignty over this life-saving resource?
- › Should the Federal Government uphold its obligation to protect the voluntary blood system, as it agreed to do under the Memorandum of Understanding that created the current national blood system?
- › Should the Federal Government interfere in the operations of Canadian Blood Services?
- › Should the Federal Government adhere to the national blood authority’s warnings to stop licensing paid-plasma collectors?

Key Facts to Consider:

80% of stakeholders in Canada have said NO to paid-plasma in Canada. (ATIP Health Canada)

Only 4% of the population donates blood today and that provides self-sufficiency in blood and plasma for transfusion for Canadians. (Canadian Blood Services)

Canadian Blood Services has developed an ambitious plasma collection strategy, which they intend to implement in order to increase domestic supply. (Canadian Blood Services, 2017)

Profitmaking plasma collection clinics will not help Canada become self-sufficient in plasma products. This is a fundamental myth that has been perpetuated to help support the case for allowing paid plasma in Canada. (Macleans, 2017)

Canadians did not ask to be paid for their donations; in fact, evidence demonstrates Canadians will eagerly donate plasma voluntarily. (Plasmavie , 2018)

Health Canada falsely stated that paid-plasma schemes “coexist” without harm to voluntary public blood systems and supplies. The European Blood Alliance issued a report in **2013** detailing the harm caused by private blood collectors by offering cash incentives to donors. (European Blood Alliance, 2013)

Furthermore, Canadian Blood Services has repeatedly warned Canadian Health Minister’s and Health Canada that CPR’s operations are already causing harm in Canada. (Canadian Blood Services, 2018)

“...we do know that expansion of commercial plasma collection will impact not only Canadian Blood Services’ efforts to fulfill our mandate to ensure Canada’s plasma sufficiency level via plasma collection, but Canadian Blood Services’ whole blood collection, as well. Recruiting new donors into the blood system every year is challenging enough, without the impact of commercial entities competing for donors and adding a layer of confusion. Recent polling of the public’s views around remunerating donors emphasizes this. As an example, our ongoing monitoring in Moncton and Saskatoon reveals:

- › Fluctuations in donations among donors aged 17 to 24.
- › Confusion and misunderstanding among donors over the distinction between Canadian Plasma resources and Canadian Blood Services.
- › Additional costs to recruit donors and plain collections above budgeted approaches.”

As A Legislator, What Can You Do?

Support the Protection of Canada's Voluntary Blood System:

- › Support the swift passing of the Voluntary Blood Donations Act, Bill S-252.
- › Write to the Federal Health Minister & Prime Minister Trudeau to request a full moratorium on licensing paid-plasma collectors that are in queue – there are 18 waiting for approval.
- › Request that open, transparent hearings on this issue take place at the federal level.
- › Become a blood donor and promote blood donation within your communities

The governments of Ontario, Alberta, British Columbia and Quebec support our position.

The most trusted domestic and international public health organizations, with expertise on this issue, support our position: Canadian Blood Services (Canadian Blood Services, 2017), the World Health Organization (WHO Blood Safety, 2018), the International Federation of the Red Cross and Red Crescent Society (IFRC, 2017), the International Society of Blood Transfusion (ISBT), the European Blood Alliance (EBA, 2016) and the International Plasma Fractionation Association (IPFA, 2018).

Who is BloodWatch.org And Why Do You Care So Much?

BloodWatch.org is a not-for-profit, non-partisan organization that collaborates with domestic and international stakeholders working towards the common goal of ensuring blood, blood products and human tissue remain a public resource. Tainted blood survivors founded BloodWatch.org, along with their family members and safe blood advocates who care deeply about ensuring Canada's blood donation system remains voluntary.

BloodWatch.org believes that decisions regarding our public blood policy should be wholly transparent and serve the sole interests of Canadian patients.

We would be delighted to send you any additional documentation you require. **Please email info@bloodwatch.org and we will provide the links to the ATIP documents we have acquired and additional supporting material.**

Also, Who Owns Private Paid-Plasma in Canada?

Protect the Sovereignty of Our Blood Supply

Unlike Canadian Blood Services, which is accountable solely to the Canadian public, shareholders and investors own these private paid-plasma clinics. For example, Canadian Plasma Resources is partnered with a German-based company, Biotest AG. The China-based financing firm, Create Group Corp, recently bought Biotest AG. (Bloomberg, 2018) Prometics (formally Cangene in Winnipeg) is no longer Canadian-owned and was sold to an American-based private company, Emergent Biosolutions. (Globe & Mail, 2013)

Blood products are a life-saving resources. Canadians deserve to have confidence in our blood system. We deserve a blood system that is accountable exclusively to us, as citizens, and not foreign shareholders.

Private-paid plasma collection schemes are not integrated into our Canadian blood system. Corporations aiming to export Canadian blood plasma and make a profit privately own them. They are not “blood operators” in the sense that they do not provide a service to Canadians.

References:

Alberta Government. (2017, March 30). Retrieved from <http://www.qp.alberta.ca/documents/Acts/V05.pdf>

ATIP Health Canada. (n.d.). Retrieved from <https://drive.google.com/file/d/0B4cSbmqms-ILXzMwTDI2Wndubm8/view>

BC Government. (2018, May 31). Retrieved from <https://www.leg.bc.ca/parliamentary-business/legislation-debates-proceedings/41st-parliament/3rd-session/bills/third-reading/gov29-3>

Bloomberg. (2018). Retrieved from <https://www.bloomberg.com/news/articles/2018-01-17/china-s-creat-is-said-to-edge-closer-to-u-s-accord-for-biotest>

Canadian Blood Services. (n.d.). Retrieved from <https://blood.ca/en>

Canadian Blood Services. (2017, January 24). *Canadian Blood Services Proposes Ambitious Plan To Secure Plasma Supply*. Retrieved October 15, 2018, from Canadian Blood Services: <https://blood.ca/en/media/canadian-blood-services-proposes-ambitious-plan-ensure-secure-supply-canadian-plasma-immune-globulin>

Canadian Blood Services. (2018, February 7). Retrieved from https://bloodwatch.org/cms/wp-content/uploads/2018/09/NS-2018-FOI-2018-06717-HEA_Release-Package.pdf

Canadian Encyclopedia . (2006, February 7). Retrieved from <https://www.thecanadianencyclopedia.ca/en/article/krever-inquiry>

Canadian Press. (2016, June 17). Retrieved from ctvnews.ca: <https://atlantic.ctvnews.ca/plans-for-a-paid-plasma-donation-clinic-in-n-b-raises-ethical-debate-1.2950056>

Canadian Press. (2018, April 27). Retrieved from <https://www.cbc.ca/news/canada/british-columbia/bc-introduces-legislation-to-ban-sale-of-blood-plasma-1.4637127>

CPR. (2016). *CPR Business Plan*. Retrieved from <http://bloodwatch.org/cms/wp-content/uploads/2017/10/CPR-Business-Plan.pdf>

EBA. (2016, October). *EBA fact sheet on European self-sufficiency for blood components and plasma for fractionation*. Retrieved October 15, 2018, from European Blood Alliance: https://europeanbloodalliance.eu/wp-content/uploads/2016/11/EBA_Pos_Paper-EU_self_sufficiency-1.pdf

European Blood Alliance. (2013). *Blood, Tissues and Cells from Human Origin*. Amsterdam: European Blood Alliance.

Expert Panel, W. H. (2012, June). *WHO Blood Safety Expert Consensus Statement Self-Sufficiency*. Retrieved October 15, 2018, from World Health Organization: http://www.who.int/bloodsafety/Expert_Consensus_Statement_Self-Sufficiency.pdf

Globe & Mail. (2013). Retrieved from <https://www.theglobeandmail.com/report-on-business/cangene-bought-by-us-rival-for-236-million-latest-canadian-biotech-taken-private/article15913167/>

Globe & Mail. (2017, August 1). Retrieved from <https://www.theglobeandmail.com/news/national/ottawa-approved-for-profit-plasma-clinic-despite-warning/article35860933>

Health Canada. (2018). Retrieved from <https://www.canada.ca/en/health-canada/programs/expert-panel-immune-globulin-product-supply-related-impacts-canada.html>

Health Canada Myths. (2018). Retrieved from <https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/activities/fact-sheets/plasma-donation-canada/myths-facts.html>

IFRC. (2017, June). Retrieved from <https://media.ifrc.org/ifrc/what-we-do/health/voluntary-blood-donation/>

IPFA. (2018). *About Section*. Retrieved from <https://ipfa.nl/about-us>

ISBT. (n.d.). *Code of Ethics*. Retrieved from http://www.isbtweb.org/fileadmin/user_upload/ISBT_Code_Of_Ethics_English.pdf

Krever, H. (1997). *Commission of Inquiry on the Blood System in Canada*. Ottawa, Ontario, Canada: Government of Canada.

Macleans. (2017, November 22). Retrieved from [macleans.ca: https://www.macleans.ca/society/a-bloody-mess-the-story-behind-paid-plasma-in-canada/](https://www.macleans.ca/society/a-bloody-mess-the-story-behind-paid-plasma-in-canada/)

MOU, F. (1996, April 26). MOU. *Canadian Blood Services Federal / Territorial / Provincial Memorandum of Understanding*.

Ontario Government. (2014, December 11). Retrieved from [Ontario.ca: https://www.ontario.ca/laws/statute/14v14](https://www.ontario.ca/laws/statute/14v14)

Plasmavie . (2018). Retrieved from <https://www.plasmavie.ca/index.fr.html>

The Canadian Press, K. L. (2014, March 18). Retrieved from [CTVnews.ca: https://www.ctvnews.ca/health/ontario-vows-to-shut-private-clinics-that-pay-people-for-blood-plasma-donations-1.1734926](https://www.ctvnews.ca/health/ontario-vows-to-shut-private-clinics-that-pay-people-for-blood-plasma-donations-1.1734926)

The Star Phoenix. (2016, February 18). Retrieved from [thestarphoenix.com: https://thestarphoenix.com/news/local-news/plasma-opening](https://thestarphoenix.com/news/local-news/plasma-opening)

WHO Blood Safety. (2018). Retrieved from https://www.who.int/bloodsafety/voluntary_donation/en/