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Banning Compensation for Donations of Blood and Blood Components in Ontario

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A Provincial/Territorial Health Reform Analysis

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Abstract

In 2014, Ontario passed Bill 21: Safeguarding Healthcare Integrity Act, which enacted the Voluntary Blood Donations Act, 2014, to ban all forms of compensation for donations of blood and blood components. Ontario justified this action by invoking the principles of the 1997 Krever Commission, which defined blood as a public resource of such value and importance that it must remain under the singular control of an organization that only serves the public interest. This reform was introduced with the intention to prevent another public health disaster like that of the tainted blood scandal in the 1980s, protect voluntary donor pools, and stop potentially exploitative plasma collection techniques. Responding to the licensing of a private plasma collection agency by Health Canada, Ontario met with key stakeholders such as Canadian Blood Services, Canadian Plasma Resources, blood advocacy organizations, and patient groups before finally passing Bill 21. By placing a ban against blood collection agencies besides Canadian Blood Services and by implementing aggressive consequences for violations, Ontario ensured all forms of blood donation would remain voluntary unless deemed necessary by Canadian Blood Services. Similar bills were introduced with differing outcomes in Alberta, British Columbia, and the Canadian Senate in 2017, 2018, and 2019 respectively. The contentious and varying opinions on blood donation regulation at the provincial and federal levels of government demonstrate that this topic will remain relevant to Canadian politics for the foreseeable future.

En 2014, l'Ontario a adopté le projet de loi 21: loi sur la sauvegarde de l'intégrité des soins de santé, qui a mis en exécution et validé la loi sur les dons de sang volontaires, afin d'interdire toutes formes d'indemnisation pour les dons de sang et de composants sanguins. L'Ontario a justifié cette mesure sur la base des principes de la Commission Krever de 1993, définissant ainsi le sang comme une ressource publique d'une valeur et importance telles qu'il doit rester sous le contrôle singulier d'une organisation qui ne sert que l'intérêt public. Cette réforme a été introduite dans le but de prévenir une autre catastrophe de santé publique comme celle du scandale du sang contaminé dans les années 80, de protéger les donneurs volontaires et d'empêcher les techniques de collecte de plasma pouvant conduire à l'exploitation des donneurs. En réponse à l'agrément d'une agence privée de collecte de plasma par Santé Canada, l'Ontario a rencontré des intervenants clés, tels que la Société canadienne du sang, Canadian Plasma Resources, des organisations de défense du sang et des groupes de patients avant de finalement adopter le projet de loi 21. En interdisant la collecte de sang par les agences outre la Société canadienne du sang et en mettant en œuvre un arsenal répressif en cas de violation, l'Ontario a veillé à ce que toutes les formes de don de sang restent volontaires, autres que la Société canadienne du sang juge le contraire nécessaire. Des projets de loi similaires ont été présentés, avec des résultats différentes en Alberta, en Colombie-Britannique et au Sénat canadien respectivement en 2017, 2018 et 2019. Les opinions tranchées et divergentes des gouvernements provincial et fédéral sur la réglementation des dons de sang aux paliers de gouvernement provincial et fédéral démontrent que ce sujet demeurera d'importance pour la politique canadienne dans un avenir proche.

Key Messages

- Canadian Plasma Resources' request to collect blood plasma in 2012 began a contentious debate about the merits and disadvantages of compensating donors for blood collection.
- In 2014, Ontario passed Bill 21, invoking the principles of the landmark 1997 Krever Commission, to ban all forms of compensation for donations of blood and blood components.
- In the absence of federal leadership and national consensus, Ontario's Bill 21 laid the foundation for British Columbia and Alberta to pass similar legislation, while the debate surrounding the reform offered other provincial and territorial governments insight into Canadians' views on blood donation regulations.

Messages-clés

- La demande de Canadian Plasma Resources de pouvoir collecter du plasma sanguin en 2012 a lancé un débat houleux sur les mérites et les inconvénients de la compensation des donneurs de sang
- En 2014, l'Ontario a passé la Loi 21, reposant sur les principes établis par la décisive commission Krever de 1997, interdisant toute forme de compensation pour les dons de sang ou de composants sanguins.
- En l'absence de direction fédérale ou de consensus national, la Loi 21 de l'Ontario a posé les bases de législations similaires en Colombie-Britannique et en Alberta, tandis que le débat autour de la réforme procurait aux autres gouvernements territoriaux ou provinciaux des informations sur les perceptions des Canadiens en matière de réglementation des dons de sang.

1 BRIEF DESCRIPTION OF THE HEALTH POLICY RE-FORM

On 22 July 2014, the Honourable Eric Hoskins, Minister of Health and Long-Term Care of Ontario, introduced Bill 21: Safeguarding Healthcare Integrity Act, 2014, an Act to safeguard health care integrity by enacting the Voluntary Blood Donations Act, 2014 and by amending certain statutes with respect to the regulation of pharmacies and other matters concerning regulated health professions. The first schedule enacts the blood donation regulations preventing the paid collection of blood and blood products that will be the focus of this health reform analysis.

The Voluntary Blood Donations Act, 2014 prevents any person from offering or providing any form of compensation in return for blood, blood components or blood products. It also prohibits donors from accepting any offered compensation. However, exemptions exist. Any blood that is donated solely for research purposes can be compensated under this act. Canadian Blood Services (CBS), the independent organization established as Canada's blood authority alongside Héma-Québec, and the donors who donate to them, are also exempt. Thus far, CBS has not felt it necessary to pay donors in Canada, and all blood collection is strictly voluntary, meaning it is unpaid.

2 HISTORY AND CONTEXT

- **1980s:** Over 32,000 Canadians are infected with HIV or Hepatitis C after being transfused with tainted blood products that had been collected by the Canadian Red Cross (CRC). The CRC was slow to implement screening when it became apparent that a new pathogen (the human immunodeficiency virus) could be transmitted through blood, delayed implementation of HIV tests, purchased blood from questionable sources in the US such as prisons, and were not adequately supervised by the Canadian government.
- November 1997: The results of the Krever Commission, a royal commission investigating the government's role in the 1980s public health disaster, are released (Krever 1997). Justice Horace Krever recommends that "blood donors should not be paid for their services except in rare circumstances," because blood is a public resource that should be under the purview of an independent organization, eventually leading to the creation of CBS (Wilson 2007).
- **November 2012:** Canadian Plasma Resources (CPR), a for-profit company, applies for a license from Health Canada to collect plasma in Ontario. They intend to pay donors.
- **April 2013:** Health Canada invites key stakeholders to hold a roundtable discussion on the topic of paid plasma donation (Health Canada 2013a). Subsequently, Health Canada approves CPR's license.

- March 2014: Soon after, CPR receives a license from Health Canada and opens its first two clinics—one in Toronto, Ontario and the second in Hamilton, Ontario. They face criticism for opening their clinics near homeless shelters and vulnerable populations. In response, The Honourable Deborah Matthews cites the Krever Commission to introduce Bill 178: Voluntary Blood Donations Blood Act. The bill soon dies on the order paper (Legislative Assembly of Ontario 2014a).
- July 2014: The Honourable Eric Hoskins presents Bill 21: Safeguarding Healthcare Integrity Act, 2014 to the Ontario Legislative Assembly (Legislative Assembly of Ontario 2014b). Within Bill 21, he reintroduces the Voluntary Blood Donations Act, 2014, adding appropriate exemptions to address concerns that arose from Bill 178 readings.
- **December 2014:** Bill 21: Safeguarding Healthcare Integrity Act, 2014 receives Royal Assent.

3 GOALS OF THE REFORM

The Voluntary Blood Donations Act, 2014 was a complex piece of legislature because it outlined an ambitious vision for the future of Ontario's, and indeed Canada's, blood collection system. It did not just ban the paid collection of blood and blood products by for-profit companies. By endorsing the Krever Commission and its principles, Ontario framed this reform as one that is necessary to uphold the public interest. However, this reform also addressed more pressing and logistical concerns. It allowed Ontario to attend to the perceived risk of exploitation of vulnerable populations, guarantee blood safety, and prevent international markets from accessing Canadian blood and blood products.

3.1 Stated

- 1. Provide recognition for the following principles (Government of Ontario 2014a):
 - (a) Within Ontario's health care system, blood donations are viewed as a public resource.
 - (b) Blood donors should not be paid, except in exceptional circumstances.
 - (c) The integrity of the public, voluntary blood donor system in Ontario must be protected.
- 2. Strengthen the government's enforcement powers in the case of violations (Government of Ontario 2014b).

3.2 Implicit

- 1. Prevent loss of voluntary blood/plasma donor pools to paid clinics (CBC News 2016).
- 2. Prevent Ontario blood products from being sold on international markets at the expense of the Canadian population's health (Kingston 2017).

- 3. Prevent the exploitation of vulnerable populations who may donate blood for basic income (Panitch and Horne 2019).
- 4. Maintain the "Canadian way" that has historically held that the act of donating blood should only be altruistically motivated (Legislative Assembly of Ontario 2014b).

4 FACTORS THAT INFLUENCED HOW AND WHY

4.1 The issue came onto the government's agenda: problems, policies, and politics

Plasma, an isolatable component of blood, is harvested because it can be fractionated to generate valuable pharmaceutical products such as immunoglobulins that treat bleeding disorders and immune disorders in clinical settings (Health Canada 2018a). Blood collection in Canada is voluntary, despite the fact that Canada is the second highest global user per capita of immunoglobulins and derives only 16.7% of its plasma needs from domestic sources (Health Canada 2018b). To meet demand, Canada purchases the rest of needed plasma and plasma products from the United States. One proposed solution to diversify plasma collection sources and reduce Canada's dependence on the United States is to boost domestic blood and plasma donations through paid compensation to donors.

In November 2012, Canadian Plasma Resources applied for licenses from Health Canada to open two paid plasma clinics (CUPE 2016). Upon receipt of CPR's request for licensing, Health Canada held a round-table discussion inviting key stakeholders from groups such as CBS, Ontario Ministry of Health, and the Canadian Hemophilia Society (Health Canada 2013a). After addressing issues introduced by these stakeholders, Health Canada approved CPR's request. In doing so, Health Canada clarified their mandate is to evaluate applications solely on the basis of health and safety and ensure stringent safety regulations and guidelines are followed if applications are approved. They emphasized that the onus to disallow compensation for plasma and blood donation for any other reason was on legislators (Health Canada 2013b). As a result, immediately after Health Canada's approval, paid plasma clinics were allowed in Canada because of a lack of provincial/territorial legislation preventing their operation.

However, after the locations for CPR's new clinics were revealed, there was public concern about blood product safety despite Health Canada and CPR assurances. In Toronto, the clinic was adjacent to a men's homeless shelter, and in Hamilton, it was adjacent to a methadone clinic (Kingston 2017). The public concern about safety was not well-founded or supported by scientific evidence; blood donors go through extensive screening processes and are tested for transmissible diseases, after which blood products are further processed and filtered before they are made available to health care systems. The concerns may have only arisen and received widespread recognition because of stigma associated with these vulnerable populations. During the proceedings and discussions surrounding Bill 21, the clinics, in light of their locations, were regarded as a corporate attempt to exploit nearby vulnerable populations by paying them to donate.

Finally, the approval of the licensing request led the Ontario government, blood advocacy organizations and patient groups to recall the tainted blood scandal, which was caused when the Canadian Red Cross was collecting blood on behalf of the government. While it would be highly unlikely that such an incident is repeated today with multiple safety checks and rigorous Health Canada oversight, parallels were nevertheless drawn to CPR's request to collect blood.

4.2 The final decision was made: interests, ideas, and institutions

As a result of these factors and public pressure, the Ontario government quickly responded by passing Bill 21: *Safeguarding Healthcare Integrity Act*, 2014 (Legislative Assembly of Ontario 2014b). By positioning the ban on compensation for plasma as necessary to safeguard the integrity of Canadian health care and extending the ban to include whole blood and other blood products, Ontario played on the public's collective pride in the Canadian health care system. They aimed to regain the public's trust in the government and Canada's blood authorities after allowing CPR's questionably-located clinics to operate for several months.

This bill was supported by blood advocacy groups such as BloodWatch, patient groups such as the Canadian Hemophilia Society, and professional groups such the Registered Nurses' Association of Ontario (BloodWatch 2019). For them, passing this bill was necessary to set precedent in Canada, reduce the possibility for a public health crisis like that of the tainted blood scandal of the 1980s, and implement the principles outlined in the landmark Krever Report. Proponents of this bill also aimed to prevent potential reductions in levels of voluntary blood donation and ensure that Canadian blood did not make its way to international markets for private gain. They argued that CPR's blood products could make their way to international markets, serving to increase blood insecurity in Canada instead of improving Canada's plasma self-sufficiency. Finally, the ethics of selling organs, as well as the concern for a "slippery-slope" where the sale and purchase of other human biological material besides blood might eventually be allowed, was raised.

Economically-speaking, it was in the interest of CPR as well as the Ontario government to block Bill 21. CPR had already invested \$8.5 million in their clinics and hired and trained over 30 full-time personnel (Babbage 2014). CPR made an additional promise to invest \$400 million in Ontario to open ten plasma collection centres and a fractionation plant in the future (Legislative Assembly of Ontario 2014c). CPR and pharmaceutical companies touted the economic benefits of paid plasma clinics, discussed technology advancements that made parts of the Krever Report irrelevant, emphasized the safety of their blood collection procedures, and discussed the hypocrisy of banning paid plasma collection in Canada while CBS actively purchases plasma that is compensated for from the United States.

Interestingly, CBS changed their position on paid compensation for blood donation between 2013 to 2014. In the national round-table meeting with Health Canada when CPR first requested to be licensed, they cited international research demonstrating that concurrent systems of paid and voluntary donations have negligible effects on voluntary donations (Health Canada 2013b). They supported the diversification of blood collection systems. However, a few months after CPR's clinics began operating, Dr. Graham Sher, CEO of CBS, stated that they supported the government of Ontario in passing Bill 21 for the citizens of Ontario (Legislative Assembly of Ontario 2014c). It is hypothesized that this change may have been because of decreasing rates of voluntary donations at CBS clinics that were located close to those of CPR, or even because they wished to align themselves with public sentiment against paid compensation for blood.

5 HOW THE REFORM WAS ACHIEVED

5.1 Policy instruments

Bill 21 was unanimously carried during its third reading on 10 December 2014 with 93 votes for and none against. By placing a ban on all compensation for blood and blood components donations while exempting CBS and donations for research purposes, the government ensured that: 1) CBS could decide to offer payment in times of dire need and 2) Canadian blood research remained unaffected. The bill received Royal Assent on 11 December 2014.

5.2 Implementation and communication plans

Upon assent, Bill 21 was immediately in force. To ensure the contents of this act were followed, subsections gave the Minister of Health and Long-Term Care the power to appoint health inspectors to inspect blood collection facilities in Ontario. In case of violations, fines of up to \$50,000 per day for first offences and \$200,000 per day for subsequent offences for corporations were defined. Besides news releases directed toward the general public, it is unclear if Ontario had a formal strategy to communicate the results of this bill to all relevant stakeholders (Government of Ontario 2014a; 2014c). It is assumed that all stakeholders were privately kept abreast of developments until 11 December 2014, when the bill finally received Royal Assent.

6 EVALUATION

Today, CPR operates two plasma clinics—one in Saskatoon, Saskatchewan and another in Moncton, New Brunswick. The CEO of CBS, Dr. Graham Sher, publicly denounced the Saskatoon private clinic in a 2016 media interview, citing decreasing numbers of voluntary donations at their own clinic (*CBC News* 2016). This suggests that CBS may also have assessed donation rates after the opening and subsequent shut down of CPR's clinics in Ontario in 2014, but this data is not publicly available. Following Ontario's enactment of the *Voluntary Blood Donations Act*, 2014, Alberta and British Columbia followed suit by passing similarly named bills in 2017 and 2018, respectively (Province of Alberta 2017; Legislative Assembly of British Columbia 2018). This response by western Canada after CPR publicly demonstrated interest in moving their operations shows wider support of the reform implemented by the Ontario government as well as the principles outlined in the Krever Report. At the federal level, Senator Pamela Wallin introduced S-252 in 2018 to the Senate, proposing to alter the *Blood Regulations* to ban donor compensation by organizations besides CBS (Parliament of Canada 2018). This bill died on the floor in May 2019, demonstrating that blood donation regulation will continue to be relevant and divisive at the provincial and federal level of government. In this political climate, Bill 21: *Safeguarding Healthcare Integrity*, 2014 which enacts the *Voluntary Blood Donations Act*, 2014, will continue to be studied and cited by various stakeholders and governments as they clarify and publicize their positions in the near future.

7 STRENGTHS, WEAKNESSES, OPPORTUNITIES AND THREATS

Table 1 summarizes the strengths, weaknesses, opportunities, and threats of banning compensation for donations of blood and blood components as per Bill 21. The implicated stakeholder perspective is indicated in brackets.

Strengths	WEAKNESSES
Enforces the principles necessary to develop a safe public blood collection system as out- lined by the Krever Commission (CBS, pub- lic). Supports public interest, altruistic donation, and pride in Canada's public health care sys- tem. Allows donor compensation in case of drasti- cally low blood storage levels (CBS, public) and for research purposes (researchers, pub- lic).	 Loss of investments by CPR in the Ontaria economy (CPR, government). Does not reflect safety improvements and technological advances made in the last 2! years (CPR).

Table 1: SWOT Analysis

Opportunities	THREATS
 Ensures the public's trust and faith remains with Canada's blood authorities (CBS, government, public). Prevents the potential exploitation of low-income and vulnerable populations (CBS, government, public). Allows CBS to implement and expand their strategy to increase voluntary plasma donation rates (CBS). 	 Canada's plasma self-sustainability, portially resulting from greater donation methods due to compensation, does not increating (government, public). Lack of national consensus on blood registion undermines movement towards develoing a single independent organization op ating with the public's best interest in methods.

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