

***Ethicists and Economists express concerns about banning compensation for plasma donors with regards to ensuring the security of a safe Immune Globulin Product Supply***

**Submission to the Expert Panel on Immune Globulin Product Supply and Related Impacts in Canada**

Contact: Peter Martin Jaworski, peter.jaworski@georgetown.edu

**1. INTRODUCTION**

1.1 We are professional ethicists in the fields of medical ethics, business ethics, and/or normative ethics, and academic economists who study how incentives and other reward mechanisms affect individual behaviour. We all share the goal of improving social welfare.

1.2 The Provinces of Quebec (1994), Ontario (2014),<sup>1</sup> and Alberta (2017)<sup>2</sup> have passed Voluntary Blood Donation Acts or their equivalents that prohibit, amongst other things, compensation for plasma donations for purposes of further processing into plasma-derived medicinal products (hereafter: “PDMPs”), like Immune Globulin (hereafter: “Ig”). Currently, the Nova Scotia legislature is debating a Voluntary Blood Donations Act,<sup>3</sup> and the British Columbia government has suggested that it is interested in pursuing similar legislation.<sup>4</sup>

1.3 We have strong reservations regarding any Act or legislation (hereafter: “Acts”) that would prohibit compensation for blood plasma donations, where the donated plasma will be processed into plasma-derived medicinal products (hereafter: “PDMPs”), like Immune Globulin (hereafter: “Ig”). (We do not here address blood plasma collected for transfusions or other purposes.) Both the ethical and the economic arguments against a compensatory model for blood plasma for further manufacture into PDMPs (hereafter: “the compensatory model”) are weak. Moreover, significant ethical considerations speak in favour of the compensatory model, and therefore against the Acts.

1.4 Below, we respond to the ethical arguments offered in favour of the Acts: that the compensatory model would result in **wrongful exploitation** (§2); that the compensatory model would promote the view that human beings, their bodies, or subparts thereof, are **mere commodities** (§3); and that the compensatory model would incentivize donation for personal gain over donation from **altruistic motives** (§4). We agree with Health Canada, Canadian Blood Services, and all major medical oversight bodies that there are no **safety issues**

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<sup>1</sup> Text of the Act: [http://www.ontla.on.ca/web/bills/bills\\_detail.do?locale=en&BillID=3015](http://www.ontla.on.ca/web/bills/bills_detail.do?locale=en&BillID=3015)

<sup>2</sup> Text of the Act: <http://www.qp.alberta.ca/documents/Acts/V05.pdf>

<sup>3</sup> Hansard debate:

[http://nslegislature.ca/index.php/proceedings/hansard/C98/house\\_17oct11/#HPage1055](http://nslegislature.ca/index.php/proceedings/hansard/C98/house_17oct11/#HPage1055)

<sup>4</sup> See:

<https://beta.theglobeandmail.com/news/national/blood-agency-seeking-855-million-in-funding-to-boost-plasma-supply-document-reveals/article35980339/?ref=http://www.theglobeandmail.com&>

associated with PDMPs, including Ig, made with paid donors (§5). With regard to the **security** of Canada's supply of PDMPs, including Ig, we note that it has been and currently is overwhelmingly dependent upon the compensatory model, and that this is likely to continue well into the future. Given this fact, we note that the goal of having a **sufficient** quantity of PDMPs, including Ig, is undermined by the Acts (§6). Given the moral urgency of increasing the supply of PDMPs, including Ig, and the weakness of the economic and ethical arguments thus far presented against the compensatory model, we conclude that **the Acts are not justified** (§7).

## 2. **WRONGFUL EXPLOITATION**

*The Acts are intended, as we understand them, to prevent wrongful exploitation. We agree that wrongful exploitation is a significant worry. Our view is that a practice may be wrongfully exploitative when there is undue risk, undue inducement, or an unfair division of the benefits from an exchange. We do not think that compensation, per se, meets these criteria, and so conclude that a compensatory model need not be wrongfully exploitative.*

2.1 Plasmapheresis is a non-invasive procedure. The procedure takes between 60 and 90 minutes per donation. Plasma clinics in both the U.S. and Canada are required to inform donors of any risks. In addition, donors go through medical screening, must provide proof of residence, and have to meet certain weight and age requirements. Additionally, unlike kidneys and other organs for which ethical concerns about wrongful exploitation arise, blood plasma quickly regenerates. Donors do not permanently "lose" a body part. As the burdens here are limited, they do not provide solid grounds for concern about wrongful exploitation based on undue risk.

2.2 Donors receive, on average, \$25-50 per donation. In Saskatchewan, where this practice has existed since 1984, donations are compensated at greater-than-minimum-wage levels. Canadian Plasma Resources pays between \$25 and \$30, while in the U.S., donors receive between \$25 and \$50 per donation. Compensation is therefore not low, but it is not, on the other hand, so high as to unduly induce a potential donor into a donation. Given that the risks are not undue, and that payment, although not low, is not too high, there is no particularly good reason to worry about wrongful exploitation based on undue inducement.

2.3 Compensation to donors represents approximately 30-40% of the total revenue per 800 mL of blood plasma in Canada and the U.S. Currently, Canadian Plasma Resources receives approximately 0% in profits. Therefore, donors appear to receive the majority of the financial benefits per individual exchange. Faced with these figures, worries about wrongful exploitation based on an unfair division of the benefits of exchange are difficult to substantiate.

2.5 We therefore conclude that worries about wrongful exploitation have weak grounding, whether they are based on undue risk, undue inducement, or a concern about an unfair division of the benefits from exchange.

## 3. **COMMODIFICATION**

*The Acts are also intended, as we understand it, to avoid promotion of the view that human beings, their bodies, or subparts thereof are appropriately viewed as commodities. Insofar as anything compensated for is a commodity, it is trivially true that the compensatory model promotes the view that blood plasma is a commodity. But this is ethically irrelevant. The relevant ethical concern is that the compensatory model would promote the view that human beings (etc.) are “mere” commodities, meriting no more ethical regard than other mere commodities, such as cars or clothing. However, there is no evidence that the compensatory model would promote this view.*

3.1 There is no evidence that compensation for blood plasma donations in, for example, Saskatchewan, the United States, Germany, Austria, Hungary, or the Czech Republic has promoted the view that donors or their blood plasma are regarded as mere commodities. There is as yet no evidence that Saskatchewanians have different attitudes towards their blood plasma than, say, British Columbians currently have.

3.2 Everyone involved in blood plasma donation in Canada -- the nurses, the doctors, the administrators, the medical scientists, the professors who study the matter, the chief executives of Canadian Blood Services, the manufacturers of plasmapheresis machines, the fractionators, and so on -- receives compensation, except the donor. There is no evidence that Canadians regard the services so provided, nor the people providing those services, as mere commodities in virtue of the fact that they are financially compensated. For the argument that donor compensation would so promote this view to be compelling, one would need an explanation for why the connection between compensation and commodification applies exclusively to compensating donors, and not to these other forms of compensation. No such explanation has been offered, nor is any apparent or plausible.

3.3 Proponents of the Acts have provided no evidence, empirical or otherwise, that the compensatory model for blood plasma donation, in contrast with similar practices referenced above, would promote the view that donors or their blood plasma are mere commodities, or would be so regarded. We therefore conclude that worries about commodification are not well-grounded.

#### 4. **ALTRUISM**

*The Acts are also intended, as we understand it, to avoid incentivizing donation for monetary gain over donation from altruistic motives. We agree that altruism is desirable, and that we need to be careful when considering policies to preserve and promote altruistic and benevolent motives and actions. However, this argument with respect to this compensatory model is unpersuasive.*

4.1 The compensatory model leaves open the possibility of donors' opting out of compensation, or the operation of a parallel non-compensatory model. The United States does

just this, and has an approximately 50% higher voluntary, unpaid, per capita blood donation rate than Canada. Germany, Austria, and the Czech Republic, where plasma donors can be compensated, all have higher rates of voluntary, unpaid per capita blood donation than Canada.

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4.2 Compensation and altruism are not mutually exclusive. In many cases, people who are compensated are motivated simultaneously (or even primarily) by altruistic impulses. This is true of many doctors and nurses. There is no reason to believe that a compensated blood plasma donor would be solely or exclusively motivated by personal financial gain.

4.3 Even if the compensation model came with costs in terms of the value of promoting altruistic motivations, this must be weighed against the value of obtaining a sufficient quantity of blood plasma to meet Canada's need for PDMPs, including Ig. Arguably, preventing avoidable pain, suffering, and death among current and future patients is morally more urgent than preserving altruistic motivations amongst donors.

4.4 We therefore conclude that preserving altruistic motivation is not a sufficient reason to object to the compensatory model.

## 5. SAFETY

*Proponents of the Acts refer to the 1980s tainted blood scandal, and to the subsequent Krever Inquiry's findings presented in 1997. Proponents suggest that the safety of the blood supply is suspect when a compensatory model is used. But these claims conflate two separate issues -- the compensatory model for blood plasma donations for, on the one hand, further manufacture into PDMPs and, on the other, purposes of transfusion.<sup>6</sup> We remind everyone that the compensatory model for the collection of blood plasma for purposes of transfusion is not at issue. The safety of plasma-derived medicinal products made from paid donors is well-established.*

5.1 Health Canada released the following Question and Answer in a Fact Sheet on its website:

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<https://www.canada.ca/en/health-canada/services/drugs-health-products/public-involvement-consultations/biologics-radiopharmaceuticals-genetic-therapies/backgrounder-paper-plasma-donations-canada.html>  
(Accessed: Nov. 7, 2017)

<sup>6</sup> "...for transfusion of (cellular) blood components, the collection and assessment of epidemiological data are critical. However, for plasma-derived medicinal products, the relation between a safe medicinal product and donor epidemiology is less straightforward as a result of the virus removing and/or inactivating capacity of the production process."

<http://www.sciencedirect.com/science/article/pii/S0887796313000357#bb0025> "Viral safety of human plasma-derived medicinal products: Impact of regulation requirements," 2013.

**Many Canadians taking plasma products were infected with HIV and hepatitis during the years of the tainted blood crisis. The Krever Inquiry Report recommended that blood donors should not be paid. Isn't allowing payment for plasma increasing the risk of another tainted blood crisis?**

No. Lessons of the tainted blood crisis must never be forgotten, and action has been taken since then to help prevent a tragedy like that from happening again. There are no plans to change Canada's voluntary blood for transfusion donor system. However, technological advancements have made plasma products safer. New measures such as heat treatment, filtration or treatment with chemicals have been put into place to remove or inactivate viruses or other contaminants when producing blood products from plasma. There has not been a single case of transmission of hepatitis B, hepatitis C or HIV caused by plasma products in Canada since the introduction of modern manufacturing practices over 25 years ago, despite the fact that most of the plasma donors were paid.<sup>7</sup>

5.2 Dr. Graham Sher, the CEO of Canadian Blood Services, has said, "It is categorically untrue to say, in 2015 or 2016, that plasma-protein products from paid donors are less safe or unsafe. They are not. They are as safe as the products that are manufactured from our unremunerated or unpaid donors."<sup>8</sup>

5.3 We accept the consensus view of medical scientists and professionals represented in the above, that compensating donors does not compromise the safety of PDMPs, including Ig.

5.4 With respect to the donors, we accept the consensus view of medical scientists and professionals that donating blood plasma is safe, and agree that Canadians should be encouraged to donate, with or without compensation.<sup>9</sup>

5.5 Canada has been importing PDMPs from the United States where donors are compensated. If there were safety concerns, we would not be engaged in this practice. In addition, proponents of the Acts do not call for a prohibition on the importation of PDMPs made from compensated donors. There is no reason to believe that PDMPs made from compensated Canadian donors would be any less safe than PDMPs made from compensated U.S. donors.

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<https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/activities/fact-sheets/plasma-donation-canada.html> (Accessed: Oct. 13, 2017)

<sup>8</sup> "Are products made from paid donors safe?" Canadian Blood Services, YouTube video [https://www.youtube.com/watch?v=vVtq4\\_ZKZXA&index=3&list=PLGp4DY\\_C\\_9dQw0x21pOTKPtFj41DGb\\_P](https://www.youtube.com/watch?v=vVtq4_ZKZXA&index=3&list=PLGp4DY_C_9dQw0x21pOTKPtFj41DGb_P) (Accessed: Oct. 13, 2017)

<sup>9</sup> See, for example, Crocco, I., Franchini, M., Garozzo, G., Gandini, A.R., Gandini, G., Bonomo, P. and Aprili, G., 2009. Adverse reactions in blood and apheresis donors: experience from two Italian transfusion centres. *Blood transfusion*, 7(1), p.35. ("In conclusion, the results of our 5-year survey document that apheresis and blood donation are safe procedures for the donor with a low incidence of adverse reactions; the adverse reactions that did occur were mostly mild and resolved rapidly.").

5.6 The risks of harm both to donors of blood plasma and patients who rely on PDMPs, including Ig, are negligible. We therefore conclude that safety concerns are not a good reason to oppose the compensatory model.

5.7 We note that the suggestion that PDMPs manufactured from compensated donations are unsafe is an unfounded allegation that runs contrary to medical expert consensus. Such unfounded allegations may be harmful insofar as they stoke unjustified fears that cause patients to avoid necessary treatments. We therefore caution proponents of the Acts not to imply or suggest that PDMPs made with compensated donors are risky or unsafe. Doing so is arguably unethical.

## 6. SECURITY

*The security of our supply of PDMPs, including Ig, is dependent on paid plasma donors. In 2016, for example, over 80 per cent of our immune globulin was imported from the United States, where donors are paid. Canadian Blood Services expects a doubling of demand for PDMPs by 2020. Even if Canadian Blood Services opens the 40 plasma clinics they have requested funds for, they anticipate meeting, at most, 50 per cent of the domestic demand for PDMPs. They have no plans to stop using PDMPs made with compensated plasma donations.*

6.1 It is morally urgent for Canada to have a sufficient quantity of PDMPs, including Ig, to meet the domestic demand for these products. Demand for PDMPs is expected to continue growing, with a 40% increase in global demand by 2020.<sup>10</sup>

6.2 Canada, along with the majority of the rest of the world, currently relies on the U.S., which uses a compensatory model, for the security of its PDMP supply, including Ig.<sup>11</sup>

6.3 The U.S. is able to supply the majority of the world with PDMPs, including Ig, because compensation has enhanced supply. The compensatory model, therefore, currently is essential to Canada's security of PDMPs, including Ig.

6.4 From a moral standpoint, focusing only on Canada may actually be too narrow; Canada should seek to be a net contributor to the global supply of PDMPs, including Ig. The goal of meeting 50% of the domestic need for PDMPs -- the most ambitious hope of Canadian Blood

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<sup>10</sup> See, for example, "Backgrounder: Plasma," Canadian Blood Services. <https://blood.ca/en/media/plasma> (Accessed: Dec. 15, 2017)

<sup>11</sup> According to Canadian Blood Services, for example: "Today, the amount of plasma we collect only meets only about 17 per cent of the need for intravenous immune globulins (IVIg), the plasma protein products in highest demand by patients. The remaining products we buy come from plasma donated by paid donors in the United States, which is not unique to Canada and ensures security of supply for patients. Without this system, patients who depend on these drugs would not have ready access to the therapies they need." <https://www.blood.ca/en/blood/plasma-sufficiency> (Accessed: Dec. 15, 2017)

Services should they receive funding for opening 40 additional clinics<sup>12</sup> -- may therefore be perceived as morally insufficient. Canada is in a position to strive to be a net exporter of blood plasma used for the manufacture of PDMPs, including Ig.

6.5 The evidence shows that a compensatory model for plasma is an essential tool for increasing supply.<sup>13</sup> We are skeptical of the claim that a non-compensatory model will promote the security of the supply of PDMPs, including Ig.

6.6 We are similarly skeptical of the claim that the compensatory model would crowd-out voluntary blood donation -- we have not seen sufficient evidence that this is so. Evidence from Saskatoon, where Canadian Blood Services competes directly with Canadian Plasma Resources, is inconclusive.<sup>14</sup>

6.6 We therefore conclude that, because improving the security of Canada's (and the global) supply of PDMPs is morally urgent, a compensatory model should not be precluded. Further, we conclude that jurisdictions that have banned the compensatory model ought to reconsider the Acts as swiftly as possible, and contribute to opening a more comprehensive conversation on the topic before taking impatient measures against the compensatory model.

## 7. CONCLUSION

7.1 In our view, none of the moral objections to the compensatory model are persuasive. Furthermore, there is a strong moral presumption against standing in the way of a model that is the most likely to promote security not only of Canada's supply of PDMPs, including Ig, but also of the global supply. We urge Quebec, Ontario, and Alberta to reconsider the Acts currently prohibiting compensation in their provinces.

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<sup>12</sup> See Kelly Grant, "Blood agency seeking \$855-million in funding to boost plasma supply, document reveals," *Globe and Mail*, August 14, 2017.

<https://www.theglobeandmail.com/news/national/blood-agency-seeking-855-million-in-funding-to-boost-plasma-supply-document-reveals/article35980339/> (Accessed: Dec. 15, 2017)

<sup>13</sup> For example, see Henry G. Grabowski & Richard L. Manning (2016) An Economic Analysis of Global Policy Proposals to Prohibit Compensation of Blood Plasma Donors, *International Journal of the Economics of Business*, 23:2, 149-166. ("...compensated plasma donation is important for maintaining adequate and consistent supplies of plasma and limits the risk of under-treatment for the foreseeable future." <http://www.tandfonline.com/doi/full/10.1080/13571516.2016.1182690>)

<sup>14</sup> Saskatoon has seen a 35.8% increase in new donors, with 1,184 such donors from April-March 2016, and 1,608 new donors in April-March 2017. Canadian Blood Services concludes that "The active donor base and donation frequency for Saskatoon does not show evidence of an impact of CPR's operations on Canadian Blood Services. The active donor base for Saskatoon continues to increase, on an upward trend." Letter to The Honourable Jim Reiter, Minister of Health, Feb. 21, 2017, at p. 7. The letter does note, however, that "The 17-to 24-year-old segment is experiencing a double-digit decline at the Saskatoon site. This could be attributed to CPR and the demographic they are targeting for recruitment. This trend is not reflective of national and regional trends for this age cohort." (p. 1). See: <http://www.healthcoalition.ca/wp-content/uploads/2017/11/ATI-Request-CPR-in-SK-Response-Package-with-Redactions-2017-09-12.pdf> (Accessed: Dec. 15, 2017).

7.2 Finally, we note that well-informed opponents of the compensatory model should not suggest that PDMPs, including Ig, made with compensated donors are riskier or less safe than PDMPs, including Ig, made with uncompensated donors. This presumption may be harmful to patients.