Donation Ethics
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Donation Ethics expresses concerns about a Senator's proposal to ban compensation for blood plasma donations in Canada.

Submission to the Senate of Canada on Bill S-252.

1. INTRODUCTION

1.1 We are professional ethicists and economists. We work in the fields of medical ethics, business ethics, or normative ethics, and study how incentives, including economic incentives like compensation, affect individual behaviour. We all share the goal of improving social welfare through our research.

1.2 The Provinces of Québec (1994),[1] Ontario (2014),[2] Alberta (2017),[3] and British Columbia (2018)[4] have passed Voluntary Blood Donations Acts or their equivalents that, amongst other things, prohibit compensation for plasma donations for purposes of further processing into plasma-derived medicinal products (PDMPs), like Immune Globulin (IG) and Albumin.

1.3 Independent Senator Pamela Wallin has introduced the Voluntary Blood Donations Act, Bill S-252, which would apply across all of Canada, and supersede any Provincial or Territorial legislation.

1.4 We have strong reservations regarding this Bill, as well as each of the Provincial Acts. 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 and the economic facts may actually speak in favour of the compensatory model, and therefore against the Bill.

1.5 Below, we respond to the arguments presented in support of Bill S-252. We agree with all major medical oversight bodies that there are **no safety issues** associated with the compensatory model (§2). We add that **raising unsubstantiated safety concerns misinforms the public** (§3). With regard to the **security** of Canada's supply of PDMPs we note that it is implausible to suggest that we can be self-sufficient in PDMPs without use of the compensatory model (§4). Relatedly, arguments that the compensatory model does not contribute to the security of the Canadian PDMP supply because plasma collected under the compensatory model is **exported** misunderstand the reasons for such exportation (§5). With regard to the likely effect of the compensatory model on uncompensated donations we note that while some **crowding out** may occur, it is not expected to have a negative net impact on the total supply, nor to in any way undermine Canada's ability to satisfy patient demand for any blood product (§4). Further, permitting the compensatory model does not represent **privatization** of Canada's publicly-funded health care model, and is in fact fully compatible with such a model (§6).

1.6 We respond to the ethical arguments offered in favour of the Bill: we object to the claim that the compensatory model would result in **wrongful exploitation** (§7). As currently practiced in jurisdictions that permit compensation, it is both respectful and fair to the donor. We regard the claim that the compensatory model would result in donation for personal gain over donation from **altruistic motives** as implausible (§8). We note the apparent **inconsistency** of relying on plasma collected abroad using the compensatory model while arguing against that model's use domestically (§9). We close our letter with a brief note addressing potential concerns about **conflicts of interest** (§10).

1.7 Given the above, the moral urgency of increasing the supply of PDMPs not just in Canada but around the world, and the weakness of the economic and ethical arguments thus far presented against the compensatory model, we conclude that **the present Bill is not justified in its current extreme form**. A broader and deeper discussion should be had before we implement a complete prohibition.

2. SAFETY

In introducing Bill S-252, Senator Wallin has said[5]: "The experts will argue that we have checks and balances in our system. And, yes, these cash-for-blood clinics are inspected and regulated. However, the issue is not clean floors or comfy chairs; the issue is clean blood." She also stated: "We didn't know what HIV was when it turned up, so we couldn't test for it. We didn't know the dangers of hepatitis C when it turned up, so we couldn't test for it. We don't know what the next blood-borne evil will be, so we can't test for that, either." Finally, she added, "Still, despite all the new science in the world, the best preventative measure against tainted blood is to have a safe and known source of blood. So you can understand why many of us are a little skeptical when we're told that all is safe now — but you can't find what you don't know you're looking for. The point of this bill is a simple one: Let's be better safe than sorry, as Krever pleaded with us to do."

We interpret these comments, and others like them, as claiming that the compensatory model, per se, raises safety concerns, while uncompensated blood donation does not, or at least raises them to a lesser extent.

2.1 Compensated and uncompensated plasma donations are **tested and regulated in the same way**. The final report of the Health Canada Expert Panel Review said, "In terms of safety, the global tragedy of the 1980s (as described in Canada by Krever) resulted in a significant international overhaul of legislation and regulation, systems and processes involved in screening and testing blood and plasma donors and their donations, the handling of plasma for fractionation, and the manufacturing processes involved in the production of PD[M]Ps. Current measures ensuring the safety of IG and PD[M]Ps are based on a multi-pronged approach. Many of the steps taken to assure the safety of these products are embedded in regulation and legislation and apply to all plasma donors, volunteer or paid, as well as those agencies and facilities collecting and processing plasma to make PD[M]Ps. In addition to the regulatory framework, fractionation industry associations have rigorous quality programs (Quality Standards of Excellence, Assurance and Leadership (QSEAL)/International Quality Plasma Program (IQPP) standards in particular) which call for

requirements beyond regulations which further enhance the safety of IG and other PD[M]Ps. The outcome of these changes has been dramatic: **there have been no confirmed cases of disease transmitted through PD[M]Ps in over 2 decades**." (*Bold in original,* pp. VII-VIII)

2.2 The primary role of the oversight and regulatory bodies responsible for regulating blood donation and blood products in Canada, the U.S., Australia, New Zealand, and European jurisdictions, is to ensure safe and clean blood and blood products, not "clean floors" and "comfy chairs." The relevant regulatory body in Canada is the Biological and Genetic Therapies Directorate.

2.3 The Network of Rare Blood Disorder Organizations, in their submission to you on this Bill, wrote: "Thanks to rigorous donor screening, testing of donations and viral clearance procedures, these products have maintained a perfect safety record with regard to pathogen transmission for the last 25 years. It is false to state that PDMPs from compensated donors are less safe than those from unpaid donors." We consider these groups, represented by the NRBDO, to have the most at stake with regard to the safety of PDMPs, and so we consider their conviction that PDMPs made under the compensatory model are safe to be of significant evidentiary value.

2.4 We accept the consensus view of medical scientists and professionals that compensating donors does not compromise the safety of PDMPs. We agree that PDMPs made under the compensatory model are "just as safe as" (Dr. Graham Sher) and "equally safe as" (Dr. Dana Devine)[6] PDMPs made with non-compensated donors.

2.5 With respect to the donors, evidence from the United States suggests that twice-weekly donations (two times within 7 days, with at least 2 days between donations) is safe. While there is insufficient evidence regarding long-term donation by individuals at this rate, the current expert consensus is that donations at that rate present a negligible risk to the donor. In Canada, however, donors are permitted to donate plasma at a frequency of only once every 6 days. We conclude that donating plasma in Canada presents negligible risks.

2.6 Given the above, we conclude that while safety considerations, as regards both PDMP recipients and donors, could, depending on the evidence, provide grounds for supporting Bill S-252, the evidence is that the compensatory model is safe. Therefore, safety concerns provide no grounds for support of Bill S-252.

3. RAISING UNSUBSTANTIATED SAFETY FEARS MISINFORMS THE PUBLIC

3.1 Tens of thousands of Canadians rely on PDMPs made under the compensatory model. Suggesting that these PDMPs are less safe than PDMPs made without use of the compensatory model is potentially harmful to these patients. A public opinion poll conducted by one of us shows that Canadians are misinformed about the safety of PDMPs made under the compensatory model.[7]

3.2 Whenever a person whose declarations are likely to be taken seriously by the public either is or can be reasonably expected to be aware of the expert consensus regarding the safety of a product,

has no grounds to doubt the accuracy of that consensus, but nevertheless raises safety concerns, that person misinforms the public.

3.3 We therefore call on all opponents to the compensatory model to stop suggesting that there are safety concerns, unless the expert consensus changes. We also call on opponents to the compensatory model to remove suggestions of a safety risk from their publicly available statements. Given that many Canadians are misinformed on this issue, we finally call on opponents of the compensatory model to reassure Canadians that PDMPs made under the compensatory model are safe.

4. SECURITY

Senator Wallin has said: "And there is evidence that a cash-for-blood system undermines the precious voluntary system. Today there are billboards along Saskatchewan highways pleading for donations." She added, "It is clear that a federal law must be in place in order to restrict Health Canada from undermining the security of the Canadian blood supply by allowing more of these private, for-profit clinics."

We interpret Senator Wallin's comments as suggesting that the compensatory model may negatively affect non-compensated blood donation, and that the compensatory model in Saskatoon has already negatively affected non-compensated blood donation there.

4.1 We accept that it is possible that the compensatory model could crowd out some non-compensated blood donation. However, this claim is unsupported by the empirical evidence available to date, including evidence from Saskatoon.

4.2 Canadian Blood Services (CBS) hypothesized that a decline in donations amongst 17-25 year-olds in Saskatoon was partly the result of Canadian Plasma Resources (CPR) opening a clinic there. As we have data from both CBS as well as CPR, we can say with confidence that any decline in blood donations at CBS in Saskatoon was not caused by CPR. The decline in donations started in October of 2015, and leveled off in March of 2016. CPR opened their clinic on Feb. 25, 2016. From opening through the end of April, CPR had a total of nine donors in the 17-25 demographic.

4.3 CBS acknowledged this. In their presentation before the Health Canada Expert Panel in October, 2017, the Panel summarized the CBS presentation as follows: "CBS indicated that there was no significant trend that CPR operations were affecting CBS Saskatoon operations, where its collections are still increasing year over year." (P. 50)

4.4 The Expert Panel, after considering the empirical evidence currently available on the issue of crowding out, concluded that there is currently "no clear evidence that unpaid or paid source plasma collection is having a negative impact on the blood supply." (P. 50) The long experience of the United States appears to show that the compensatory model can operate side-by-side with non-compensated donations effectively. Similarly, after legalizing the compensatory model in 2007, the Czech Republic saw no significant impact on non-compensated whole blood collection. Hungary

has been cited by some as an example of a jurisdiction that saw a decline in whole blood collection as a consequence of compensated plasma donations. However, the Hungarian Blood Transfusion Service reported to the Expert Panel that there has been no "data that demonstrate an impact of private plasma collection on whole blood collection," and that they believe that the reduction in whole blood donations, which has not caused shortages, is "tied to other factors." (P. 48-49)

4.5 Currently, the security of Canada's supply of PDMPs is almost entirely dependent on the compensatory model. According to a letter to Jane Philpott from the National Rare Blood Disorder Organizations, "Of the approximately 30 plasma products distributed by CBS and Héma-Québec (H-Q), only one is manufactured from plasma collected wholly from unpaid Canadian donors. Two more, IG and Albumin, are derived from a combination of U.S. paid plasma and CBS/H-Q plasma. All the others are manufactured entirely from the plasma of compensated U.S. donors. More than 70 percent of the plasma required by CBS for the PDMPs they distribute is collected from compensated U.S. donors. This figure approaches 90 percent for H-Q. Every year, demand for plasma for IG is rising faster than the plasma supply from non-compensated Canadian donors."[8]

4.6 Despite a variety of efforts in various jurisdictions around the world, no jurisdiction has achieved self-sufficiency without the use of the compensatory model. The Expert Panel reports that "No country in the world has been able to meet their need for plasma with a solely volunteer model." In addition, the report notes that, on average, commercial plasma clinics that use a compensatory model collect 40,000-50,000 litres per clinic, while clinics that do not use the compensatory model collect, on average, only 4,000 to 15,000 litres per clinic. (P. 47)

4.7 Many incentives that, in some jurisdictions, technically count as non-compensation or non-remuneration are, in fact, compensation. 11 European jurisdictions offer a paid day off work for those who donate blood or plasma. All of these jurisdictions therefore use a compensatory model, despite the fact that only three of these jurisdictions recognize it as compensation.

4.8 The experience of H-Q provides further support for the view that self-sufficiency in PDMPs without use of the compensatory model is deeply implausible. In 2014, H-Q set a target of 200k litres of plasma collected per year at their four Plasmavie clinics. In 2016/17, the four clinics collected only 44k litres combined, missing their target by 78%. We predict that Plasmavie will continue to miss its targets. We also predict that CBS will fail to meet its targets for self-sufficiency in plasma, unless CBS makes use of the compensatory model which they are currently legally permitted to use, and which we urge them to use as soon as possible.

4.9 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. While worries about security would, depending on the empirical evidence, provide grounds for support of Bill S-252, the current evidence does not provide such grounds, and in fact provides evidence that security requires the compensatory model.

5. EXPORT

In introducing the Bill, Senator Wallin said, "The companies in operation are currently exporting out of this country the plasma they have collected, making no contribution to our blood supply." She added, "It is also important that Canada should be self-sufficient in blood and blood products. Paid-for blood is all exported and sold to the highest bidder. Let me say that again. None of the blood that is collected from paid donors in Canada stays in this country."

We interpret her comments as suggesting that the compensatory model does not, of necessity, promote security of supply in Canada.

5.1 Plasma clinics in Canada, the U.S., and Europe require two separate licenses. One license permits them to operate within a jurisdiction, while a second license permits them to sell plasma within that jurisdiction. Canadian Plasma Resources initially was licensed only by Health Canada, which gave them the right to operate and sell only within Canada, and not abroad. Our understanding is that the intention behind the founding of CPR was to increase Canada's supply of plasma for purposes of making PDMPs. Our understanding is that this remains the intention of CPR.

5.2 Canadian Blood Services decided not to purchase plasma from CPR. This is so even though CPR offered Canadian plasma to CBS at an approximately 20% discount on the American plasma that CBS was purchasing. Only after CBS declined CPR's offer of all of the plasma it was collecting did CPR seek additional licensing to be able to sell their plasma abroad.

5.3 CBS may choose at any time to accept the offer of plasma by CPR, which would contractually obligate CPR to sell only to CBS.

5.4 To the extent that Senator Wallin's argument is persuasive, this has nothing per se to do with the compensatory model, nor with permitting private plasma clinics to operate in Canada. Instead, it is an argument best directed at CBS: CBS should be urged to contractually obligate Prometic in Winnipeg, CPR in Saskatoon and Moncton, and any other plasma clinic that may open in Canada to sell plasma to CBS.

6. PRIVATIZATION

6.1 Opponents of the compensatory model sometimes conflate the issue of compensating donors with privatization, but the two are independent. CBS is legally permitted to compensate donors, even in jurisdictions that have already passed a Voluntary Blood Donations Act, and even if no one else is compensating donors (or collecting donations at all). Thus, if CBS were to pay donors, that would not mean that our blood system is therefore private. (It is also possible for private collection facilities to operate without the compensatory model, though such facilities would presumably be non-profit.)

6.2 There is no proposal for CBS and Héma-Québec to stop being the exclusive buyers of all blood, plasma, and blood products, including PDMPs, made in Canada, and therefore nothing threatening the possibility of CBS and H-Q being the sole users of the compensatory model.

6.3 Whether or not we should permit private plasma collection facilities depends on what would best promote the health and health equity of Canadians currently and in the future. Since these clinics are safe, do not undermine uncompensated blood collections, operate at a lower cost to Canadians, and contribute to the global supply of PDMPs, we see no reason to prohibit them. However, even if there are such reasons, they would do nothing to undermine our argument that CBS itself should adopt the compensatory model.

6.4 We conclude that worries about privatization provide no grounds for supporting Bill S-252.

7. WRONGFUL EXPLOITATION

Senator Wallin has asked, "Are we exploiting young people at universities who are always short of cash?" She has also said, "Cash for blood incentivizes the wrong behaviour. Canadian donors are not meant to be a revenue stream for private companies looking to make a profit."

We interpret her comments as suggesting that the compensatory model is wrongfully exploitative.

7.1 To establish a charge of wrongful exploitation, those making the claim must meet at least one of a three-pronged test for exploitation concerning undue risk, undue inducement, or an unfair division of the benefits from trade. The test of undue inducement includes background conditions that a potentially exploited person confronts.

7.2 As discussed above (§2.5), compensated plasma donations present no undue risk to donors.

7.3 Compensated plasma donation also does not unduly induce donations. In Canada, donors are paid about CAD$40-50 per donation which takes approximately 1.5 hours. This amount is neither extremely low (it is well above the minimum wage), nor is it so high as to cloud a potential donor's judgement about what is best for her.

7.4 The amount of compensation represents a fair division of the benefits from exchange. The amount given to donors represents approximately 30% of the total revenue from a litre of plasma. By way of comparison, this is considerably higher than the fraction of a good's value that wages generally represent. One could argue that this estimate is problematically low, since the benefits include the health benefits to an eventual recipient, but it is hard to see how this would speak against the compensatory model, as opposed to speaking for higher compensation.

7.5 Canadian Blood Services and Héma-Québec collect revenue from uncompensated blood and plasma donations. Donors are and will be a revenue stream, regardless of whether the donor is

compensated or not. The only difference is whether or not donors receive a portion of the revenue that is generated from their donations.

7.6 Everyone who participates in the supply chain for PDMPs is compensated, except for the donor. It is at least surprising that this is so. Opponents of the compensatory model have not adequately explained why it is morally inappropriate for donors to receive compensation while it is morally appropriate for all other persons involved in the acquisition, manufacture, and distribution of PDMPs to be compensated.

7.7 The overwhelming majority of Canadians agree with our view that compensating donors is "morally appropriate." In the most recent public opinion poll, conducted by one of us, more than 70% of Canadians expressed favour toward legislation that would allow payments for donors, and many of these indicated moral appropriateness as one of the reasons for their position.

7.8 It is more plausible to argue that a failure to provide a fair share of the revenue to the donor is wrongfully exploitative. That is, when everybody else involved in the transaction—from the administrators to the phlebotomists to the nurses and doctors to the makers of plasmapheresis machines and so on—receives compensation, to fail to also compensate the donor appears wrongfully exploitative.

7.9 We conclude that worries about wrongful exploitation provide no grounds for support of Bill S-252, and are better regarded as arguments in favour of expanding the compensatory model.

8. ALTRUISM

Senator Wallin has said: "We want people volunteering to donate blood because it is the right thing to do, not because they want a gift card. To see posters posted above urinals in universities enticing young men to sell their blood strikes a blow at the very heart of our volunteer system. It undermines our natural instincts to be altruistic—to be our brother's or sister's keeper."

We interpret Senator Wallin's comments as suggesting that donors should only be motivated by altruistic considerations, and that the compensatory model conflicts with altruistic motivations.

8.1 Accepting, for the moment, the assumption that altruism and compensation are incompatible, a separate question is why altruism is uniquely important only at this specific point in the supply chain for PDMPs, but not at other points in the supply chain. We anticipate that no one would support a Voluntary Nurses/Doctors/Phlebotomists During Blood Donations Act nor a Voluntary Blood Collection Systems Act, nor a Voluntary Canadian Blood Services Employees Act. We anticipate that most people think it is morally appropriate for nurses, doctors, phlebotomists, administrators, and so on, to be compensated for their work in our blood collection system.

8.2 We endorse the following views: we want people to be teachers because they love teaching, and not just because they want a teacher's salary; we want people to become nurses or doctors

because they want to help heal the sick, and not just because they want a nurse's or doctor's paycheck; we want senators to accept appointment to the Senate because they care about the common good, and not just because they want the salary and financial benefits of being a Senator; and so on. None of these desires provide grounds for supporting a Voluntary Teachers, Nurses, Doctors, or Senators Act. Similarly, and for the same reasons, we believe that wanting people to donate because it is the right thing to do and not just for compensation provides no grounds for banning compensation for plasma donation.

8.3 The reason is that altruism and compensation are not incompatible. We believe that the choice to be a teacher, a nurse, a doctor, or a senator is frequently driven primarily by a desire to educate, and heal, and to promote the common good altruistically. We see no reason why an offer of compensation is incompatible with donors choosing to donate primarily for altruistic reasons.

8.4 We conclude that worries about altruism provide no grounds for support of Bill S-252.

9. INCONSISTENCY

9.1 We end with a note regarding apparent inconsistencies. It strikes us as inconsistent to argue that the compensatory model is wrongfully exploitative if practiced in Canada, but to rely on precisely that model in the U.S. and Europe to ensure the security of Canada's supply. It is also inconsistent to argue that all and only donors should receive no compensation, while everyone else is compensated for their contribution to the supply and delivery chain of PDMPs.

10. CONFLICTS OF INTEREST

10.1 We end by noting that we, the undersigned, have no conflicts of interest. None of us is receiving any funding or compensation for presenting this letter, nor for anything associated with this letter or its content. We have received no financial support for this effort whatsoever. All expenses related to this effort are funded by us as individuals. If the Senate chooses to pass Bill S-252, contrary to our advice and arguments, none of us will be made financially worse or better off as a consequence. Likewise if the Senate chooses to heed our advice and arguments and reject Bill S-252, none of us will be made financially better or worse off as a consequence.

SIGNED,[*]

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[1] Text in the Civil Code of Québec
[2] Text of the Act
[3] Text of the Act
[4] Text of the Act
[5] Senator Wallin's comments appear in Hansard.
[6] Dr. Dana Devine, Chief Researcher at Canadian Blood Services and editor-in-chief of Vox Sanguinis, tweeted on June 14, 2018, "Philosophical arguments aside, the scientific evidence supports the position that products made from plasma from paid donors are equally safe as that from unpaid donors."
[7] http://www.nber.org/papers/w24572
[8] http://www.nrbdo.ca/uploads/8/5/3/9/8539131/letter_in_support_of_paid_plasma_collection_-_feb_2016.pdf
[*] The views expressed are those of the signatories and are not necessarily shared by the institutions with which they are affiliated. All signatories are Canadian or work at Canadian institutions, with the exception of David Faraci, who signs as co-founder of Donation Ethics.