Bloody Well Pay Them

The case for Voluntary Remunerated Plasma Collections

Peter Jaworski, Ph.D

NISKANEN CENTER

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WAITLIST ZERO

CONTENTS

Executive summary 5

About the author 7

Acknowledgements 7

Introduction 11

1 The global supply of plasma 25

2 Resistance to modernisation: myths and misconceptions 48

Conclusion 61

Appendix A Resistance to modernisation: Naive moralisms 63

EXECUTIVE SUMMARY

- Blood plasma is used in a wide, and growing, range of life-saving therapies. It is now being trialled to treat Covid-19, including by the United Kingdom's National Health Service.
- There are significant global shortages of blood plasma. Demand is growing at a rate of 6-10% per year. Three-quarters of people do not have access to the appropriate plasma therapy, largely outside of developed countries.
- Shortages are significantly exacerbated by the World Health Organisation's policy — adopted by the United Kingdom, Australia, New Zealand and some Canadian provinces — to rely exclusively on Voluntary Non-Remunerated Blood Donations (VNRBD).
- The United Kingdom imports 100% of its supply of blood plasma, Canada (84%), Australia (52%), and New Zealand (13%). They are increasingly dependent on imports for blood plasma from countries that remunerate donors. This inflates the global blood plasma price, making it unaffordable for low to middle income countries.
- The United States, which allows remuneration of donors, is responsible for 70% of the global supply of plasma. Together with other countries that permit a form of payment for plasma dona-

tions — including Germany, Austria, Hungary, and Czechia — they account for nearly 90% of the total supply. The dependence on a small number of countries is a serious health security threat.

- Non-remunerated donations are estimated to be 2-4 times *more* expensive than remunerated collections, because of the expense of recruiting and retaining donors, including through marketing. Australia, for example, could save $200 million annually by importing all blood plasma.
- There are significant global shortages of plasma therapies. The growing global demand cannot be met without remuneration.
- The evidence is clear that remunerating individuals for blood plasma donations is safe, would ensure a secure supply of plasma, does not discourage non-remunerated blood donations, and would provide significant patient benefits, including peace of mind.
- In order to ensure a safe, secure, and sufficient supply of plasma therapies, the United Kingdom, Canada, Australia, and New Zealand should adopt Voluntary Remunerated Plasma Collections (VRPC):
    - VRPC means individuals are paid, in cash or in-kind, to give plasma of their own free will. It also means collections using modern deferral and testing techniques, such as deferring higher-risk donors and advanced viral detection tests.
    - VRPC would allow the Canzuk countries to at the very least become self-sufficient, and potentially contribute to the humanitarian goal of increasing the global supply of blood plasma for low to middle income countries.

ABOUT THE AUTHOR

Peter Martin Jaworski, Ph.D., is an Associate Teaching Professor in Strategy, Ethics, Economics and Public Policy at Georgetown University's McDonough School of Business.

Peter is a Canadian who received his Ph.D. in Philosophy from Bowling Green State University, his MSc in Philosophy & Public Policy from the London School of Economics, and a MA in Philosophy from the University of Waterloo.

He has published in *Ethics, Philosophical Studies*, the *Canadian Journal of Law and Jurisprudence*, the *Journal of Business Ethics*, amongst others. His work has appeared in or been cited by *The Economist*, the *Washington Post*, the *Globe and Mail* (Canada), the *Toronto Star* (Canada), *Financial Review* (Australia), *USA Today*, and others.

He is an adjunct fellow with the Niskanen Center, as well as the Cato Institute.

ACKNOWLEDGEMENTS

For help with gathering data and editorial suggestions, Peter would like to thank Luke Semrau, Sahar Akhtar, Govind Persad, Nikola Kovacikova, William English, David Faraci, Julia Fabens, Jason Brennan, Samuel Hammond, John Hasnas, Matthew Lesh, Thomas Mulligan, Abraham Singer and Ben Bronner.

"IVIg demand is rising at a rate that is unsustainable."

- National Blood Authority Annual Report, 2013/14, p. 32

"In Wales alone requests for immunoglobulin have increased by 35% since 2013, and there is now concern the situation is unsustainable in the long term."

- BBC News, April 15, 2019

"Over the 10 years to 30 June 2018 immunoglobulin annual demand growth averaged 6.43% per annum. In the 2018/19 financial year the rate of annual increase is forecast at a 7.0% growth rate. This rate of increase year on year is not considered sustainable."

- New Zealand Blood Service, Annual Report, 2019/20, p. 18

"We rely too heavily on a foreign supply of plasma to meet the Ig needs of patients in Canada. This degree of reliance is not only unsustainable, it puts patients at risk."

- Canadian Blood Services, Annual Report 2017-2018.

"Dependence on import of plasma and plasma derived medicinal products outside EU and EFTA could, in crisis situations, jeopardize the supply and treatment to patients."

- European Blood Alliance, 2015 Annual Report, p. 6

"Should some novel transmissible agent appear in the United States, a prion or a virus resistant to inactivation or removal technology used in the plasma fractionation industry, US plasma collections could face a serious threat with disastrous consequences for global supplies of plasma."

- Strengers, "Plasma is a strategic resource," Transfusion (2016)

"This situation exposes European patients to the risk of sudden interruptions of plasma supplies from the U.S."

- Unnamed official, European Directorate for the Quality of Medicines and Healthcare (EDQM), (June 8, 2020), Reuters.

INTRODUCTION

Most nations have not been able to keep up with demand for human blood plasma in order to make plasma-derived medicinal products, or plasma therapies. This is a result of a policy, supported by the World Health Organisation, of relying exclusively on "Voluntary Non-Remunerated Blood Donations," or "VNRBD," even for the distinctly unique case of collecting blood plasma for plasma therapies. In order to meet the demands of patients, every country has come to rely increasingly on plasma from the United States, one of the few countries that permits some form of payment for plasma. The United States is responsible for 70% of the global supply of plasma. Along with the other countries that permit a form of payment for plasma donations (including Germany, Austria, Hungary, and Czechia), they together account for nearly 90% of the total supply.

This situation is unsustainable, a risk to security, and, most importantly, a threat to the millions of patients who currently depend on plasma therapies, those who will in future, and those who would benefit from them but do not have access. The arguments offered by the World Health Organisation and others against permitting remuneration for plasma collections used for the manufacture of plasma therapies are antiquated, but unfortunately resilient, artifacts of the available technology, the prevalent social scientific theories, and the then-reasonable moral theories of the 1970s, '80s, and possibly early '90s.

What was appropriate and reasonable then, however, is no longer so.

There is a simple, straightforward, and positive solution to this worrisome situation. The United Kingdom, Canada, Australia, and New Zealand, could embrace the policy of "Voluntary Remunerated Plasma Collections," or VRPC (defined below), domestically. These

KEY TERMS

PLASMA

Plasma is the straw-coloured part of our blood. It represents 55% of the total volume of blood, and carries red and white blood cells, platelets, as well as a variety of proteins including antibodies called immune globulins, albumin, and clotting factor.

RECOVERED AND SOURCE PLASMA

Modern plasma collection techniques include two plasma collecting methods. The first, called "recovered plasma," is plasma that is separated from a whole blood collection. Donors give whole blood and, afterwards, the blood is spun in a centrifuge which separates the plasma from the red and white blood cells and platelets, allowing the collection centre to isolate each of these components. The second, called "source plasma," separates the plasma from the other blood components while the donor is in her chair, allowing the centre to capture only plasma while returning the remaining blood components to the donor. This process, called "plasmapheresis," permits a donor to not only donate much more frequently but also to donate a much higher volume of plasma as compared to the plasma contained in a whole blood donation.

nations already rely on VRPC for a growing proportion of their plasma therapy needs. VRPC is effective where VNRBD for plasma therapies is not, VRPC is just as safe as VNRBD for plasma therapies, and VRPC is two to four times less expensive than VNRBD. VRPC recognizes the significant time commitment and expense involved in donating plasma through remuneration, and also enfranchises more people to participate in this altruistic act by removing financial barriers to donation. VRPC promotes altruism, the building of community, and is not exploitative.

In order to ensure a safe, secure, and sufficient supply of plasma therapies, the UK, Canada, New Zealand, and Australia should withdraw prohibitions on voluntary remunerated plasma collections, and thereby ensure domestic security of supply for our patients, and begin to contribute to the global supply of plasma.

SARS-CoV-2 and other uses

Transfusing the blood plasma of those who have recovered from Covid-19, called convalescent plasma, appears to help against the novel coronavirus.[1] The very same treatment has been used successfully as early as the 1918 Spanish Flu epidemic, and more recently with more similar infections such as MERS and the first SARS.[2] The UK's National Health Service has already begun trials of transfusing blood plasma of recovered Covid-19 patients.[3]

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1 Shen, C., Wang, Z., Zhao, F., Yang, Y., Li, J., Yuan, J., ... & Wei, J. (2020). Treatment of 5 critically ill patients with COVID-19 with convalescent plasma. Jama, 323(16), 1582-1589.

2 Chen, L., Xiong, J., Bao, L., & Shi, Y. (2020). Convalescent plasma as a potential therapy for COVID-19. The Lancet Infectious Diseases, 20(4), 398-400.

3 Catherine Burns & Rachael Buchanan, "Coronavirus: Thousands signal interest in plasma trial" BBC News, May 2, 2020, https://www.bbc.co.uk/news/health-52510865.

Convalescent plasma may also soon find another use in the form of a hyperimmune globulin. Hyperimmunes are plasma-derived medicinal products, or plasma therapies, made from isolated specific antibodies, in this case against SARS-CoV-2. Up to now, plasma therapies typically treat relatively rare immunological, haematological, and neurological ailments. The prospect of an anti-SARS-CoV-2

PLASMA-DERIVED MEDICINAL PRODUCTS (PLASMA THERAPIES)

Plasma is used both for direct transfusion and to manufacture plasma-derived medicinal products (plasma therapies) — also known as plasma-derived proteins, plasma protein products, plasma-derived therapies, plasma therapies, and so on.

These plasma therapies involve isolating and concentrating specific proteins through a process called "fractionation." They include albumin and clotting, or coagulation, factor, as well as Immune Globulin (Ig). Albumin is used to treat patients who have suffered severe burns, and those who are in shock. Clotting factors are used for patients who suffer from rare bleeding disorders like hemophilia, and von Willebrand disease. There are now recombinant clotting factors, which are therapies made not from human blood plasma, but from cell lines that express the protein. Most people with hemophilia in advanced nations, for example, make use of recombinant Factor VIII (rFVIII), and so are no longer reliant on human source plasma. However, there are types of hemophilia that still require non-recombinant clotting factors, and there are times when the non-recombinant version is required or preferred.

hyperimmune may expand the portfolio for which plasma therapies are indicated to a non-rare infection.[4] Meanwhile, polyvalent human immune globulin (Ig) is currently being used to treat children who have contracted a Kawasaki Syndrome-like ailment after initially recovering from Covid-19. Covid-19 has not only created potential new uses for therapies made from human blood plasma, it has also simultaneously dampened general plasma donations at most of the world's dedicated plasma collection centres, located in the United States.[5] Given how long it takes to manufacture plasma therapies, any decline in donations now would affect the supply of plasma therapies in seven to 12 months.[6]

These new uses for plasma therapies, and the reduction in plasma donations, will put additional strain on what was, even prior to this pandemic, a strained global supply. Demand for plasma used to manufacture plasma therapies, especially for Ig, has been outstripping

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4 There is also the hope that a plasma therapy may prove effective for other, non-rare diseases like Alzheimer's or dementia. See "Plasma exchange for Alzheimer's disease Management by Albumin Replacement (AMBAR) trial: Study design and progress," Boada, Merce et al., Alzheimer's & Dementia Translational Research & Clinical Interventions, 2019.

5 A Bio Products Laboratory spokesperson was quoted in The Guardian as saying "We do expect the rapid spread of Covid-19 could adversely impact the supply of plasma." https://www.theguardian.com/world/2020/mar/25/mexico-us-uk-blood-plasma-donations-coronavirus.

6 This was recognized at a special meeting of the European Commission on June 3, 2020. According to the Reuters story: "Although no shortages for transfusions were recorded, experts said problems may arise later in the year for supplies of plasma-derived drugs… If this so-called convalescent plasma, or a medicine derived from it, prove definitively effective against the disease, that could further strain Europe's supplies, the [unnamed] EDQM official said, adding that a strategy for its collection at industrial scale should be quickly devised." Francesco Guarascio, "Europe wants to make its own drugs, but it needs American blood plasma," (June 8 2020), Reuters, https://www.reuters.com/article/us-health-coronavirus-eu-plasma-analysis/europe-wants-to-make-its-own-drugs-but-it-needs-american-blood-plasma-idUSKBN23F1F7

domestic plasma collections in nearly every country in the world. There has been steady and significant downward descent in the proportion of plasma therapies manufactured from domestically-sourced plasma, and a steady upward climb in reliance on the United States.

National blood operators like Canadian Blood Services have warned about the dangers of over-reliance on one country for the global supply of plasma, cautioning against putting "all of our eggs in one basket."7 Along with Canadian Blood Services, New Zealand Blood Services and Australia's National Blood Authority have each raised the alarm, describing our current global plasma situation variously as "unsustainable," a "significant risk," a "serious threat," putting "patients at risk."

Nearly all the world's plasma collections happen to currently be in one basket, the United States. The possibility of supply interruptions for large parts of the United States, as happened in the UK with vCJD, is, while small, not non-existent. So, too, with temporary interruptions, as may happen in the case of the novel coronavirus, or as did happen in the summer and autumn of 2019 for Ig.8 This shortage affected not just patients outside of the United States, it affected patients in the United States as well. Given the present political situation, there is a risk of supply interruption based on an executive order, or a similar political decision, that prioritizes American patients. We also cannot ignore the tight connection between growth in the volume of Ig demanded by U.S. patients (8.7% CAGR from 2015 through 2017), and growth in the U.S. supply of Ig (9.5% CAGR from

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7 Canadian Blood Services, "ANNUAL REPORT 2016–2017" (October 2017) , P.12 and P. 8 http://itsinyoutogive.ca/Annual/2017/cbs-2016-2017-ar-en.pdf.

8 Shaw, Gina. "Nationwide, the Shortage of Immunoglobulin Is Impacting Practice: How Neurologists Are Managing It." Neurology Today 19.20 (2019): 1-32.

2015 through 2018).[9]

IMMUNE GLOBULIN (Ig)

The plasma therapy with the largest market share by far is "immune globulin" (Ig). This, too, has multiple names, and is sometimes called "immunoglobulin" or "gamma globulin." Immune globulins are antibodies that our immune system makes in order to fight off antigens or infections. For people with primary immune deficiencies (PID), Ig treatment (Ig Replacement Therapy, or IgRT) provides them with the antibodies that their immune system does not produce. PIDs are usually congenital, while secondary immune deficiency (SID) is an acquired version of immune deficiency, for whom IgRT is also essential. In recent years, the variety of diseases and syndromes that Ig has been found to be effective against has grown, especially in the field of neurology and haematology. IgRT has been found to be effective for many patients with Guillain-Barre Syndrome, or Multifocal Motor Neuropathy, for example.

TOWARDS VOLUNTARY REMUNERATED PLASMA COLLECTIONS

On June 11, 2009, the World Health Organization (WHO) issued "The Melbourne Declaration on 100% Voluntary Non-Remunerated Donation of Blood and Blood Components."[10] The Declaration was

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9 GRIFOLS, "Investor and Analyst Meeting 2019", (June 2019) , P. 17, https://www.grifols.com/documents/51507592/90066043/IAD+2019+Grifols.pdf/e2505992-1b9c-4168-9f08-b68a75170c4c.

10 The Melbourne Declaration on 100% Voluntary Non-Remunerated Donation of Blood and Blood Components, 11 June 2009, https://www.who.int/worldblooddonorday/Melbourne_Declaration_VNRBD_2009.pdf.

a re-commitment to, what they call, "Voluntary Non-Remunerated Blood Donations" or "VNRBD," as well as to World Blood Donor Day, celebrated every June 14th.[11] The Declaration set a target date for achieving 100% VNRBD in safe, secure, and sufficient blood and blood products, including plasma-derived medicinal products. That target date was 2020.

This year will end without a sufficient supply of plasma based on 100% non-remunerated plasma collections, neither will 2030. With each passing year from 2009 to the present, the world has moved further from that target, and closer to being nearly entirely dependent on the United States.

The policy of "non-remunerated blood donations" in blood and blood products (including plasma therapies) was initially recommended at a joint conference between the World Health Organisation and the International Red Cross and Red Crescent Societies in the form of a World Health Assembly resolution WHA28.72 in 1975.12 It has since been reaffirmed several times, including with the 2009 Declaration. The United States did not adopt this policy for plasma collections.

While the United Kingdom, Canada, Australia, and New Zealand have approved of the 11 year old Declaration, based on the now 45 year old World Health Assembly resolutions that they adopted, none of them have lived up to the resolutions in practice. While they do not remunerate residents within their own borders, each of them

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11 Blood safety: proposal to establish World Blood Donor Day, WHA58.13, Fifty-eighth World Health Assembly, May 23, 2005, https://www.who.int/bloodsafety/WHA58_13-en.pdf?ua=1.

12 Twenty-eight World Health Assembly, Utilization and supply of human blood and blood products (WHA28.72), https://www.who.int/publications-detail/utilization-and-supply-of-human-blood-and-blood-products-(wha28.72).

rely on the remuneration of American donors to meet their domestic needs. In practice, this means that British pounds and Canadian, Australian, and New Zealand dollars are used, after conversion, to remunerate American donors. VNRBD plasma therapies is more honoured in its breach than in its observance; better to be ignored than followed.

HYPERIMMUNE AND COVID-19

Ig can be fractionated further to isolate specific antibodies against specific conditions, like Covid-19. This is called a "hyperimmune globulin," or, simply, "hyperimmune." Currently, hyperimmunes are used against rabies, tetanus, sepsis, and a number of other conditions. It is thought that the specific antibodies present in the plasma of those who have recovered from Covid-19 can be used to treat patients infected with the novel coronavirus. Such a hyperimmune is likely to be not only more effective than a transfusion of convalescent plasma, but also be safer for the patient with fewer side effects and lower risk. In addition, some recovered children seem to come down with a Kawasaki syndrome-like disease, against which Ig appears to be effective.

The evidence suggests that VRPC is the only way of ensuring a safe, secure, and sufficient supply of plasma for fractionation. Contributing to the global supply is simply not possible with non-remunerated plasma collections. Meanwhile, the reason Germany, Austria, Hungary, and Czechia are either already contributingto the global supply, or at least trending significantly upward in terms of

domestic collections, is because they permit a version of VRPC.[13]

WHY THESE NATIONS?

The United Kingdom, Canada, Australia and New Zealand were chosen based on their similar blood and plasma collection policies and infrastructure, cultures and histories, wealth, and adoption of the latest medical technologies. They already look to each other for guidance with regard to their blood and plasma operations .[14]

These nations can also assist one another to attain strategic independence in their supply of plasma therapies. These countries are likely to prioritise each other as trade partners. Should the United States choose to alter their policies, demand will shift to the European nations of Germany, Austria, Hungary, and Czechia. These nations currently do not collect enough plasma to meet that expanded demand, and could prioritise existing relationships within the European Union. An Anglosphere-wide approach would secure not only strategic independence, but self-sufficiency in plasma therapies.

Finally, while the United States is the largest per capita user of immune globulin, Canada and Australia round out the top three,

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13 Each of these nations permit giving donors a sum of money, although that sum is capped to what they take to be the average expenses involved in donation. They thus call this "compensation" rather than "remuneration."

14 Australia's National Blood Authority, for example, calls this "Horizon Scanning" and explains that, "The NBA maintains constant horizon scanning and intelligence gathering, including from existing and potential suppliers, relevant industry analysts, and communications with comparable organisations in countries including the United Kingdom, Canada and New Zealand." NATIONAL BLOOD AUTHORITY AUSTRALIA, "ANNUAL REPORT 2018–19", (September 2019) , P. 51, https://www.blood.gov.au/system/files/D1938846-NBA-AnnualReport-2018-19-APDF-Accessible.pdf.

while New Zealand is ninth.[15] This high demand with limited supply results in increased costs for plasma therapies, affecting the ability of emerging, low and middle income countries to treat patients who require plasma therapies for their survival.

DEFINITION OF VOLUNTARY REMUNERATED PLASMA COLLECTIONS

Voluntary remunerated plasma collections (VRPC) means that a person gives plasma of their own free will and receives payment for it, either in the form of cash, or in kind which could be considered a substitute for money. This would include time off work. Tokens, large or small, tax credits, or contributions for education, are compatible with voluntary remunerated plasma collections.

VRPC also means collections that use modern deferral and testing techniques. This includes deferring higher-risk donors, and donors for whom donating is a risk to their health; use of advanced viral detection tests, as required by regulators like Health Canada, the U.S. Food and Drugs Administration, the European Medicines Authority, or the Therapeutic Goods Association, for the presence of viruses including, but not limited to, HIV, HBV, and HCV; adherence to the IQPP voluntary certification program or its equivalent; and adhering to the use of plasma therapy-appropriate modern viral inactivation and removal steps including, but not limited to, heat treatment, solvent and detergents, and nanofiltration with and without UV lights.

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15 "Plasma-Derived Medicinal Products (PDMPs) and Plasma Supply into the Future," Patrick Robert, The Marketing Research Bureau, Inc., European Blood Alliance and International Plasma and Fractionation Association (EBA-IPFA), Jan 14-15, 2020, at slide 20, https://ipfa.nl/wp-content/uploads/2019/08/1_5_ROBERT-Robert_IPFA-EBA_January14_Dispatch.pptx-FINAL-READY-FOR-PUBLICATION.pdf

These requirements can only be met by nations enjoying a high level of development. The United Kingdom, Canada, Australia, and New Zealand meet this criteria. To the extent that a nation is unable to meet these stringent requirements, they cannot be said to be using Voluntary Remunerated Plasma Collections.

1. THE GLOBAL SUPPLY OF PLASMA

Countries that exclusively use non-remunerated plasma collections for domestic plasma collections rely increasingly on the United States. The United States currently supplies approximately 70% of the global need, including about two-fifths of Europe's needs,[16] nearly all of the UK's, over four-fifths of Canada's, over half of Australia's, and around 12% of New Zealand's needs for plasma therapies. To put this into perspective, at present, 5% of the world's population is responsible for more than half of all the plasma collected in the world.[17]

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16 "The Evaluation of the EU legislation on safety and quality of Blood, Tissues and Cells - Plasma collection," Stefaan Van der Speiegel, IPFA-EBA workshop on plasma collection, Jan 14, at slide 12

17 "The Evaluation of the EU legislation on safety and quality of Blood, Tissues and Cells - Plasma collection," Stefaan Van der Speiegel, IPFA-EBA workshop on plasma collection, Jan 14, at slide 12.

The global plasma supply situation has resulted in a staggering volume of plasma and plasma therapy exports from the United States. According to an estimate by The Economist, exports of plasma and plasma therapies represented approximately 1.6% of total exports by GDP, or U.S.$26 billion, in 2018, up from US$23.6 billion in 2016 .[18] To put this figure into perspective, that is more than exports of steel and aluminum, or the 11th most valuable export by value. Current projections, meanwhile, suggest that this figure will rise to U.S.$44.3 billion by 2023.[19] Demand for plasma therapies is growing at 6-10% per year. According to the UK's NHS National Immunoglobulin Report 2018/19, "The global Ig market continues to see exponential growth, with additional treatment diagnoses and sustained growth in high dose neurology driving global volumes to an all-time high."[20]

The shortages in the United States and those of other wealthy, developed nations pales in comparison to the much worse situation in emerging, low and middle income countries. In 2015, the World Health Organisation estimated that approximately 1.4 million people around the world have a primary immune deficiency, with a majority

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18 "Lift bans on paying for human-blood plasma" The Economist, May 12, 2018, https://www.economist.com/leaders/2018/05/12/lift-bans-on-paying-for-human-blood-plasma; See Allied Market Research, "Blood Plasma Derivatives Market Expected to Reach $44,333 million, Globally, by 2023" https://www.alliedmarketresearch.com/press-release/blood-plasma-derivatives-market.html; See also Padraig Belton, "Should we pay people for donating blood?" BBC News, November 15, 2018, https://www.bbc.co.uk/news/business-46197271; See also US Trade Numbers WorldCity, "EXPORTS: PLASMA, VACCINES, BLOOD" https://www.ustradenumbers.com/export/plasma-vaccines-blood/.

19 Allied Market Research, "Blood plasma derivatives market expected to reach $44,333 million, globally, by 2023," https://www.alliedmarketresearch.com/press-release/blood-plasma-derivatives-market.html.

20 NHS, "Immunoglobulin Database Annual Report 2018/19", (December 2019) , P. 8, http://igd.mdsas.com/wp-content/uploads/ImmunoglobulinDatabaseAnnualReport201819.pdf.

of them requiring Ig therapy. However, "Over 75% do not have access to appropriate therapy."[21] The WHO concluded that more plasma was needed and insisted on the "recognition that supply has become a safety concern… Plasma is a precious resource, and data indicate that demand will only grow…" According to the most recent data available, North America and Europe together account for 74% of all the Ig used in the world, followed by Asia and the Pacific at 18%. Latin America uses just 5%, while the Middle East and Africa consume just 2%.[22] That represents millions of people who could be helped by plasma therapies, and choosing to contribute to the global supply by permitting voluntary remunerated plasma collections is one of the easier ways for wealthy countries to help.

VRPC vs. VNRBD

Wealthy countries have their needs for plasma therapies met thanks mainly to commercial plasma collections in the United States, but they also rely on commercial plasma collections in Germany, Austria, Czechia and Hungary, which permit a form of remuneration as well. All but the last of these are the only countries able to collect enough plasma to be self-sufficient with respect to Ig. All together, these five nations are responsible for 89% of the global plasma supply, and are

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21 World Health Organization, "Improving access to safe blood products through local production and technology transfer in blood establishments", (2015) , P. 14, https://www.who.int/phi/publications/blood-prods_technology_transfer.pdf.

22 https://www.edqm.eu/sites/default/files/medias/fichiers/Events/day_1.pdf, at slide 65

trending upwards because demand is growing significantly.[23]

Remuneration demonstrably leads to more donors, higher donation frequencies per donor, and so higher per capita collection volumes. In 2017, a total of 7,977,000 litres of plasma were collected in Europe, with Germany, Austria, Czechia, and Hungary contributing more than 55% of that total.[24] For example, Germany, where plasma donors can receive up to $25 Euro per plasma donation, needed 2,258,000 litres of plasma but collected 2,962,000 litres, for a surplus of 704,000 litres. This is despite the fact that Germany's demand for Ig was only slightly lower than France's at 9,032 Kg.[25] To take another example, consider the change to the laws regarding plasma collections in Czechia. In 2006 and 2007, the two years prior to the change, they collected 70,130 and 90,285 litres of plasma, respectively. After permitting compensated plasma donations, Czechia collected 272,217 litres in 2008, followed by 517,317 litres in 2009, and 663,639 litres in 2010. Over the three years from 2007 to 2010, Czechia man-

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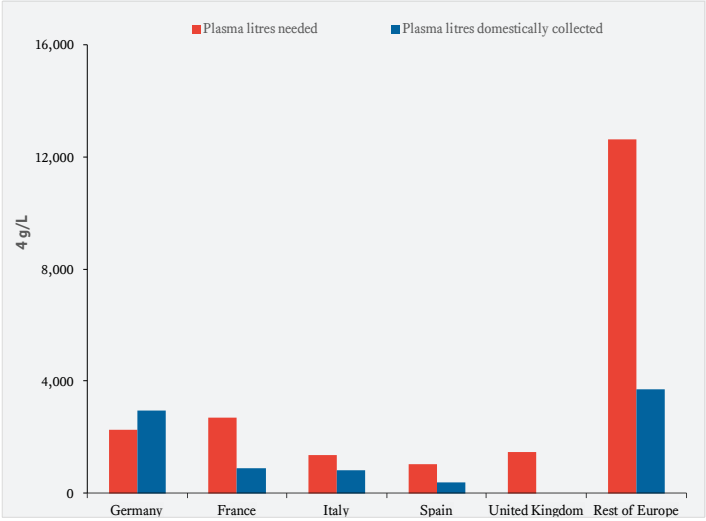
23 According to the Marketing Research Bureau, global consumption of Ig stood at 199,312 kilograms in 2018, requiring 57.8 million litres of plasma (that year, a litre of plasma could yield 3.45 grams of Ig). They predict that by 2026, 93.2 million litres would need to be collected to meet the predicted demand of 365,196 kilograms of Ig (assuming greater efficiency of yield at 3.85 grams of Ig per litre). Patrick Robert, "Plasma-Derived Medicinal Products (PDMPs) and Plasma Supply into the Future," The Marketing Research Bureau, Inc., European Blood Alliance and International Plasma and Fractionation Association (EBA-IPFA), (Jan 14-15, 2020), Slide 6. According to Sanquin, the national blood operator in the Netherlands, explained that "[w]ithout new policy measures" the U.S. will account for more than 90% of plasma therapies in Europe by 2025. Rene AW van Lier, "Meeting the demand for plasma in the Netherlands," Session 2.3, PPTA meeting. The Netherlands, incidentally, is 40-50% self-sufficient.

24 "Key Economic and Value Considerations for Plasma-Derived Medicinal Products (PDMPs) in Europe," Kluszchynski, T. et al., Vintura, at p. 45.

25 https://www.edqm.eu/sites/default/files/medias/fichiers/Events/day_1.pdf, at slide 71

aged to increase plasma collections seven-fold.[26]

Figure 1. Plasma in Europe



Relying exclusively on non-remunerated plasma collections has led to shortfalls in every European nation. To give a few specific examples: In 2017, France consumed 10,873 Kilograms of Ig, which (using an overly generous conversion of 4 grams of Ig per litre of plasma collected) means that they needed 2,718,000 litres of plasma. That year, France collected 892,000 litres, representing a shortfall of 1,826,000 litres. Spain, home to Grifols, one of the four largest plasma companies in the world with plasma collection centres in the U.S., consumed 4,203 Kg of Ig in 2017, requiring 1,051,000 litres of plasma. Spain only managed to collect 373,000 litres, a shortfall of 677,000 litres. Italy had a shortfall of 545,000 litres to meet the needs of its patients who consumed 5,500 Kg of Ig (Italy collected 1,375,000

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26 (2015) P. 3, https://www.uzis.cz/sites/default/files/knihovna/ai_2016_15_transfuzky_2015.pdf

litres of plasma).[27]

With respect to per capita collection volumes: In 2014, the U.S. collected 66 litres of plasma per 1,000 people. Austria, Czechia, and Germany collected 56.6 litres, 33 litres, and 31.6 litres per 1,000 people, respectively.[28] By 2017, these rates increased in each country: The United States nearly doubled to 113 litres per 1,000 people, with Austria, Czechia, and Germany collecting 75 litres, 45 litres, and 36 litres per 1,000 people respectively.[29] By way of comparison, consider countries that do not permit remuneration: The Netherlands, the next-largest European contributor per capita in 2017, had a rate of 19 litres per 1,000. Italy gave 14 litres per 1,000, France had 13 litres per 1,000 (down from 16.3 litres per 1,000 in 2014), and Norway and Sweden both had 12 litres per 1,000. Portugal gave 9 litres, while Poland, Finland, Estonia, and Spain collected 8 litres per 1,000.[30]

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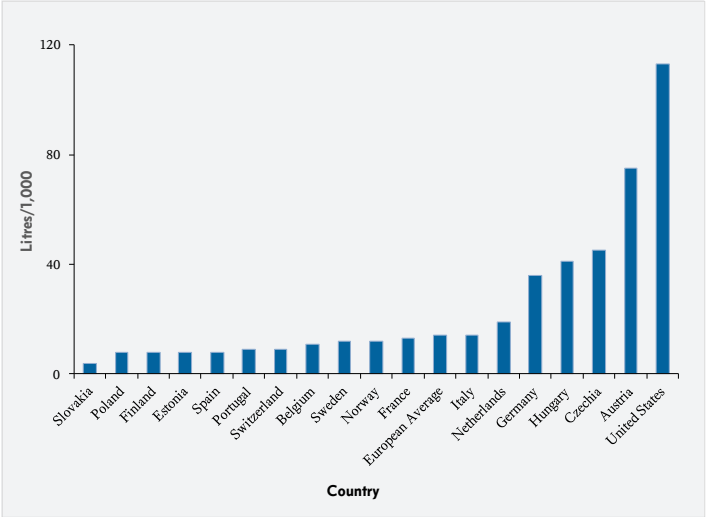
27 In many of these cases, the need is understated. Italy, for example, has a cap on how much Ig a doctor is permitted to prescribe, while the United Kingdom's demand management programme is very restrictive.

28 Health Canada Expert Panel, Table 3.2

29 Despite this increase in Austria, Czechia, and Germany, the growth in demand is such that the United States will provide a greater and greater total proportion of the need within Europe. As the European Commission explained: "While in the EU, the number of private plasma collection centres increased from 37 in 2005 to 103 in 2016, this is far from sufficient to keep up with increasing demand for manufacturing of plasma derived medicines." European Commission, "Evaluation of the Union legislation on blood, tissues and cells", (October 2019) , P. 54, https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/swd_2019_376_en.pdf.

30 Tomasz Kluszczynski, Silvia Rohr and Rianne Ernst, "Key Economic and Value Considerations for Plasma-Derived Medicinal Products (PDMPs) in Europe", (March 2020), P.47, https://www.vintura.com/wp-content/uploads/2020/03/White-paper-key-economic-and-value-considerations-for-plasma-derived-medicinal-products-PDMPs-in-Europe_Vintura-and-PPTA.pdf.

Figure 2. Plasma collections, 2017



With respect to donor frequency, plasma donors in the United States donate 17.3 times on average within a calendar year, or 21.4 times within 12 months of their first donation according to a 2017 study.[31] Compare that frequency to Quebec's at 5.9 in 2019,[32] or Australia at a mean of 4-5 plasma donations per year according to a 2011 study.[33] Across all European blood operators who are members in the European Blood Alliance, the average frequency of plasma donations

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31 George Brooks Schreiber and Mary Clare Kimbar, "Source Plasma Donors: A Snapshot," Transfusion, (2017), https://www.pptaglobal.org/images/presentations/2017/Schreiber.AABBposterAbstract_Source_Plasma_Donors_A_Snapshot_2017_9.27.17.pdf

32 HÉMA QUÉBEC, "The Start of a New Era", (2018-2019), P. 21, https://www.hema-quebec.qc.ca/userfiles/file/RA-2018-2019/Hema-Quebec_2018-2019_Annual_Report.pdf.

33 Liliana L.Bove, Tim Bednall, Barbara Masser and Mark Buzza, "Understanding the plasmapheresis donor in a voluntary, nonremunerated environment", (May 2011) , https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1537-2995.2011.03168.x.

per year was 4.5 in 2015.[34] In the Netherlands, the average plasma donor gave 5.1 times per year in 2015, 5.2 times in 2016, 5.4 in 2017, and 5.29 times in 2018.[35]

The growth in demand, meanwhile, is primarily a consequence of expanding approved indications for Ig therapy, as well as more accurate and earlier diagnoses of patients who would benefit from it. There is also growth in what the NHS calls "grey" uses, or what are sometimes called "off-label" uses of Ig. These "off-label" uses of Ig are not a significant influence on the demand. In Canada, for example, and according to Canadian Blood Services, off-label use is estimated to be around 4-11%.[36]

CANZUK

Taken together, the British, Canadian, New Zealand, and Australian situation is comparable to Europe's. Each nation has seen significant growth in use of immunoglobulin therapy in the five-year period covering 2014 through 2019, outstripping domestic growth in collections. Each of these countries have become more reliant on the United States to help fill the gap between the volume of Ig needed to help treat patients and the volume of plasma collected domestically.

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34 European Blood Alliance, "EBA ANNUAL REPORT 2015", (2015) , P. 22, https://www.europeanbloodalliance.eu/wp-content/uploads/2016/05/EBA_annual_report_2015.pdf.

35 Sanquin, "ANNUAL REPORT 2018", (2018) , P. 27, https://www.sanquin.nl/binaries/content/assets/sanquinen/about-sanquin/annual-reports/sanquin_annual_report_2018.pdf.

36 Canadian Blood Services, "Navigating complexity: Ensuring security of supply of PDMPs in the Canadian context", (January 2020) , P. 7, https://ipfa.nl/wp-content/uploads/2019/08/2_3_BEDARD-Responding-to-increased-demand-for-PDMPs_Canadian-Perspective_v4_NoNotes16x9.pdf.

UNITED KINGDOM

Of all these nations, the United Kingdom is the furthest from the objective of sourcing plasma therapies using only non-remunerated plasma collections. Fully 100% of their plasma therapies are imported from commercial sources using VRPC. This is a result of the decision by the UK government to stop collecting plasma for plasma therapies in 1999 in response to the theoretical risk of the transmission of variant Creutzfeld-Jakob disease, which is not detectable by modern screening tests .[37] This also motivated other countries, including the United States, Canada, Australia, and New Zealand, to defer donors who have spent more than three months in the UK between 1980 and 1996. This approach is out of an abundance of caution, since there is no conclusive evidence that anyone has ever been infected by vCJD through use of a plasma therapy.

Recently, however, a number of groups, especially patient groups, have begun urging the UK government to reestablish plasma collections. For example, Primary Immunodeficiency UK (PID UK) began such a lobbying effort in 2018.[38] According to PID UK, "spontaneous" development of CJD is the same in the UK as compared with other countries. To maintain an abundance of caution, it may be best that only those residents of the UK who were born after 1996, or those who did not reside in the UK from the period of 1980 through 1996 inclusively, be given the option to donate plasma. This would still represent a sufficiently large population for successful plasma collections, especially in jurisdictions with large student and immigrant populations. The best approach is for the UK to permit com-

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37 See GOV.UK, "Measures currently in place in the UK to reduce the potential risk of vCJD transmission via blood" https://www.gov.uk/government/news/measures-currently-in-place-in-the-uk-to-reduce-the-potential-risk-of-vcjd-transmission-via-blood.

38 PID UK, "Instability in Immunoglobulin supply" http://www.piduk.org/advocacy/instabilityinimmunoglobulinsupply.

mercial voluntary remunerated plasma collections. This would create domestic collections, and would make it possible for the UK to be in a position to eventually contribute to the global supply.

NHS England is responsible for Ig therapy in England and Northern Ireland through the Commercial Medicines Unit. Similar to other countries, Ig use is growing at just under 10% per year. In 2016, NHS England purchased 5,695,718g of Ig. In 2017, 6,194,613g were purchased, representing an 8% increase. In 2018, sales were 6,745,697g, representing a 9% increase. The 2019 figure is 7,575,127g, a 12% increase. In 2018/19, $228million pounds was spent on Ig therapy.[39]

CANADA

Canada is the second most dependent on the United States for its supply of plasma therapies. Demand for Ig has more than doubled over the past decade, with 51% growth from 2015. In Canada, all blood and blood products are distributed by Canadian Blood Services (CBS), with the exception of Quebec, where Hema-Quebec fulfills this function. Outside of Quebec, and according to the latest CBS Annual Report (2019), Canada's self-sufficiency rate stands at a mere 13.5 per cent .[40] In 2015, Canada's self-sufficiency rate stood at 21%, but each successive year has seen that number drop, from 21% to 18%,

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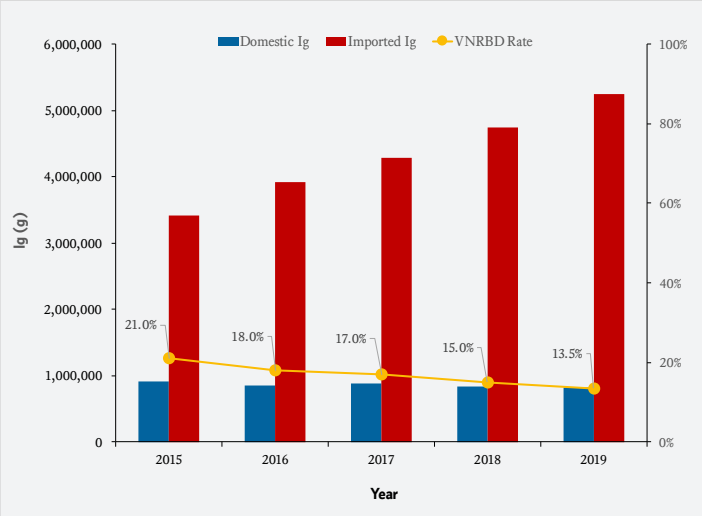
39 NHS, "Immunoglobulin Database Annual Report 2018/19", (December 2019) , P. 7, http://igd.mdsas.com/wp-content/uploads/ImmunoglobulinDatabaseAnnualReport201819.pdf.

40 Canadian Blood Services, "Every Day," Annual Report 2018–2019, P. 33, https://blood.ca/sites/default/files/CBS-AR2019-en.pdf.

to 17%, to 15%, to the current 13.5%.[41]

Figure 3. Canada (without Quebec)



According to Graham Sher, the CEO of CBS, "...as the use of (Ig) therapies continues to rise, Canada's plasma sufficiency is now estimated at less than 13.5 per cent. If current trends continue, it will fall below 10 per cent within the next five years, leaving more than 90 per cent of Canadians who require Ig drugs totally dependent on plasma supplied from other countries. Meanwhile, growing demand will increase pressure on prices worldwide and, in some cases, availability could be threatened."[42] (Emphasis added).

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41 Canadian Blood Services, "CEO mid-year review", (December 6, 2018) P. 14, https://blood.ca/sites/default/files/2018%E2%80%932019%20Mid-Year%20Review%20Dr.%20Graham%20Sher%2C%20Chief%20Executive%20Officer_FINAL.pdf

42 Canadian Blood Services, "Every Day," Annual Report 2018–2019, P. 39, https://blood.ca/sites/default/files/CBS-AR2019-en.pdf.

Quebec has maintained a roughly constant reliance on commercial plasma from the United States. This has coincided with quite significant increases in domestic plasma collections through four Plasmavie dedicated plasma collection centres that started operating in 2013/2014. In 2015, Quebec's dependency on commercial VRPC was larger than the rest of Canada's, with a self-sufficiency rate of 16.1%. Unlike the rest of Canada, Quebec increased their self-sufficiency rate to 17.7% in 2016, 21% in 2017, and 21.5% in 2018. According to their latest Annual Report 2018/2019, however, despite a 15.7% increase in plasma collections (from 105,160 litres to 113,149 litres), Quebec's self-sufficiency rate declined slightly to 21.3% in 2019.[43]

Quebec's experience with non-remunerated plasma collections is revealing. They have repeatedly failed to meet their goals, revising them several times. When the Plasmavie experiment was announced in 2014, they targeted a self-sufficiency rate for Ig of 30% by 2020: "At a conference on IVIg organized by Héma-Québec and attended by national and international experts as well as stakeholders, it was determined that an objective of 30% self-sufficiency was needed."[44] They will not reach that goal. A year later, it was 30%, or a volume of 200,000 litres by 2020.[45] They will reach neither goal. The year after that, they stopped talking about the proportion of demand, and

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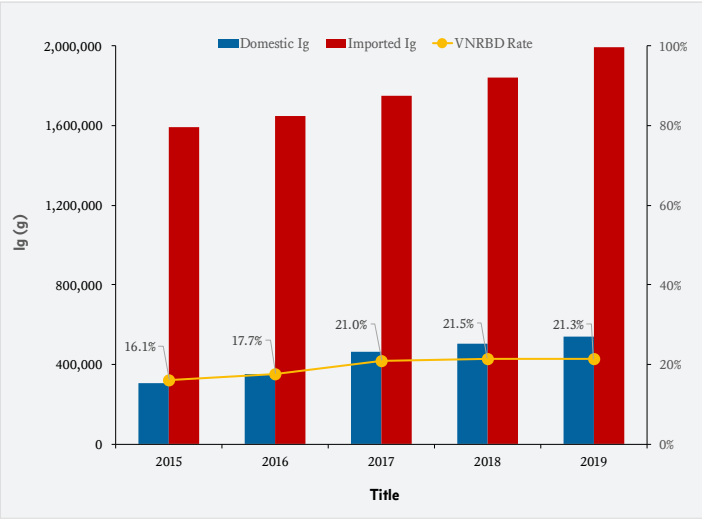
43 HÉMA QUÉBEC, "The Start of a New Era", (2018-2019), https://www.hema-quebec.qc.ca/userfiles/file/RA-2018-2019/Hema-Quebec_2018-2019_Annual_Report.pdf.

44 See HÉMA QUÉBEC, "Reaffirming our objectives", (2014-2015), P. 15, http://www.hema-quebec.qc.ca/userfiles/file/media/anglais/publications/RA_2014-2015_ANG(2).pdf.

45 See HÉMA QUÉBEC, "A year of transformation", (2015-2016), P. 16, http://www.hema-quebec.qc.ca/userfiles/file/RA-2015-2016/RA_2015-2016_ANG-2.pdf.

downscaled the volume to 150,000 litres.[46] It is unlikely that they will meet this goal. They did not comment on the consensus by experts that 30% self-sufficiency was "needed."

Figure 4. Quebec



Canadian Blood Services is currently attempting to increase plasma collections by opening three "proof-of-concept" dedicated plasma collection centres in Lethbridge (Alberta), Sudbury (Ontario), and Kelowna (British Columbia). They are hoping to eventually expand these to 40 centres over seven years, at a cost of $CAD855 million dollars, to be paid for by provincial and territorial governments. They have set a target of 50% self-sufficiency. The results of Quebec's experiment with non-remunerated plasma collections does not make this expensive experiment appear promising.

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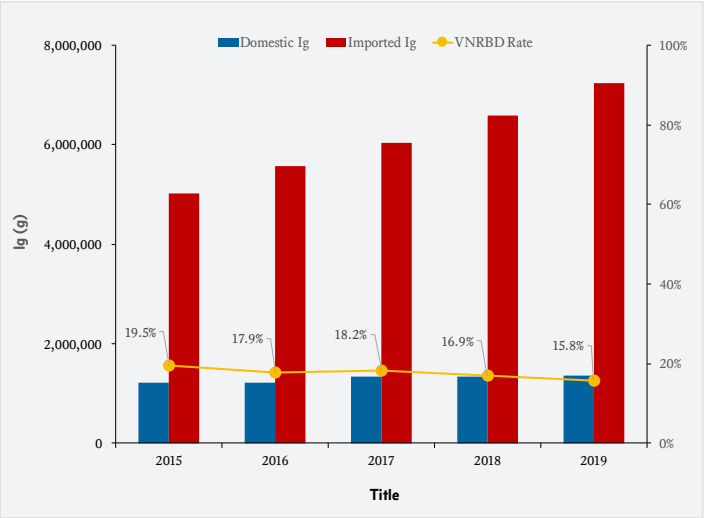
46 See HÉMA QUÉBEC, "Hema-Quebec is all of us!", (2016-2017), P. 34, https://www.hema-quebec.qc.ca/userfiles/file/media/anglais/publications/AR_2016-2017_EN.pdf

Figure 5. Canada



NEW ZEALAND

New Zealand was touting its status as "the only country in the world" that managed "to achieve and maintain self-sufficiency status, as defined by the World Health Organisation" as recently as 2013 .[47] But they hit what they described as a "significant turning point" in their history in 2015 , when the New Zealand Blood Service (NZBS) announced that it was likely that they would need to import commercially-sourced Ig plasma therapy.[48]

Peter Flanagan, the medical director of the NZBS, explained that

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47 NZBLOOD, "It's in our Blood - Thank You New Zealand (Celebrating World Blood Donor Day 14th June)" https://www.nzblood.co.nz/news/2013/it-s-in-our-blood-thank-you-new-zealand-celebrating-world-blood-donor-day-14th-june/.

48 Gareth Thomas, "NZ to import medical plasma products" Radio New Zealand, June 9, 2015, https://www.rnz.co.nz/news/national/275741/nz-to-import-medical-plasma-products.

there was a "very significant" and "unusual" increase in demand for Ig. While the NZBS had managed to double year-over-year donations by June of 2015, Flanagan estimated that they would have to double it again to meet demand. Anticipating the need to import commercial products, Flanagan said that: "Those products will be manufactured from plasma that has been collected from paid donors. Nonetheless, the systems used for their manufacture assure safety and I'm sure that they will be entirely suitable for use in the New Zealand context."[49]

According to their latest Annual Report, they imported 1,540 grams of Privigen (and 288 grams of Hizentra) in 2015, representing 0.5% of total Ig product issued (335,302 grams).[50] In 2016, however, that number increased significantly to 10.4% of total Ig product issued (357,311), followed by 11.5% in 2017. Having started an aggressive effort to increase plasma collections at the end of 2015, they were able to report on their success in 2018: "With the combined effort of our donors and staff we have increased the amount of plasma donated by nearly 60% in just two years."[51] Despite the impressive increase in donations, it was not enough to keep up with demand. By the end of 2018, 11.8% of Ig issued was imported, while 2019 again saw the percentage of imported Ig products increase to 12.5%. Current projections by the NZBS show that they expect to rely on commercial

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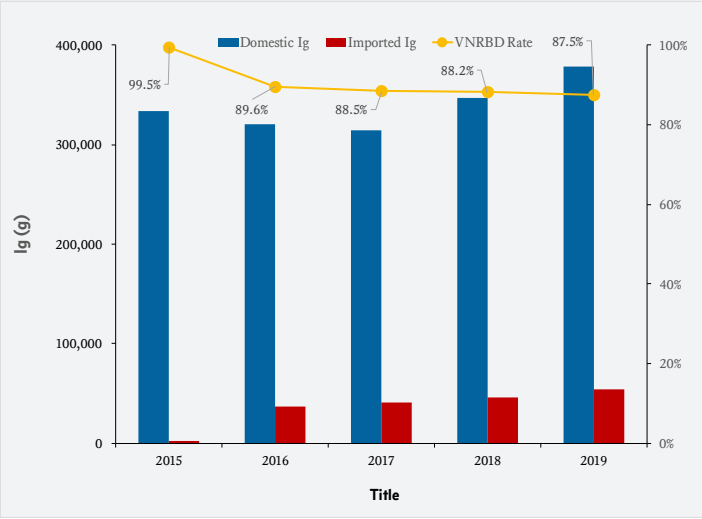
49 Gareth Thomas, "NZ to import medical plasma products" Radio New Zealand, June 9, 2015, https://www.rnz.co.nz/news/national/275741/nz-to-import-medical-plasma-products.

50 New Zealand Blood Service, "Annual Report 2018/19", (2018-2019) , P. 30, https://www.nzblood.co.nz/assets/About-NZBS/PDFs/New-Zealand-Blood-Service-2018-19-Annual-Report.pdf.

51 New Zealand Blood Service, "Saving Lives, It's in our blood," Annual Report 2016-2017, (2016-2017) , P. 8, https://www.nzblood.co.nz/assets/About-NZBS/PDFs/Annual-Report-2016-2017-web.pdf.

imports for 15.3% of total Ig product issued by 2022.[52] According to their Annual Statement of Performance Expectations, 2019/20:

Figure 6. New Zealand



"Over the 10 years to 30 June 2018 immunoglobulin annual demand growth averaged 6.43% per annum. In the 2018/19 financial year the rate of annual increase is forecast at a 7.0% growth rate. This rate of increase year on year is not considered sustainable."[53] (Emphasis added).

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52 New Zealand Blood Service, "Celebrate 20", Annual Report 2018-2019, (2018-2019) , P. 30, https://www.nzblood.co.nz/assets/About-NZBS/PDFs/New-Zealand-Blood-Service-2018-19-Annual-Report.pdf

53 New Zealand Blood Service, "Annual Statement of Performance Expectations 1 July 2019 – 30 June 2020", (May 2020) , P. 18, https://www.nzblood.co.nz/assets/About-NZBS/PDFs/NZBS-SPE-for-2019-20-FINAL-30-May-2020.pdf.

AUSTRALIA

Australia was approximately 60% self-sufficient in 2015, with the remaining 40% dependent on commercial Ig therapies made by CSL Behring. That same year saw Australia "set a target of 70 per cent sufficiency to ensure 'strategic independence' in plasma."[54] But the most recent figures available in the National Blood Authority's Annual Statement reveal that imports have only grown, with greater distance from "strategic independence." In 2019, 51.6% of the 6.57 million grams of Ig product distributed was imported .[55]

From 2015 to 2019, reliance on imported Ig products had grown each year. There is reason to believe that this trend will continue. Unlike in New Zealand, growth rates for immune globulin are higher, and often hit double-digits. According to the National Blood Authority's latest annual statement, demand for Ig products grew at 10.2% in 2015, 12.4% in 2016, 11.2% in 2017, 10.6% in 2018, and 7.2% in 2019.[56]

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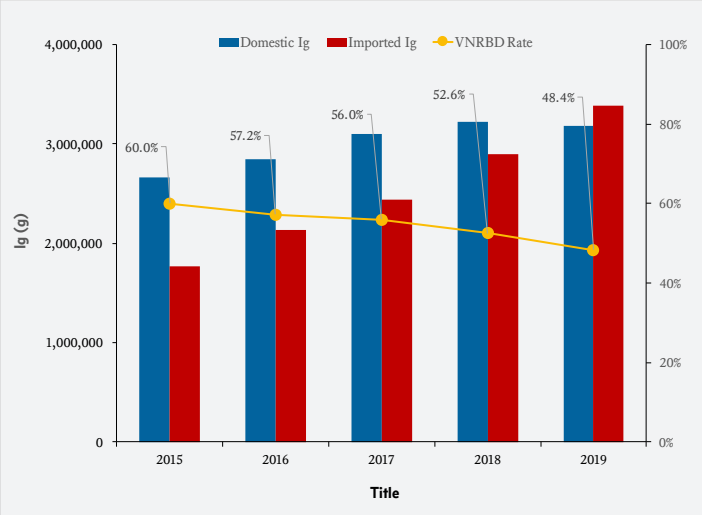
54 Canadian Blood Services, "ANNUAL REPORT 2015-2016 ", (2015-2016) , P. 26, http://itsinyoutogive.ca/Annual/2016/_resources/pdf/MainReport-En.pdf.

55 National Blood Authority, "OBJECTIVE 1. SECURE THE SUPPLY OF BLOOD AND BLOOD PRODUCTS", Figure 2.10, https://www.blood.gov.au/pubs/1819report/part-2-annual-performance/objective-1-secure-supply-blood-and-blood-products.html.

56 National Blood Authority, "OBJECTIVE 1. SECURE THE SUPPLY OF BLOOD AND BLOOD PRODUCTS", Table 2.11, https://www.blood.gov.au/pubs/1819report/part-2-annual-performance/objective-1-secure-supply-blood-and-blood-products.html.

Figure 7. Australia



On September 27, 2017, the National Blood Authority opened its first pilot plasma donor center in Townsville, as part of a two-year pilot project. They also opened a similar centre in Canberra on June 5, 2018. The latter was chosen "to trial simultaneous operation of a mixed collection facility and a plasma only facility in the same city."[57] However, much like the Plasmavie experiment in Quebec, and New Zealand's aggressive attempts at collecting more plasma through non-remunerated plasma collection centres, there is no evidence to suggest that these plasma centres will do anything other than slow the growing dependence on imports from the United States.

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57 National Blood Authority Australia, "ANNUAL REPORT 2017–18", (2017-2018) , P. 42, https://www.blood.gov.au/pubs/1718report/sites/default/files/publication/nba-annual-report-2017-18.pdf.

VRPC WOULD HELP

There is no evidence to suggest that Canada, New Zealand and Australia will be able to meet their goals of strategic independence, never mind self-sufficiency, using non-remunerated plasma collections. Instead, the available evidence points to continuing and growing reliance on plasma collected in the United States.

This conclusion is not controversial. Canadian Blood Services, for example, recognized early on that it is not possible to reach self-sufficiency with VNRBD, calling it a "given" in 2014: "Given that self-sufficiency is not operationally or economically feasible in a volunteer, unpaid model…"[58] The European Commission was similarly blunt. Commenting on the refusal of some European Union member states to adopt anything other than VNRBD (what they called "VUD," or "Voluntary Unpaid Donations") for plasma collections, the European Commission explained that, "some Member States do not permit private plasma collectors to run donation programmes for this reason, limiting the volumes of plasma collected and contribut-

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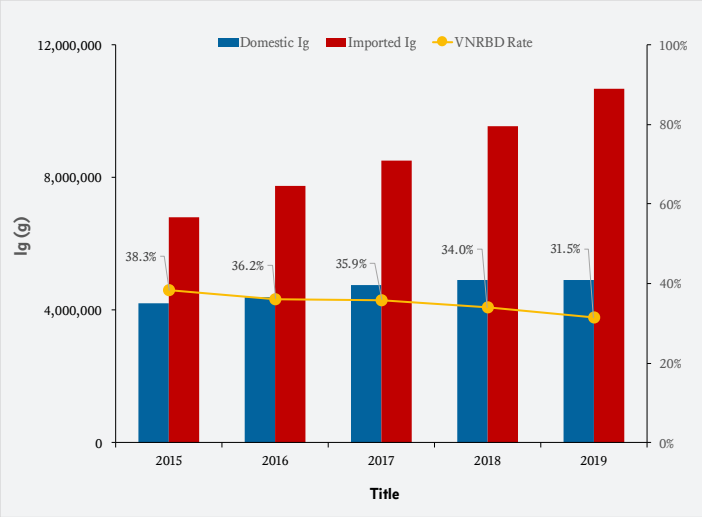
58 The quote continues: "…Canadian Blood Services strives to maintain a sufficiency of 30 per cent for immunoglobulin (Ig). The demand for Ig continues to rise in Canada and internationally, and, to meet our needs, Canadian Blood Services purchases surplus recovered plasma (from voluntary donations) from the United States for fractionation."
Canadian Blood Services, "Annual Report 2013–2014", (2013-2014) , P. 40, http://itsinyoutogive.ca/Annual/2014/pdf/cbs_ar2014_EN.pdf. The annual report from the year prior was similarly blunt: "As self-sufficiency is not operationally or economically feasible in a volunteer, non-remunerated model, Canadian Blood Services strives to maintain a sufficiency of 30% for Ig. The demand for Ig continues to rise in Canada and internationally, and to meet our needs Canadian Blood Services purchases surplus recovered plasma (from voluntary donations) from the United States for fractionation, which increased by 4,572 litres or 17.0% in 2012/2013 over 2011/2012." Canadian Blood Services, "Management Analysis", (March 2013), P. 43, http://itsinyoutogive.ca/Annual/2013/pdfs/cbs_ar2013_finreport_en.pdf.,

ing to the reliance on the US for this substance."[59]

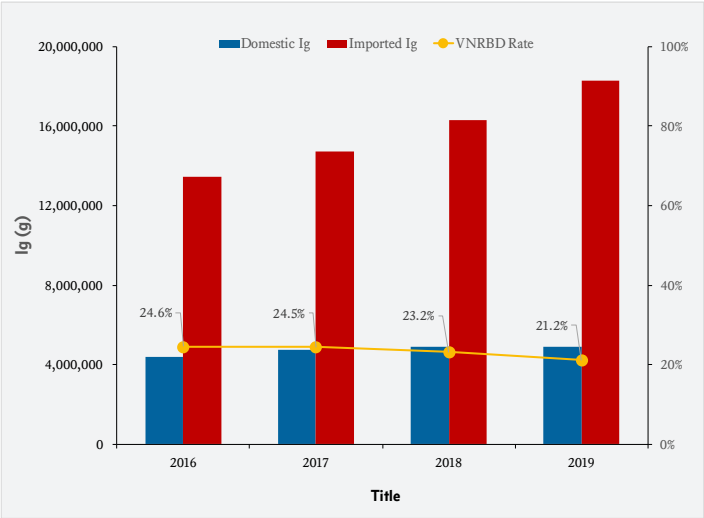
Put plainly, there is a fundamental tension between VNRBD for plasma collections for plasma therapies and strategic independence in plasma therapies. It is evident that nations face a choice between either one or the other. VNRBD for plasma therapies makes self-sufficiency a windmill against which nations tilt.

Figure 8. Canada, Australia, and New Zealand



59 European Commission, "Evaluation of the Union legislation on blood, tissues and cells", (October 2019) , P. 50, https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/swd_2019_376_en.pdf.

Figure 9. Canada, Australia, New Zealand and the United Kingdom



"A prohibition on paying donors for plasma for commercial fractionation use would deny patients access to these products, both here in Canada and around the globe. When lives are at risk, that's simply not an option."

Dr. Graham Sher, CEO, Canadian Blood Services, The Star, March 13, 2013[60]

"Seventy percent of the plasma required for these two products is produced from compensated U.S. donors. We submit that paying Ontarians is no more or less ethical than paying Americans, as we do today for most of the plasma-derived medicinal products used in Ontario and across Canada."

- Network of Rare Blood Disorder Organizations, Testimony Regarding Bill 21 [COMPENSATED COLLECTION OF PLASMA, December, 2014]

"...the systems used for their manufacture assure safety and I'm sure that they will be entirely suitable for use in the New Zealand context."

- Peter Flanagan, Medical Director, New Zealand Blood Services[61]

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60 https://www.thestar.com/opinion/commentary/2013/03/13/prohibiting_payforplasma_would_harm_patients.html

61 https://www.rnz.co.nz/news/national/275741/nz-to-import-medical-plasma-products

"...from a scientific and clinical perspective, paying donors to obtain a source of supply for the manufacture of immune globulin (Ig) and other specialized plasma protein products is not a safety issue... products made from plasma that comes from paid donations are as safe as those that use plasma from unpaid donors."

- Canadian Blood Services, "ANNUAL REPORT 2015-2016", (2015-2016) , P. 27[62]

"As patient organisations, we call for global sufficiency of PDMPs as the ultimate goal of any regional effort to collect more plasma. Any measure or new policy aimed at increasing plasma collection should ensure that it is both patientand donor-centered, with the goal to meet growing clinical needs for PDMPs."

- Johan Prevot, Platform of Plasma Protein Users (PLUS), P. 44.[63]

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62 http://itsinyoutogive.ca/Annual/2016/_resources/pdf/MainReport-En.pdf.

63 https://www.vintura.com/wp-content/uploads/2020/03/White-paper-key-economic-and-value-considerations-for-plasma-derived-medicinal-products-PDMPs-in-Europe_Vintura-and-PPTA.pdf

2. RESISTANCE TO MODERNISATION: MYTHS AND MISCONCEPTIONS

Canada, Australia, and New Zealand could and should be net contributors to the global supply, while the UK, due to unique circumstances, can do so but over a longer time horizon. Fulfilling this obligation requires walking the only evidence-based path available: permitting Voluntary Remunerated Plasma Collections.

The concerns that originally motivated VNRBD for plasma therapies were based on good evidence and reasonable arguments, but advancements in testing, in viral inactivation and removal technologies, clearer evidence regarding the impact of VRPC on non-remunerated blood collections, and better arguments with respect to the legitimate moral concerns, have all made VNRBD inappropriate and unjustified for plasma collections for plasma therapies.

OVERVIEW

Dr. Graham Sher, CEO of Canadian Blood Services, wrote an opinion piece in The Toronto Star on March 13, 2013, as efforts to prohibit remunerated plasma collections in Ontario were getting serious. Entitled "Prohibiting pay-for-plasma would harm patients," he wrote: "A prohibition on paying donors for plasma for commercial fractionation use would deny patients access to these products, both here in Canada and around the globe. When lives are at risk, that's simply not an option."[64]

Nevertheless, Ontario would go on to pass The Voluntary Blood Donations Act in 2014 stopping Canadian Plasma Resources from opening those three voluntary remunerated plasma collection centres in the province. The company looked west to Alberta, but Alberta would follow suit in 2017, passing the same law. British Columbia then did so in 2018. Of the ten commercial plasma centres the company had planned to open, only two--one in Saskatoon, Saskatchewan, and the other in Moncton, New Brunswick--ever did. These laws were passed despite the fact that every patient organization representing those who are dependent on human-sourced

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64 Dr Graham Sher, "Prohibiting pay-for-plasma would harm patients" The Star, March 13, 2013, https://www.thestar.com/opinion/commentary/2013/03/13/prohibiting_payforplasma_would_harm_patients.html.

plasma therapies opposed it.[65] Patients lost in those provinces. They did manage to succeed at the federal level, when an attempt to have the Voluntary Blood Donations Act passed in the Canadian Senate in 2018 was rejected by the Senate Committee tasked with evaluating the proposed prohibition.[66]

But much of the damage had already been done. Instead of 10 plasma centers, Canadian Plasma Resources opened only two. The political atmosphere, meanwhile, also put at least a temporary halt to the plans that Prometic Plasma Resources, operating in Winnipeg, had to expand in Canada. They cancelled plans to open nine plasma centres there. If all 19 centers had opened, Canada would have collected between 570,000 to 760,000 additional litres of plasma this year. Canada would have been well on its way to self-sufficiency.

SAFETY

Myths regarding the relative safety of remunerated plasma collections as compared with non-remunerated plasma collections for plasma therapies persist. This may be a result of the public's ignorance regarding the current reliance on American voluntary remunerated plasma collections, or because of the public's conflation of blood and plasma collections for transfusion as compared with plasma collections for further manufacture into plasma therapies.

The question of whether or not plasma therapies made with plasma collected in accordance with the VRPC standard are safe or not is a

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65 See Testimony Regarding Bill 21, Network of Rare Blood Disorder Organizations, December, 2014, https://www.nrbdo.ca/uploads/8/5/3/9/8539131/bill_21_-_nrbdo_testimony.pdf.

66 The Committee concluded: "your committee recommends that this bill not proceed further in the Senate…" See: Sentate of Canada, Committee Report, April 9, 2019, https://sencanada.ca/en/committees/report/72084/42-1.

non-starter.[67] Each of the countries discussed have a commitment to the provision of safe products, and, as we have seen, each country increasingly or, in the case of the UK, entirely, relies on plasma therapies made with plasma using the VRPC standard. Health Canada, the National Blood Authority, the Therapeutic Goods Administration, NHS Blood and Transplant, the U.S. Food and Drug Administration, the European Medicines Association, and New Zealand Blood Services all recognize that plasma therapies are equally safe whether the plasma is collected via VNRBD or VRPC.

For example, in Canada, when Canadian Plasma Resources opened its first remunerated plasma collection centre, the opposition was fierce and raised concerns regarding safety. However, Canadian Blood Services, in its 2015-2016 annual report, made it clear that such concerns were merely political, and not based on evidence: "... from a scientific and clinical perspective, paying donors to obtain a source of supply for the manufacture of immune globulin (Ig) and other specialized plasma protein products is not a safety issue… products made from plasma that comes from paid donations are as safe as those that use plasma from unpaid donors."[68] The Network of Rare Blood Disorders (an umbrella organization for the various Canadian patient groups that rely on human-sourced plasma therapies) was similarly clear: "Thanks to rigorous donor screening, testing of donations and viral clearance procedures, these products have

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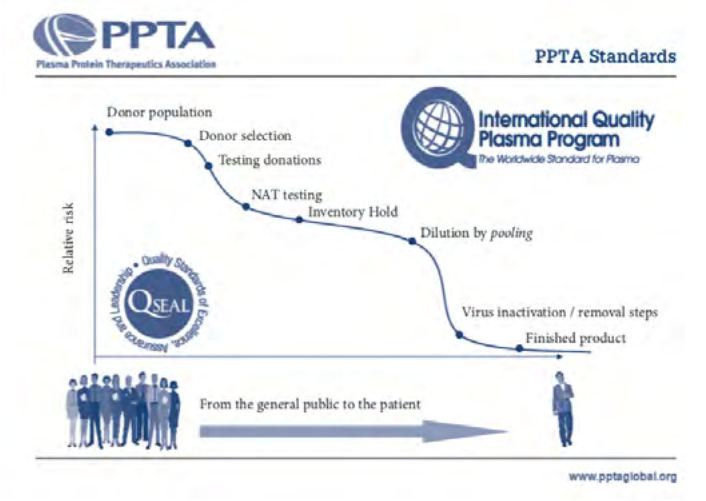
67 Regarding safety, Merlyn H. Sayers commented that this "criticism of cash incentives deserves closure." She explains that advances in testing have minimized safety concerns even for transfusion purposes, and "As for derivatives prepared from source plasma, many aggressive pathogen reduction steps during manufacture have promoted safety significantly." Sayers, Merlyn H. "Paid donors: a contradiction in terms and contraindicated in practice." Transfusion (2020), P. 1.

68 Canadian Blood Services, "ANNUAL REPORT 2015-2016", (2015-2016) , P. 27, http://itsinyoutogive.ca/Annual/2016/_resources/pdf/MainReport-En.pdf.

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."[69] Peter Flanagan, Medical Director for New Zealand Blood Services said, "Those products will be manufactured from plasma that has been collected from paid donors. Nonetheless, the systems used for their manufacture assure safety and I'm sure that they will be entirely suitable for use in the New Zealand context."[70]

Figure 9. PPTA Standards[71]



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69 Quoted in Donation Ethics, July 26, 2018, https://donationethics.com/senateplasma.

70 Gareth Thomas, "NZ to import medical plasma products" Radio New Zealand, June 9, 2015, https://www.rnz.co.nz/news/national/275741/nz-to-import-medical-plasma-products.

71 Ethics and plasma donation: an overview, at p. 30, https://www.fundaciogrifols.org/documents/4662337/46347319/q47_eng/c22a1e0f-f7a5-4673-bfe2-5e262d9a957b

SECURITY OF SUPPLY

It is no longer reasonable, given the evidence, to continue to insist that non-remunerated plasma collections are able to meet domestic needs, never mind the global needs. Non-remunerated plasma collections have failed everywhere to secure a sufficient supply. There is now not a single jurisdiction anywhere in the world that meets its needs exclusively based on non-remunerated plasma collections. The five countries that permit voluntary remunerated plasma collections discussed above supply nearly nine-tenths of the world's plasma needs.

From a global perspective, the supply is threatened by wealthy, developed countries bidding up the price and nearly completely consuming medicines that patients in emerging, low and middle-income countries could benefit from. Non-remunerated plasma collections cannot increase the global supply of plasma, and so the costs of plasma therapies remain high. With more voluntary remunerated plasma collections, plasma companies can be expected to lower the price of plasma therapies, and to reach out to other markets around the world in order to make up in volume what they lose in price-per-unit.

The only safety issue of real concern is the issue of security or surety of supply. The World Health Organisation has insisted on the "recognition that supply has become a safety concern…".[72] The Health Canada Expert Panel summarized the views of patient groups as follows: "the major concern is not the issue of using paid donors but relates to assuring an adequate supply of plasma for patient needs

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72 World Health Organization, "Improving access to safe blood products through local production and technology transfer in blood establishments", (2015) , P. 14, https://www.who.int/phi/publications/blood-prods_technology_transfer.pdf.

which they view as the paramount safety risk."[73] Canadian Blood Services has also raised alarm bells, saying, "We rely too heavily on a foreign supply of plasma to meet the Ig needs of patients in Canada. This degree of reliance is not only unsustainable, it puts patients at risk."[74]

The specific risks are two-fold. The first is the "unsustainable" increase in demand in developed nations. The second, more important, "risk" comes from emerging economies. These countries are improving their ability to accurately diagnose diseases, and are likely to be able to afford a greater volume of Ig therapy relatively soon. Demand for Ig will increase. As the 2016/17 CBS Annual Report warned, "we face a higher risk of supply interruptions and rising costs driven by international competition, especially from emerging markets."[75] The most recent 2019 shortage highlighted this fact, while the 2020 pandemic threatens to make the situation worse.

FAILURE AND EXPENSE

As has been shown in Section 2, plasma collections using VNRBD repeatedly fail to meet collection targets, while VRPC, by contrast, results in more donors making more frequent donations, leading to higher collection volumes per capita. Not only is VRPC effective at ensuring a safe, secure, and sustainable supply of plasma therapies, it is also significantly less expensive as compared with VNRBD. As the Health Canada Expert Panel reported, "the cost of collecting large

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73 Health Canada, "PROTECTING ACCESS TO IMMUNE GLOBULINS FOR CANADIANS", (May 2018) , Part VIII, https://donationethics.com/static/IGReport.pdf.

74 Canadian Blood Service, "Annual Report 2017–2018", (2017-2018) , P. 16, https://www.blood.ca/sites/default/files/CBS%20Annual%20Report_2018.pdf.

75 Canadian Blood Service, "ANNUAL REPORT 2016–2017", (2016-2017) , P. 2, http://itsinyoutogive.ca/Annual/2017/cbs-2016-2017-ar-en.pdf.

volumes of source plasma utilizing volunteer donors is 2-4 times more expensive than the commercial plasma collection model".[76] Convincing individuals to spend an hour and a half to give plasma in exchange for cookies and milk requires frequent and expensive donor recruitment efforts, including a large marketing budget. Convincing these same individuals to donate more frequently requires more effort. Remuneration is sufficient to generate spontaneous word-of-mouth advertising by donors, and motivates them to give more frequently.

For example, in Australia, imports of Ig cost A$120 million and made up 44% of demand, while domestic collections comprising 56% of the total cost A$413 million in 2016-2017. According to the economist Robert Slonim: "This implies the domestic supply of immunoglobulin costs over three times more per unit than what is imported, despite domestic donors not being compensated… It also implies Australia could save over A$200M annually by importing all immunoglobulin."[77]

Even bearing in mind the savings to the UK, Canada, New Zealand and Australia through reliance on American plasma, the expense of current plasma therapies are what they are in part because of supply and demand dynamics affected by a failure of these nations to collect sufficient plasma on their own. As with every product or service, increases in supply relative to demand puts downward pressure on price. If, counterfactually, these countries were to significantly increase the productivity of their plasma collections, there would be

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76 Health Canada, "PROTECTING ACCESS TO IMMUNE GLOBULINS FOR CANADIANS", (May 2018) , Part VIII, https://donationethics.com/static/IGReport.pdf.

77 Robert Slonim, "How Australia can fix the market for plasma and save millions," The Conversation (September 2, 2018), https://theconversation.com/how-australia-can-fix-the-market-for-plasma-and-save-millions-101609.

pressure to increase global fractionation capacity, and would increase the number of plasma therapies available. This would have the effect of mitigating the higher costs as a result of "international competition" between Canada, Australia, New Zealand, and the UK, as well as other developed nations.

Not only would plasma therapies become more affordable for wealthy nations, but the lower price would also increase accessibility to those whose lives would be saved or improved in emerging, and middle-income countries, with some in low-income countries benefiting as well. To compete, a higher supply of plasma therapies would result in lower prices and a consonant effort to make up the per unit loss to margins in volume of sales by expanding into underserved markets like the Middle East, India, some of the countries of Africa, and so on.

FEAR OF EXPORT

Some have raised the theoretical security of domestic supply concern that commercial plasma operators may choose to export plasma and plasma therapies "to the highest bidder," rather than ensure domestic supplies are met first. Whatever else is true of this objection, it takes some nerve for anyone within Canada, Australia, or New Zealand to raise it. It amounts to decrying that companies might do to one of these nations what they have been doing to the United States for more than 20 years.

This is, however, not a realistic concern for the UK, Canada, New Zealand and Australia. These nations are, in fact, almost always "the highest bidders." There is also the opportunity of contracting, as these nations already do, which creates guarantees in the short- to medium-term (depending on the length of the contract). But should this concern present a significant political rather than practical challenge for permitting commercial VRPC, measures less extreme

than prohibition could be enacted. For example, nations can always make licenses conditional on granting the host nation a first-purchaser agreement, or require that domestic needs are secured first. Hungary, for example, requires commercial companies like Kedrion to first meet all of the needs of Hungarian patients before they are permitted to export plasma or plasma therapies.

CROWDING

Some blood operators, like Canadian Blood Services, have expressed the concern that plasma collections using VRPC will "crowd out" blood collections using VNRBD .[78] The European Blood Alliance calls these concerns "erosion and/or fragmentation of a community-based donor population."[79]

The academic literature on "crowding," as it is called, is specific and technical.[80] However, for this discussion, the worry can be summarized as the simple concern that VRPC will negatively affect blood and plasma collections for transfusions, for which it is not unreasonable to use VNRBD exclusively. The concern seems intuitively sensible, captured by the thought that if you had the option of giving blood for free or plasma for money, you would prefer to give plasma.

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78 An important topic about which we have expressed concern is the issue of commercial plasma collectors competing for the same donors and "crowding out" the voluntary, non-remunerated blood sector. The report notes that this issue requires ongoing oversight, monitoring and vigilance," Candaian Blood Services, Annual Report 2017-2018, (2017-2018), P. 16, https://blood.ca/sites/default/files/CBS%20Annual%20Report_2018.pdf.

79 Pierre Tiberghien, "Increasing plasma collection by blood establishments to reach European plasma strategic independence ", (January 2020) , Slide 8, https://ipfa.nl/wp-content/uploads/2019/08/1_2_TIBERGHIEN-EBA-IPFA-plasma-meeting-Amsterdam-Pierre-Tiberghien-Vdef.pdf.

80 For more, see……Possibly because of this, Canadian Blood Services has most recently changed the language from "crowding out" to "encroachment."]

While the concern is sensible, the evidence available suggests that voluntary remunerated plasma collections attract a different population and have no impact on non-remunerated blood and plasma collections. Remunerated plasma collections in Winnipeg, Saskatoon, and Moncton have not had a negative impact on blood collections in those cities. According to a presentation by Canadian Blood Services on Jan 14, 2020, Prometic Plasma Resources "has co-existed [with CBS] for decades with no impact." Similarly, Canadian Plasma Resources in Saskatoon had "transient dips in blood collection (in 17-24 age cohort), but no sustained impact."[81] Remunerated plasma collections have also not had an impact on non-remunerated blood donations in the United States.[82] When Czechia permitted compensated plasma collections in 2007, whole blood donations were essentially unchanged, per 1,000 (2001=40, 42, 42, 42, 41, 39, 39, 40, 42, 43, 2011=40), as were the total number of donors per 1,000 (32, 32, 32, 31, 30, 31, 28, 35, 40, 36, 38).[83] In Germany, according to Dr. Franz Weinauer, the Medical Director of the blood donation service for the Bavarian Red Cross, there was no impact on blood donations in

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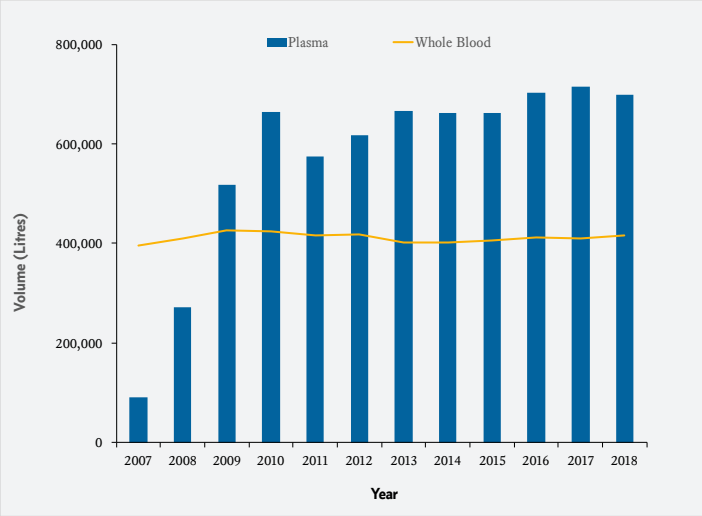
81 Canadian Blood Services, "Navigating complexity: Ensuring security of supply of PDMPs in the Canadian context", (January 2020) , Slide 19, https://ipfa.nl/wp-content/uploads/2019/08/2_3_BEDARD-Responding-to-increased-demand-for-PDMPs_Canadian-Perspective_v4_NoNotes16x9.pdf.

82 For both Canada and the U.S., the introduction of remunerated plasma opportunities had no, or a slightly positive, effect on non-remunerated blood collections. See Peter Jaworski and William English, "Paid plasma in Canada has not decreased unpaid blood donations," working paper (2020).

83 M.P. Janssen, L.R. van Hoeven and G. Rautmann, "Trends and observations on the collection, testing and use of blood and blood components in Europe 2001-2011 report", (2015) https://www.edqm.eu/sites/default/files/trends_and_observations_on_the_collection_testing_and_use_of_blood_and_blood_components_in_europe_20.pdf.

Bavaria from the opening of plasma collection centers.[84]

Figure 10. Czechia



One explanation for these results is that remunerated plasma donations appeal to different individuals from non-remunerated blood donations, or to the same individuals at different stages in their lives (in the U.S., it is common for someone to sell their plasma while they are a student, and then switch to donating blood later in life). As Weinauer explained with respect to the evidence in Germany, "... blood and plasma donors are not part of the same donor population."[85]

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84 See Dr. Franz Weinauer, "German Red Cross (DRK) in Bavaria (BRK)-with both Whole Blood and Plasma Centers," Symposium on plasma supply management, EDQM (2019) https://www.edqm.eu/sites/default/files/medias/fichiers/Events/day_1.pdf

85 https://www.pptaglobal.org/images/source/2018/FALL/4._Interview_w_Dr._Franz_Weinauer.pdf, at p. 13

Even if, contrary to the evidence, VRPC had a negative effect on blood collections, that effect is most likely to be small, and is not likely to affect the ability of blood collectors to meet the declining need. Modern surgical techniques, including use of drugs to reduce bleeding, and improved patient blood management have each contributed to this decline in need.[86]

However, if this concern presents a significant political obstacle, additional policies can eliminate this theoretical concern. For example, Hungary requires that any person wishing to be compensated for plasma donations has to first donate blood.

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86 For example, see Canadian Blood Services, Annual Report 2017/18, at p. 12.

CONCLUSION

The concerns regarding the safety of voluntary remunerated plasma collections were reasonable as late as the early 1990s, but no longer provide support for objecting to voluntary remunerated plasma collections. The concerns about "crowding" or "encroachment," however intuitive, have found no empirical support in any of the countries that have permitted versions of voluntary remunerated plasma collections.

Meanwhile, non-remunerated plasma collections have failed to ensure strategic independence, at significantly higher costs. Non-remunerated plasma collections are in tension with domestic security of supply. Prohibition of VRPC represents the greatest safety threat not only to the patients currently reliant on plasma therapies wealthy nations, but also to future patients, and to the more than 1.4 million individuals in low and middle income countries that ought to be on plasma therapies.

As we have seen, there is a simple and straightforward path ahead. A way that will ensure the safe, secure, and sufficient supply of plasma therapies not just for our wealthy and developed nations, but for emerging, low and middle income countries as well. All it requires is

for us to get out our broom and to sweep the antiquated myths and misconceptions, and our stubborn adherence to the old ways of doing things into the dustbin of history. All it takes is for us to eliminate the prohibitions on voluntary remunerated plasma collections.

We have the ability to contribute to the global supply of plasma. It's in us to give, rather than merely take. Now is the time for us to contribute.

APPENDIX A. RESISTANCE TO MODERNISATION: NAIVE MORALISMS

Apart from the empirical concerns, opponents of remunerated plasma collections express a series of moral objections to the practice of voluntary remunerated plasma collections. Some of these objections, like worries about "commodification" and altruism, do not withstand basic scrutiny. One argument, the worry about wrongful exploitation, is a reasonable and significant concern. But much of the weight and significance of this objection relies on misconceptions regarding the economics of plasma, and opponents overlook the fact that simple policy tweaks are sufficient to eliminate this concern entirely.

Perhaps most importantly, opponents have failed to give us guidance regarding how much moral weight we ought to attach to each of the moral objections to voluntary remunerated plasma collections as compared with the moral weight of the additional lives that will be saved from adopting voluntary remunerated plasma collections. It is, for example, morally permissible to lie in order to avoid a greater moral injustice. Given that VRPC will save more lives than the current VNRBD standard for plasma collections, how morally important is that compared with, say, additional "commodification" or a decrease in the ability of people to express altruism? Without this guidance, we do not know how they would make an all-things-considered judgement regarding this issue, and so these objections remain importantly incomplete.

To summarize, what opponents of voluntary remunerated plasma collections are required to show is that their argument meets each of the following steps:

- Step 1: There is a reasonable and legitimate moral concern;
- Step 2: That we have reason to believe each of the empirical claims the concern depends upon;
- Step 3: That there are no simple or minor policy tweaks that can avoid or eliminate the moral concern, and;
- Step 4: That the moral concern is significant enough to outweigh the moral importance of saving more lives.

In each case, however, opponents have failed to do this. What we are left with are moral arguments in favour of permitting voluntary remunerated plasma collections. From a moral perspective, therefore, the United Kingdom, Canada, New Zealand and Australia, have moral reason to urgently permit VRPC within their borders.

ALTRUISM

Worries about altruism are consistent with step 1. above. We have

reason to encourage and promote prosocial, altruistic expression. We also have reason to celebrate it when we see it, and to encourage it as much as we can. Altruistic acts, after all, promote what the World Health Organisation has called "community solidarity." While this objection to voluntary remunerated plasma collections meets the criteria in step 1, it falters on step 2.

Casual observation suggests that most residents of the UK, Canada, New Zealand and Australia are unaware of their reliance on plasma donors in the United States for life-saving plasma therapies. It is not uncommon for Canadians and Australians, for example, to report that our countries manage to collect enough plasma without "having to pay donors," and then to believe the implication that remunerated plasma collections in the United States represent the inferior altruistic impulse and greater selfishness of Americans as compared with Canadians and Australians.

As has been shown, however, the claim is false and so the implication does not follow. But even if the claim were true, the implication would still not follow. The implication depends on the claim that remuneration for plasma rules out the possibility of having altruism as one's motive. But this claim is either false, or has insufficient empirical support.

The view that remuneration rules out altruistic motives is not a view that opponents of remunerated plasma collections endorse with respect to other, related, things. For example, nurses and administrators of blood systems are remunerated, but opponents of remuneration for plasma collections do not argue in favour of an all-volunteer nursing staff nor all-volunteer blood system administration on the grounds that we only want altruistic people in our blood system. Absent empirical studies showing that altruism is a possible motive for nurses and administrators but not a possible motive for plasma

donors, the view appears to consist of nothing more than stereotypes and prejudice regarding remunerated plasma donors. At its best, it is special pleading.

SPACE FOR ALTRUISM

A different altruism-based objection is a concern about "space for altruism" which has trouble even getting up the very first step.[87] The claim is that payment for plasma would eliminate this particular space. But to think that we lack opportunities for the expression of prosocial, altruistic concern for others is to lack imagination. We can shovel snow from our neighbour's yard in Canada, or their leaves in New Zealand. We are not running out of "space" for altruism.

And if this were a serious concern, why not consider changing who is required to volunteer and who receives remuneration? For example, we could expand a space for altruism by insisting that all nurses and administrators at Canadian Blood Services be volunteers, rather than remunerated. By so expanding the space, we could remunerate plasma donors and so collect more plasma. We could thereby save more lives without losing spaces for altruism. Notice that the objection that we would have a shortage of nurses or administrators cannot succeed since the similar objection that we currently have a shortage of plasma is not persuasive to opponents. However, there is no attempt on anyone's part to change the nurses at plasma collection centres from remunerated to volunteer, which suggests that the "space for altruism" objection is not morally important.

Finally, the purpose of our blood and plasma collecting organisations is, primarily and most importantly, to save lives through the collec-

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87 See Richard Titmuss, "The Gift Relationship" (1971), https://books.google.co.uk/books/about/The_Gift_Relationship.html?id=cwTPAAAAMAAJ&redir_esc=y.

tion and distribution of blood and blood products, including plasma therapies. It is at least strange, and possibly manipulative, to use these organisations as an instrument to expand spaces for altruism and so give people an opportunity to be or express altruistic concern. This orthogonal purpose would be fine if it did not conflict with the primary purpose of these organisations, but it does so conflict. And since it does, we must prioritise their primary purpose over any additional purposes we might find for our national blood operators.

COMMODIFICATION

The thought that payment for plasma should lead to commodification suffers from many confusions that make it difficult to see how it gets past the first step. For example, many who wield it, including the World Health Organisation, often do not define it. Without a clear definition, we cannot know what, exactly, is at stake here, nor how to measure it.

Contemporary moral theorists have, however, given us a better understanding. Commodification involves the wrong of treating others merely as an instrument, much like we use very many things that have a price tag. It is the concern that a person's dignity will be ignored, or that she will be disrespected. The concern in this context is that permitting a price tag on human blood plasma will increase the extent to which we think of persons, or at least those persons who choose to sell their plasma, as a mere instrument.

This at least passes Step 1. How we treat one another is morally important, as are the attitudes we have towards other people. However, this claim depends upon an empirical claim — that permitting voluntary remunerated plasma collections will result in greater instrumentalisation of persons — and there is as yet no empirical support for it, failing Step 2. Worse than that, the empirical claim is, on its face, really difficult to believe. Do opponents really think

that there are greater rates of "commodification" in Winnipeg, Saskatoon, and Moncton, than in, say, Saint Johns, or Regina? As the signatories of a letter to the Health Canada Expert Panel put it, "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."[88] It should also worry opponents that no one has yet bothered to present any empirical evidence, even suggestive, regarding this concern at all.

This objection also requires an explanation for why paying donors is the Achilles heel that results in commodification. Consider, for instance, that in every country phlebotomists and nurses who extract plasma are paid, the doctors who prescribe immune globulin are paid, the administrators who operate our blood and plasma organizations collect salaries as well; the chair within which the donor sits and the needle and syringe that is used has a price tag, as does the electricity and the water used at the donor centre which is metered and comes at a price; similarly someone pays for every plasma transfusion, for every plasma-derived medicinal product; the raw plasma itself is something that has a price tag. There are price tags everywhere from vein to vein, in every country in the world. We need to know why remunerating the donor leads to commodification, while all the other

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88 Jaworski, P. M., D. Faraci, et. al. Open Letter to the Expert Panel on Immune Globulin Product Supply and Related Impacts in Canada, Donation Ethics (16 January 2018) https://donationethics.com/plasma. Published as Appendix G, "Protecting access to immune globulins for Canadians," Final Report of the Expert Panel on Immune Globulin Product Supply and related impacts in Canada," Health Canada (2018) PP. 157-165, https://donationethics.com/static/IGReport.pdf.

practices are immune from this concern. This seems extraordinarily unlikely, making this Achilles heel theory read more like a parody than a serious moral objection.

WRONGFUL EXPLOITATION

The only moral objection to VRPC that survives basic scrutiny is the worry that it may contribute to the wrongful exploitation of the poor and vulnerable.[89] There are a variety of ways of understanding wrongful exploitation. The most popular version claims there is an unfair division of the benefits from trade: That the remuneration the donor receives is too little as compared to the large profits the companies receive. Apart from unfairness, we may also be concerned that especially poor and vulnerable donors will donate plasma in circumstances where it would be harmful to their health.

Worries about the unfair division of benefits are most likely the result of misconceptions regarding the division of benefits between donors and the plasma companies. While specific details are proprietary, the best estimates are the following: A unit of raw plasma sells for approximately U.S.$250-300. A unit consists of a litre. The average donation yields roughly 800mL, and is compensated at $20-50. For a litre of plasma, donors receive between US$30-60. Per litre of

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89 Consider the variety of articles published in the popular press regarding this issue: "The Twisted Business of Donating Plasma" (May 28, 2014), DARRYL LORENZO WELLINGTON, "The Twisted Business of Donating Plasma" The Atlantic, May 28, 2014, https://www.theatlantic.com/health/archive/2014/05/blood-money-the-twisted-business-of-donating-plasma/362012/; KATHRYN EDIN and H. LUKE SHAEFER, "Blood Plasma, Sweat, and Tears" The Atlantic, September 1, 2015, https://www.theatlantic.com/business/archive/2015/09/poor-sell-blood/403012/; H. LUKE SHAEFER and ANALIDIS OCHOA, "How Blood-Plasma Companies Target the Poorest Americans" The Atlantic, March 15, 2014, https://www.theatlantic.com/business/archive/2018/03/plasma-donations/555599/;Zoe Greenberg, "What Is the Blood of a Poor Person Worth?" The New York Times, February 1, 2019, https://www.nytimes.com/2019/02/01/sunday-review/blood-plasma-industry.html.

plasma, the revenue is split 20-30% for the donor, and 0-5% for the company in the form of profit. It is hard to see how this is unfair.[90]

Instead of looking at the division of benefits, we can look at this in terms of time and effort. It takes approximately 90 minutes to donate plasma. The process is not painful, and requires the donor to sit in a chair squeezing a ball repeatedly during extraction, and then pausing when the red and white cells and platelets are being returned. For that, donors receive $20-50, or $15-35 per hour. It is also hard to see how this is unfair.

There is additional possible profit from finished products. If prices are cited, articles will highlight an expensive plasma therapy — for example, a 40g dose of the Ig therapy Privigen cost Australia's National Blood Authority $1,800 in 2019.[91] Compare that to the $30 to $50 a donor receives for a donation. However, what is not mentioned is that it takes more than one donation for a year's supply of Ig, it takes 130 or so. It is also true that a fractionation facility costs between $500 million to a billion dollars. And even if the division of benefits still seems unfair, how does the division improve by giving

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90 In 2015, the WHO estimated the price of a litre of plasma to be between US$ 70 to US$ 110 per litre [WHO], World Health Organization, "Improving access to safe blood products through local production and technology transfer in blood establishments", (2015) https://www.who.int/phi/publications/blood-prods_technology_transfer.pdf. Credit Suisse recently estimated that payment to donors represented 42% of collection costs (with labour at 19%, rent at 14%, and testing at 10%), while collection costs made up 56% of the total costs to CSL Behring (fractionation costs made up the second-largest cost at 36%). See "CSL: The moral maze in the race for liquid gold," Credit Suisse, Market Daily (20 April 2020), Figure 12 and 13, P. 38.

91 National Blood Authority Fact Sheet, January 1, 2019, https://www.blood.gov.au/system/files/National-Blood-Authority-Fact-sheet-Supply-of-plasma-derived-and-recombinant-blood-products-2019.pdf.

the donor precisely $0?[92] Non-remunerated donations are worse than remunerated ones on this score.

It is sometimes said that plasma centres are located in poorer neighbourhoods and so poorer people sell their plasma out of desperation, or plasma centres seek to take advantage of this poverty. It is true that U.S. plasma centres tend to be located in parts of the United States that skew poorer than the average, and it is true that we should be extra sensitive in these cases. But it is still hard to see why this is especially problematic given the benefits. The opportunity to sell one's plasma may not be the option that appeals to those who are wealthier, but it is an option that does provide some benefit, however small. We do not make people wealthier by removing an option that puts some money in their pocket.

Some raise worries about the frequency of donations, and how that may have a negative effect on a donor's health. The United States permits twice-weekly donations, up to 104 times per year. However, according to data from 2017, the average frequency of donations per 12 months was 21.4, with 14% giving more than 50 times, and 6.7% giving more than 70 times.[93] The number of people who give the maximum allowable are a minority of total donors, not the majority.

There are, however, special cases where the poverty is sufficiently

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92 As Vida Panitch and L. Chad Horne point out: "Whether 30% represents a fair share of the benefits of the exchange, it is clearly a lot fairer than 0%." See Vida Panitch and L. Chad Horne, "Paying for Plasma: Commodification, Exploitation, and Canada's Plasma Shortage," Canadian Journal of Bioethics, (2019), P. 4.

93 George Brooks Schreiber and Mary Clare Kimbar, "Source Plasma Donors: A Snapshot," Transfusion, (2017), https://www.pptaglobal.org/images/presentations/2017/Schreiber.AABBposterAbstract_Source_Plasma_Donors_A_Snapshot_2017_9.27.17.pdf

severe for donors to risk their own health by donating too frequently, or tricking centres to accept their donations by, for example, putting water bottles in one's pockets to meet the minimum weight cutoff for donation. The issue of "migrant donors" falls into this space. As Credit Suisse's ESG report for Australia's CSL Behring highlighted, the plasma collection centres at the border between the U.S. and Mexico have the highest number of donors (2,300 as compared to 1,000 per month), and have donors that donate with the highest frequencies (migrant donors make up the majority of the 0.3% of plasma donors in the U.S. that donate the maximum allowable 104 times per year).[94] CSL Plasma is also planning additional plasma collection centres along the border, raising additional concerns.

One comprehensive long-term study on high-frequency donations of plasma concluded that it was safe, but the study looked only at high-frequency donations up to 60 times per year, not the 104 times permitted in the U.S.[95]

To the extent that these figures are of concern, however, it adds to, rather than detracts from, the need to permit voluntary remunerated plasma collections in the UK, Canada, New Zealand and Australia. Each of these nations have lower poverty rates, and have more generous social safety nets, providing the poor with more alternatives. Also, apart from Canada which recently raised the permitted frequency of donations to match the U.S. rates, Australia and New

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94 See "CSL: The moral maze in the race for liquid gold," Credit Suisse, Market Daily (20 April 2020), PP. 31-59.

95 "Long-term intensive donor plasmapheresis under conditions investigated in this study is safe. All donors weighing > or = 70 kg are safely able to donate 850 ml of plasma in each session up to 60 times per year, provided they are carefully monitored." https://pubmed.ncbi.nlm.nih.gov/16907878/

Zealand permit fewer donations per 12 months.[96] CSL Behring would be likely to open plasma collection centres in Australia and New Zealand, if only Australia and New Zealand permitted them to do so. We already know that Canadian Plasma Resources and Prometic Plasma Resources wanted to expand in Canada, but such options are significantly restricted given that Quebec, Ontario, Alberta, and British Columbia have made it illegal. Bio Products Laboratory would be likely to open collection centres in the UK, if only the UK permitted it.

Germany is especially instructive here as a possible guide. Germany permits compensated donations, does allow twice-weekly donations, but caps the frequency at 60 times per 12 months. In addition, Germany checks the donor's IgG levels and total protein levels every fifth donation (as compared to the U.S. where IgG levels and total protein are checked every four months).

Further, we cannot overlook the causal or contributing role that these nations play in the extent to which this is of concern. While it is sometimes said that locating plasma centres in poorer neighbourhoods is explained by a "desire to profit," this is insufficient as an explanation. Companies attempt to manufacture or provide only so many goods as they anticipate being able to sell. Higher demand with fewer opportunities for expansion calls for locating in areas with greater anticipated collection volumes, with higher-frequency donors. The pressure for each centre to be ever-more productive is a direct consequence of insufficient plasma collections in, especially, Canada and Australia, but also the UK and, to a much lesser extent, New Zealand. Ever-greater reliance on the United States is only likely to

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96 Australia permits one donation every two weeks (https://www.donateblood.com.au/welcome-plasma), while New Zealand permits one donation every two to three weeks (https://www.nzblood.co.nz/give-blood/plasma/).

exacerbate whatever exploitative concerns may be raised.

SUMMARY

The worry regarding especially vulnerable donors is real. The remainder of the moral concerns turn on misconceptions, fail to provide the empirical evidence, and are often mere naive moralisms. They also fail to account for the moral significance of saving lives in comparison. If we lost a space for altruism, for example, but in exchange saved a single life, the trade off would be worth it. If the cost of saving a dozen lives were "commodification," whatever that ends up meaning, then the trade would be worth it.

A system of voluntary remunerated plasma collections can easily avoid the only serious moral concern, while taking seriously the moral issue that having failed to adopt the only effective plasma collection strategy these nations have contributed to creating an unsustainable global system of plasma collection that is currently a risk and a threat to patients.