Blood money: why are the federal Liberals ignoring the findings of the tainted blood scandal?

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There has been more disturbing news out of Saskatchewan that the private health services company, Canadian Plasma Resources/EXApharma, has set up a clinic in Saskatoon, Saskatchewan. This company will give blood plasma donors a $25 gift card (which can be used almost anywhere a credit card can) for each donation and sell the plasma to international markets. Despite the evidence (including the 1997 Krever Commission which looked into Canada’s horrible tainted blood scandal (how quickly politicians forget this) showing these paid blood clinics are less safe, reduce voluntary donations, prey on vulnerable communities, and that Canadian Blood Services has not stated there is a need for Canadian private clinics to supplement their supply, the Saskatchewan government is pushing ahead with their ideological plans to further privatize Canada’s health system. Provincial Health Minister, Dustin Duncan went so far as to attend the opening of the clinic and state, “We’re pleased they have chosen to open the first one in Saskatchewan.”

Saskatchewan is the home of medicare, but it is increasingly becoming the hot-bed of two-tiered health propaganda and public health policy driven by profits over patients. The Brad Wall government’s recent foray into private MRI clinics despite the evidence, and musing about trafficking in corneas, has now been followed by championing paid plasma clinics in the province. Last year in an interview, the Council of Canadians predicted that paid blood and plasma services would likely occur in Saskatchewan as the government passed legislation to open the door to private blood services, stating,

"Sale, etc., of tissue prohibited

17 Subject to the regulations, no person shall buy, sell or otherwise deal in, directly or indirectly, for a valuable consideration, any tissue for a
transplant, or any body or part of a body other than blood or a blood constituent, for the purposes of transplant, medical education or scientific research."

Health Canada has now quietly licensed a Canadian Plasma Resources facility in Saskatoon, a decision which will ultimately deregulate the safety of Canada's blood and plasma supply. This raises many serious ethical questions as to why Health Canada feels it is not ok to provide payment for organs or other body parts, but is seemingly caving under the pressure from the Saskatchewan government to allow a company to remunerate people to harvest their plasma. As a recent petition to the federal government highlights, "Our blood plasma is not meant to be a commodity that is bought and sold, we must protect our voluntary blood system in Canada and ensure we have one national operator, the Canadian Blood Services, to oversee blood collection and plasma collection in our country."

It now falls upon the federal government to show leadership and real action to prevent these plasma privateers from undermining the safety, ethics, and viability of our blood and plasma services. As with any public policy where there are hundreds of millions of dollars involved, there is a lot of smoke and mirrors surrounding this issues.

The sections the follow below will provide background information and clarity on this issue. They include:

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1.1 What is Plasma and why should we care:

There are three principal components in blood: red cells, plasma and platelets. Plasma, a thick straw-coloured part of blood is rich with proteins can
be broken down into a variety of specialized drugs like clotting products for hemophiliacs, albumin used to treat burn victims, Alpha-1 proteinase inhibitor to treat a genetic form of emphysema, and intravenous immunoglobulin (IVIG), used to treat a variety of immune deficiencies. Currently, the Canadian blood system is run by two independent agencies, Canadian Blood Services and Héma-Québec and they collect (http://www.theglobeandmail.com/life/health-and-fitness/health/paying-donors-for-plasma-have-we-forgotten-about-tainted-blood/article9232617/), respectively, 850,000 and 160,000 units of blood a year, all of it from volunteer donors.

But this story is not about health; it is about tapping into the arms of Canadians (usually those who are most vulnerable) and making profit for shareholders off the body's liquid gold. There is no critical shortage in the supply of blood plasma or plasma products in Canada, the health and public sectors are not driving this policy change. This is about an ideology that is comfortable with dismissing ethical questions and implications to trade in a raw human material by strip mining the bodies of the vulnerable for profit. In Canada it is illegal to sell human body parts, like sperm, eggs, and organs, but through legal loopholes those trying sell plasma are pushing their case and spinning what should not be a debate in the first place.

1.2 What is Plasma used for:

To generalize, there are two main uses for plasma. First, there is plasma used in transfusions for patients which (http://www.cbc.ca/news/health/paying-for-blood-plasma-raises-new-questions-1.1361316), “must be fresh, it has a limited shelf life, and it is collected domestically, from unpaid, volunteer donors, because the risk of transmitting blood borne illness is considered to be lower if the donors are not motivated by money. There is no shortage of plasma for transfusions in Canada.”

Second there is ‘source plasma’ which is used by the plasma industry as (http://www.cbc.ca/news/health/paying-for-blood-plasma-raises-new-questions-1.1361316), “a raw material that must be harvested from humans, and it is processed to make a range of pharmaceutical products. Large batches of plasma from thousands of people are pooled together, heated, filtered, and run through a series of processes to remove viruses and other contaminants. The pooled plasma is then separated into various components, to make intravenous immunoglobulin (IVIG), used in a wide variety of treatments for immune disorders, a series of coagulation factors used to treat hemophilia, and finally, albumin, used to treat burn victims.”
2.1 'Big Pharma' and Plasma:

It is this second area (source plasma) that companies like Canadian Plasma Resources are interested in while they pitch the line that there is an impending plasma shortage for life saving therapeutics. The supply of plasma is tightly controlled by a handful of large international firms who control the supply, like with oil or other resource commodities. But in this speculative market there is no peak plasma, or future shortage risk. In fact, internationally these companies have shut down plasma clinics over the last several years as many of the companies that harvest plasma control their own private clinics (expanding and contracting as is needed).

The industry is controlled by a handful of international firms, is constantly pushing its products into new markets and working to expand the customer base. Further, Big Pharma has monopolized the industry, "which now consists of five international corporations operating in the United States under Food and Drug Administration regulation: Baxter International of Deerfield, Illinois; CSL of Australia; Talecris of Research Triangle Park, North Carolina; Grifols of Spain; and Octapharma of Switzerland." A sixth big player is Biotest AG, a global company based in Germany which had €582.0 million in revenues in 2014.

Recently the US Federal Trade Commission stated, "Historically, the plasma-derived products industry has operated as a tight oligopoly," with, "intentional sharing of competitive information," by companies to avoid, "oversupplying the market or starting a price war." And, there is currently a class action suit is being launched in a U.S. District Court by a group of U.S. hospitals against two major plasma product suppliers where they allege, "a multi-year nationwide conspiracy...to fix, raise, maintain or stabilize the prices of Blood Plasma Proteins sold in the United States." This is market manipulation is paired with the fact that the demand for some types of plasma has actually fallen considerably in recent years, largely because hemophiliacs now use recombinant (synthetic) clotting products. At the same time, the demand for components of plasma like IvIG is way up.

2.2 IvIG liquid gold and Canada:

IvIG and the plasma it uses as a raw material is a $20-billion biopharmaceutical sector growing at 10% cent a year (which depending on the success of clinical trial could result in a new market worth $7.2 billion in the U.S. alone by 2017). The Council of Canadians has written a previous article on the rise of biologic drugs in Canada and how trade deals will impact their cost here, for those who want more information. It is reported that, "Based on typical industry yields and prevailing prices, it appears that a single plasma donation, for which a donor might be paid $30, results in pharmaceutical products worth at least $300. Unlike blood, which can be donated every 56 days, plasma can be given once a week."

This growth pattern is linked to the fact that IvIG is now widely used in developed countries for many 'off-label' applications, most of which lack evidence of effectiveness to justify their use. It is noted that
a plasma industry-sponsored 2003 study in Canadian hospitals found 53% by volume of off-label use of IVIG in treating adults, and 38% in paediatric treatment. Of the 90 different uses identified, 84 were ‘off-label’, that is, not evidence-based.

When compared with many other developed countries, Canada has the highest per capita consumption of IVIG. Over the last decade distribution in Canada has increased by 5 to 10% each year. In the 2014/15 fiscal year, Canada had a rise in the distribution by 6% from what it was in the previous year. While there are many diseases which IvIG has proven effective to various degrees in treating, there are many physicians (most commonly neurologists, hematologists, and rheumatologists) who choose to prescribe them in the hope that further research may ultimately prove their effectiveness. For example, in 2012, almost half of IvIG use in BC and Alberta was judged to be inappropriate or of uncertain benefit (the frequency of inappropriate use did not decrease after implementation of a utilization control program in BC). An audit conducted by the Ontario Regional Blood Coordinating Network (ORBCoN) and published in December 2015 demonstrated that 44.6% of IVIG is used for unlabeled indications.

Canadian Blood Services is responsible for manufacturing, acquiring and distributing about $500 million of plasma protein products annually. It is difficult to determine the current cost of IVIG per gram, for a variety of reasons but in the coming year we are generally going to be looking at costs from $75 to over $100 per gram. Per patient, per year, this can mean roughly anywhere between $15,000 to $300,000 depending on the amount given and frequency of treatments. Other data points out that at $100 per gram, “a typical dosage of 1g/kg body weight, a 154-pound (70 kg) person would therefore need 70 grams of IVIG, costing $7000 for each monthly infusion for the drug alone. Even at a cost of $70 per gram, the pharmacoeconomic impact of IVig is significant,” as a 70-kg pemphigus patient receiving IVig at a dose of 2g/kg, the cost for one cycle amounts to $9,800. As the average number of cycles required is 18, the total drug bill approaches $176,400. With an incidence of 1 per 100,000 population, the overall cost for the Canadian health care system exceeds $52 million.” So, the cost per gram is more than gold or platinum, white truffles or Iranian beluga caviar, or illegal rhino horn.

Since 2008, plasma pharmaceuticals have leapt from $4 billion to a more than $11 billion annual market. The U.S. is conversationally known in the industry as “the OPEC of plasma collections” and paid donors from the U.S. make up about 70 percent
industry/NI6979) of worldwide collections. This is the domestic market Canadian Plasma Resources is trying to emulate and draw the Canadian health care system into. Canadian Plasma Resources is yet another tentacle of the pharmaceutical industry trying to undermine our health system for profit, which is what paid plasma clinics are really about.

Allowing for-profit plasma companies into our blood services sector would result in plasma being sold in the private sector and publicly-funded non-profit health institutions for the profit of shareholders. It's not going to stay in Canada (http://canadians.org/blog/ontario-election-could-alter-safety-canadas-blood-supply) (we don't have any processing facilities for large scale blood plasma fractionation) and with our current trade agreements if there ever was a shortage of plasma we would be forced to sell it to the highest bidder that we have a trade agreement with. Subsequently, U.S. law makes it difficult to sue for infections (http://scholarship.law.wm.edu/wmblr/vol3/iss2/6/) contracted from the US blood supply because of special “blood shield” laws (yes, this isn't made up). However, if we keep blood collection voluntary, we're able to shore up our own resources and maintain higher quality health standards for Canadians.

![National Ig Distribution and Growth Rate (includes Quebec)](image)

2.3 Paying for Plasma does not create ‘self-sufficiency’ in Canada and other myths:

One of the myths being spread by the Saskatchewan governments is this for-profit facility will help us become self sufficient so we don't have to import plasma. First, paying for plasma creates a two-tiered and fragmented system for the collection of plasma and blood products in Canada. There are not facilities in Canada to process the plasma collected and manufacture the subsequent pharmaceutical products, so Canadian Plasma Resources will be selling their plasma to the U.S. or other markets. As it stands, only plasma collected by Canadian Blood Services that is specifically marked for Canadian use is fractionated (i.e. processed) in the U.S. and then brought back to Canada. Further, Canadian Blood Services has indicated it has no plans to buy plasma from Canadian Plasma Resources. None of the plasma obtained by the company will directly benefit Canadian patients (as the Saskatchewan government has implied); it will be sold for a profit to major pharmaceutical companies and researchers, regardless of the possible contamination risks (more on that later). So, despite the rhetoric, the company and the Saskatchewan government know that this has nothing to do with self-sufficiency but, rather, is about making profits of citizens (generally off of the most vulnerable).

If Canada did need to collect more blood and plasma, there are ways to do this and Canadian Blood Services has the tools to accomplish this after nearly a decade as an organization. Frankly, it is time for Canadian Blood Services and Dr. Graham Sher to stop making excuses and get on with a real plan to achieve self-sufficiency for blood and blood products to meet Canada’s obligations to the World Health Assembly. There are 41 nations who have achieved self sufficiency or are on their way to, but all we hear is Canadian Blood Services saying they willing to entertain a business case to raise their percentage of plasma donated while at the same time not coming out fully against paid plasma donations. As was stated (http://www.ontla.on.ca/web/committee-proceedings/committee_transcripts_details.do?locale=en&Date=2014-12-01&ParlCommID=9003&BillID=3015&Business=&DocumentID=28419) by a Harvard trained health economist during the Ontario standing committee on social policy regarding Bill 21, “Look, we know you want to get into tissue banking. We know you want to do all of these other things, but you haven't finished your work on blood. We're not self-sufficient, and we would like you to take the steps.”

In fact, Canadian Blood Services has been self-destructing its voluntary blood donations systems. They closed down a voluntary plasma center in Thunder Bay, another in Saint John, taken at least two mobile voluntary blood collection units off the road, cut clinic hours, etc, etc... sure they will highlight that they only receive $1 billion in annual funding, but if self sufficiency is your goal it is then time to get serious and start demanding more funding instead of dodging responsibilities. And while improvements in minimally invasive or keyhole surgeries have reduced the amount of blood needed in many hospitals, this also doesn't mean Canadian Blood Services should ignore is primary mandate to ensure the safety of blood
and blood related products.

Dr. Graham Sher has been with Canadian Blood Services since it began operations in September 1998 when he was that vice-president of medical, scientific and clinical management, and was appointed CEO in June 2001. He has played a huge role in deciding the priorities, strategy and culture at Canadian Blood Services. This includes (http://www.theglobeandmail.com/report-on-business/careers/careers-leadership/canadian-blood-services-seeks-corporate-transfusions/article8430935/) broadened the organization's work into organ and tissue donation, running the organization like a private corporation and seeking out corporate financing for the public body. Perhaps this explains Canadian Blood Services oddly meek position on the current paid plasma situation; which not only goes against the recommendations of global health organizations, but also Canadian Blood Services own reports (http://www.gov.nl.ca/ahe/presentations/CanadianBloodServices%20.pdf) which have recognized the importance of the Krever Commission's principles.

At the same time, there position is influenced by Ian Mumford (Canadian Blood Services former chief supply chain officer for over 17 years), who is now a director (http://www.reuters.com/finance/stocks/companyOfficers?symbol=IPO-THRB.TO) at Therapure Biopharma Inc. Therapure is a biopharmaceutical company focused on manufacturing biologics and selling blood and plasma-related products, and is a member (http://www.pptaglobal.org/about-us/current-members) of the Plasma Protein Therapeutics Association. The PPTA is an industry lobby group whose mission is, among others, to break down "artificial barriers on trade and compensated donors." PPTA have also been active in lobbying for paid plasma in Canada and supporting Canadian Plasma Resources. Lastly, a quick (https://ca.linkedin.com/in/rickprinzen) look (https://ca.linkedin.com/in/jean-paul-b%C3%A9dard-30133016) at other current executive at Canadian Blood Services shows careers with ties to companies in the pharmaceutical industry that promote paid plasma for their IgV drugs.

It is worth pointing out that the Saskatchewan minister of health (like other provincial ministers of health) elects a member for the board of Canadian Blood Services; if there was a need to collect more plasma domestically they have an avenue to implement policy for more collections. Yet, the Brad Wall government and health minister Dustin Duncan seem to be more interested in ideological projects than working to create real, long term policy solutions. What this all points to is that the new paid plasma clinic in Saskatchewan has nothing to do with evidence based health policy, but rather making profits at the expense of the safety of our blood system. Or to put it another way, saying Canadian Plasma Resources will have any positive effect on our domestic supply is absolute horse shit.

3.1 For profit plasma clinics hurt our voluntary system:

To make matters worse, we know that a two-tiered system actually reduces voluntary non-profit blood donations. The European Blood Alliance has documented that competition between voluntary non-profit blood agencies and for-profit companies that remunerated donors led to a shortage in blood supply in Austria and Germany in 2006 and 2007 (two countries to pay particular attention as there are ties to private plasma clinics in these countries and Canadian Plasma Services). Further, it has been pointed out (http://www.ontla.on.ca/web/committee-proceedings/committee_transcripts_details.do?locale=en&Date=2014-12-01&ParlCommID=9003&BillID=3015&Business=&DocumentID=28419) that, “the head of transfusion medicine [in Germany] has stated on multiple occasions that paid blood is impacting their whole blood donorship. They can't win donors back because they are being cultured to be paid for their blood, for that plasma, regardless of what it is being used for. So when you create a competitive model like that, you commodify a public resource, and you lose control over how and where and what is happening with it.”

In the two-tiered U.S. system with for-profit and voluntary blood/plasma donations, evidence shows (http://www.europeanbloodalliance.eu/wp-content/uploads/2012/08/eba-position-paper-competition-in-european-blood-component-market-final.pdf) that nearly 7% of hospitals reported that elective surgery was postponed on one or more days (median 3 days; range 1-120 days) because of blood inventory shortage. In contrast, the data from (file:///C:/Users/Michael/Desktop/Concil%20of%20Europe%20Final%20report%20%E2%80%93%20Collection,%20testing%20and%20use%20of) the Council of Europe shows where countries with a 100% non-remunerated donor base are apparently capable to collect.
sufficient blood components. An excellent recent article highlighted that “according to the WHO, countries with paid donation have on average 0.9 per cent of their population sell their blood. Countries with voluntary, non-remunerated collection systems see over 3 per cent of their population donate.” In light of finding like this (and safety concerns) over 70 countries are completely donation-based.

Pro-remuneration plasma advocates like to selectively choose quotes from the 2011 Dublin Consensus. Don’t be fooled, the Dublin Consensus simply, “a brief statement that was drawn together by organizations supported by the plasma pharmaceutical industry. It is not a scientific report. The Dublin Consensus and the ‘plasma platform’ are supported by the PPTA - which is the private sector pharmaceutical organization representing the plasma industry.” The two Canadian representatives who are signatories are David Page (the ED of the Canadian Hemophilia Society, more on him later) and Ian Mumford (who was with Canadian Blood Services at that time) and now works – as was mentioned above- for the paid plasma pharmaceutical industry. Interestingly, it is worth pointing out that despite the Dublin Consensus being a limited group of signatories and a non scientific statement, it does point to the risk in setting up parallel blood and plasma systems. The Dublin Consensus states, “The coexistence of two independent collection systems, one for blood and one for plasma, in the same region or country, could create a risk of shortage in the supply of blood components.”

For those health policy nerds among us, this modelling study using evolutionary game theory indicated that, “that the existence of paid donation tends to destroy the social norm of donation as altruistic, discouraging unpaid donation. It confirms Titmuss’ assertion that once incentives have removed the idea of altruistic donation, withdrawing them makes matters worse in the short-term, as paid donors are lost but insufficient voluntary donors replace them.” So not only do private plasma clinics like the one being operated in Saskatchewan reduce voluntary donations, but if we don't stop it now entrench itself and reduce overall blood and plasma donations in the future.

Blood and blood products are indeed something ‘that is in you to give.’ It holds the power to save lives and is something we possess that is truly a public good and resource. When companies like Canadian Plasma Resources try to turn it into commodity, it loses true merit and qualities as a public good.

Justice Horace Krever (Photo: CBC News/Archives)

3. 2 Voluntary plasma and blood donations have been proven to be the safest

We’ve been here before ... The 1997 Krever Commission which looked into Canada's horrible tainted blood scandal (During the 1980s 30,000 Canadians were infected with hepatitis C, 11,000 with HIV (http://www.hemophilia.ca/en/commemoration-of-the-tainted-blood-tragedy/) [consequently leading to $5 Billion in compensation (http://www.theglobeandmail.com/life/health-and-fitness/health/paying-donors-for-plasma-have-we-forgotten-about-tainted-blood/article9232617/) after the $17 million dollar inquiry]). David Harvey, a lawyer who represented families, organizations, and patient groups touched by tainted blood for about 20 years has pointed out after the $17 million dollar inquiry).
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"Justice Krever received and reviewed 175,000 documents totalling over a million pages. He had hearings from February 1994 to December 1995, hearing from 474 witnesses—247 days of hearings, written submissions from 89 parties, 50,000 pages of transcript, 100,000 pages of exhibits. There were witnesses from across Canada and around the world, experts in transfusion medicine, internationally renowned panels, front-line workers. With respect, it's impossible for this committee to come to a different conclusion than Justice Krever in a responsible manner."

The Krever Commission strongly recommended against paid donations to prevent vulnerable people with diseases from selling their blood for money. In the tainted blood scandal, for-profit blood brokers purchased blood from high risk population in places like Haiti, skid row in Los Angeles, Arkansas prisons and Russian funeral homes. If you see a frightening and unethical parallel with what Canadian Plasma Resources is doing in Saskatoon you are not alone (more on this later). Blood or plasma donation on a voluntary basis is particularly crucial whenever the collection system is endangered by a new infectious threat, not identifiable by lab testing. The sole means to safeguard against such unknown threats is the voluntary collection of plasma from healthy citizens who have no monetary incentive to lie about their health status.

Allowing this Canadian Plasma Resources, or similar companies, to pay donors for plasma conflicts with the recommendations of the four-year inquiry into the tainted blood scandal. These recommendations were put in place to prevent another tainted blood scandal, something the Brad Wall government and health minister Dustin Duncan seem to care little about.

In his report, Justice Krever recommended that:

- “...the Canadian blood supply system be governed by five basic principles, [including] (b) donors of blood and blood plasma should not be paid for their donations, except in rare circumstances. [Krever, Vol.3, p.1047, Recommendation #2].

- “Whole blood, plasma and platelets must be collected in sufficient quantities to meet domestic needs for blood components and blood products.” [Vol. 3, Recommendation #2, p. 1047]

- “Canadian plasma should be custom fractionated, in batches consisting only of Canadian plasma, based on specifications negotiated between the fractionator and the national blood service. These specifications should include requirements for the manufacture of the safest and the highest quality products.” [Vol.3, Recommendation #5, p. 1051]

A voluntary blood supply is deemed the safest and most reliable system of plasma and blood collection. The World Health Organization and the International Society of Blood Transfusion oppose payment fees for plasma donations. Going further, the World Health Organization wants all countries to move to unpaid donation systems by 2020 due to evidence based studies showing to volunteers having the lowest prevalence of blood-borne infections. Other organizations that that call for publicly-regulated, not-for-profit voluntary blood and plasma donation system include the International Federation of the Red Cross and Red Crescent Society, the International Federation of Blood Donor Organizations and the European Blood Alliance. So in sum, pretty much every major evidence-based, international health organizations is against paid plasma for good reason.

The tainted blood scandal has been called Canada's worst preventable public health disaster. When dealing with the lives of people we have to be practical and precautionary. Too many people have already been buried because of mistakes in the past, why make them again out of greed and misguided hubris. Michael Decter who was in involved in the original Krever Commission has stated (http://www.ontla.on.ca/web/committee-proceedings/committee_transcripts_details.do?locale=en&Date=2014-12-01&ParlCommID=9003&BillID=3015&Business=&DocumentID=28419) in regards to the current situation that, “Memories fade. New experts and those with financial gains in mind tell you that this time, it will be safe; this time, it will be different. Old lessons are forgotten. As we age, we have a responsibility to speak our remembered truth to your democratically given power... Albert Einstein commented that the true definition of insanity is doing the same thing over again and expecting different results."

3.3 How safe is plasma screening:

We know that paying for plasma compromises the safety of plasma. By providing a financial incentive to donate plasma, the clinics attract donors from vulnerable populations and put the plasma at risk. Voluntary donation is particularly crucial whenever the collection system is endangered by a new infectious threat, not identifiable by lab testing. The sole means to safeguard against such unknown threats is the voluntary collection of plasma from healthy citizens who have no monetary incentive to lie about their health status. Collected plasma from different people is pooled together and the different proteins separated by fractionation (by centrifuging) and purified out. The plasma needed for domestic uses that come from voluntary donations are smaller and safer. This is in contrast to the massive plasma pools the pharmaceutical industry and plasma monopoly use (what Canadian Plasma Sources will be selling to). A 2005 study (http://www.cvstat.ugent.be/techrep/2003-3.pdf) from Ghent University in Belgium says that in Belgium, “approximately 5,000 donations are mixed into such pools. In Germany, pools containing up to 60,000 donations are considered. In the United States, some donor pool sizes are in excess of several hundred thousand [donations]."
Health Canada has also looked into this matter and written (http://epe.lac-bac.gc.ca/100/200/301/hcan-scan/commission_blood_final_rep-e/vol3-e.pdf),

“The evaluation of safety in plasma derivatives is not straightforward. There are too many variables to permit certainty. The human plasma that is the starting material for every batch of plasma derivatives is obtained from thousands of different donors. The quality and safety of the donations are inconsistent, and every batch differs from the next. Although it should be possible in principle, if not in practice, to test a sample of every lot of every product, thorough regulation would require knowledge of, and a means of testing for, every possible hazard. Limitations on resources require the Bureau of Biologics and Radiopharmaceuticals, in considering submissions for approval of new drugs, to rely principally on a review of the manufacturers’ data about the safety, efficacy, and purity of its products and the manufacturers’ quality control; and on inspections of the manufacturers’ premises and processes. The bureau conducts a limited amount of testing in its own laboratories, and, when plasma derivatives are authorized for sale, it reviews the results of the manufacturers’ tests of lots of the plasma derivative before they are released for sale.”

In plasma screening we lack the tests for many blood-borne infections, and especially emerging diseases (remember the tainted blood scandal). There is always a risk associated with harvesting plasma and the safest strategies are not test based but based on donor selection strategies. As an exceptional report (https://www.opendemocracy.net/ournhs/lucy-reynolds/selling-our-safety-to-highest-bidder-privatisation-of-plasma-resources-uk) (worth a read by anyone interested in evidence bases discussions on this topic) by Dr Lucy Reynolds, research fellow in public health at the London School of Hygiene & Tropical Medicine, highlights,

“It is known that paying donors discourages such withdrawal from the supply, so the average infection burden of the blood rises when donors are paid... Furthermore, low cash payments tend to attract, not people with healthy lifestyles (for whom a few dollars is no incentive to take a day off work), but those living in precarious circumstances. It is especially suited to those with a frequent and urgent need to produce small amounts of cash. This profile of course fits the situation of an addicted injecting heroin user, and offers to buy blood or plasma tend to attract them particularly. If they are bled shortly after contracting HBV, HCV or HIV, the standard antibody-based tests will miss these very early infections. Unfortunately it is during very early infection that viral loads are typically at their highest. Quarantine protocols can be used to eject such donations, but these require three-month plasma storage and follow-up of every seller. They are thus expensive to run; producers omitting them can be considerably more competitive in the market.”

There are three main categories (https://www.opendemocracy.net/ournhs/lucy-reynolds/selling-our-safety-to-highest-bidder-privatisation-of-plasma-resources-uk#sdfootnote95anc) serious infection/diseases which can be passed through blood products. First off, there are,

“the known serious or fatal infections for which we can test, e.g. HBV, HIV, HCV, West Nile Virus. All of these have been passed through US-generated plasma sources, and all but the last by Chinese plasma supplies. Secondly, known serious or fatal infections for which we cannot currently test reliably, such as the prion disease variant Creutzfeld-Jakob Disease (vCJD). And lastly, unknown serious or fatal infections (for which we obviously cannot yet develop tests), including emerging animal diseases. It is worth remembering that HIV showed up in haemophiliacs infected via clotting factors very soon after its first discovery, before screening was possible. Now most older haemophiliacs are HIV-infected due to past exposure to infected blood products. New blood-borne infections come to light all the time, for example the parvoviruses... Despite screening, antibody-based tests may pass a patient with primary infection from a very recent risk as negative, allowing the infected donation to enter the transfusion supply. Thus HIV, HBV, HCV and other diseases can though false negative tests enter the supply. Quarantine protocols offer some protection against known diseases by catching false negatives in the case of plasma donations, but this only assists in the case of the diseases for which tests are both available and used. There have been persistent problems with substandard screening tests... Plasma products can be subjected to viral inactivation techniques, but these cannot destroy all known pathogens.”

By allowing this new ‘plasma clinic’ to operate, the Saskatchewan government is opening the door to international blood laundering. As there is no way to effectively detect and control the mixing of unregulated batches of plasma products which Canadian Plasma Resources is intending to export, there is an increased risk of the spread of plasma-borne infections globally. Health Canada rarely, if ever, conducts unannounced inspections of blood facilities in Canada. When there are inspections, they are announced to the blood operators weeks or months ahead and are done annually, if at that.
3.4 Why we need to worry about what's next:

Safe blood activist Dr. Antonia Swann (who's late partner James Kreppner (http://www.thestar.com/news/gta/2009/05/25/james_kreppner_47_patients_rights_activist.html) was a part of the tainted blood scandal contracting HIV and Hepatitis C and became a leading blood distribution and patients' rights advocate), has confirmed (http://www.ontla.on.ca/web/committee-proceedings/committee_transcripts_details.do?locale=en&Date=2014-12-01&ParlCommID=9003&BillID=3015&Business=&DocumentID=28419) that,

"Part of the reason Krever happened was due to private, paid donations. In light of the Krever inquiry—you have to understand that this was based on solid scientific evidence at the time, and that solid scientific evidence stands today... What I want to tell you is that we are not immune to another disease like AIDS, the next AIDS, coming down nature's pipeline of diseases. That is an ongoing threat...The point is that AIDS sounded unimaginable; it was from out of this world. What I'm telling you today is that I think it is arrogant and, more importantly, dangerous to assume that another as-yet-unknown blood-borne pathogen can't still come into the blood system... The most simple and obvious way to minimize the risk of future blood-borne pathogens, to reduce the inevitable and invisible threats to our blood system, is to rely on an altruistic rather than a private system, which scientific studies show is less safe."

New threats will arise, that is a given. How many of us had heard for the Zika virus, for example, prior to this year? When these outbreaks do occur they are not well understood, there are no diagnostic tests available, and there is no research available. For example, in 2000, Britain lost its entire plasma industry due to contamination with through the infectious agent of Mad Cow Disease (prions) and its new human variant, Creutzfeldt-Jakob Disease (vCJD) vCJD. Recently the above statements were proven correct when, the US F.D.A told (http://www.reuters.com/article/us-health-zika-blood-idUSKCN0VP2NF) Puerto Rico and the US Virgin Islands to spot collecting blood and import it because of the Zika outbreak there. The New York Times reported that, “there is no F.D.A.-licensed test to screen blood donations for Zika virus,” and the U.S. Department of Health & Human Services (HHS) has stated (http://www.hhs.gov/about/news/2016/03/07/hhs-ships-blood-products-puerto-rico-response-zika-outbreak.html), “the risk of Zika virus transmission through blood products is considered likely based on the most current scientific evidence of how Zika virus and similar viruses (flaviviruses) are spread.” There is also the Hepatitis E virus (HEV) is widespread and blood/plasma donors are often asymptomatic. An EU report (http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2015/07/WC500189012.pdf) stated that, “HEV has been recognised as a transfusion transmissible agent since 2004 and transfusion-related cases have been documented in several countries (United Kingdom, France, Japan, Saudi Arabia, People's Republic of China). Recent analysis of blood and plasma donations has identified HEV-infected donors in Europe and USA. Consequently, HEV-RNA has been detected in plasma pools used for production of medicinal products.”

When outbreaks happens, the only tool in the tool box is relying on voluntary and altruistic donations to protect the public. Paid donations have proven to increase risk and provide less safe donations. We need to be realistic and concerned with the inevitability of what is coming next and maintain our policies which emphasize safety above all else. The technological and scientific arrogance surrounding the government of Saskatchewan and Canadian Plasma Resources claims are no different than the ones lead to over 60,000 people being infected with HIV and Hepatitis C.
4.1 Who is behind Canadian Plasma Resources and Exapharma:

So who are the people is behind Canadian Plasma Resources/Exapharma and what is their expertise? A Mcleans article found out (http://www.macleans.ca/news/canada/should-we-pay-for-blood/) that, “EXAPharma (http://www.exapharma.ca/), parent to Canadian Plasma Resources, was incorporated in July 2009, a month after a meeting with Health Canada. In November 2010, they registered Canadian Plasma Resources to operate ‘plasmapheresis centres’; its website went live in March 2011; in November 2012, it applied for a federal licence. EXAPharma is owned and operated by the Riahi family, says Canadian Plasma Resources' CEO, Barzin Bahardoust. (EXAPharma's incorporation documents lists Yalda Riahi, a Toronto-area lawyer as president.)” The company EXAPharma appears (http://diablogue.org/2014/06/04/paid-plasma-debate-the-atlantic-describes-how-desperate-donors-deceive-plasma-screeners/), “to be run by members of the Toronto Iranian community, the center's manager an orthopaedic surgeon who had previously worked for the Iran Hemophilia Society.”

The federal corporate directory shows (https://www.ic.gc.ca/app/scr/cc/CorporationsCanada/fdrlCrpDtls.html?corpId=9362835&V_TOKEN=1456172695633&crpNm=plasma&crpNmbr=&bsNmbr=) three directors for Canadian Plasma Resources: Barzin Bahardoust, Leyla Soleymani, and Yalda Riahi. Barzin Bahardoust is the CEO of Canadian Plasma Resources. While he likes to appear in a doctors white coat in press photos, he is not a medical doctor. He does have his PhD (http://www.ecf.utoronto.ca/~kherani/people.htm) in electrical engineering, but it doesn't look like he has any previous experience (http://65.54.113.26/Author/51630124/barzin-bahardoust) in health or plasma businesses. His wife (https://tspace.library.utoronto.ca/bitstream/1807/26530/3/Soleymani_Layla_201011_PhD_thesis.pdf) Leyla Soleymani is one of the other directors listed on the federal corporation registry. She is also an engineer and is an associate professor (http://engphys.mcmaster.ca/faculty/dr-leyla-soleymani/) at McMaster University (where there seems to be numerous ties to the company). The third director is Yalda Riahi, who is a Windsor Law graduate and (http://www.millerthomson.com/en/our-people/yalda-riahi) is currently a corporate lawyer (http://www.iwontario.com/wp-content/uploads/2015/10/AGM-Bio1.pdf) with Miller Thomson LLP. She is also the president (https://ca.linkedin.com/in/yalda-riahi-3793b533) of EXApharma, a position she would have begun while she was an articling student. In all three cases the directors are relatively recent graduates.

A 2013 document (http://www.giveplasma.ca/tiny_mce/plugins/filemanager/files/Files/The_Need_For_Source_Plasma_Production_In_Canada.pdf) is the most recent available online listing other key people involved with Canadian Plasma Resources. The responsible physician is, or was at that time, Dr. Morris Blajchman who is (http://fhs.mcmaster.ca/medicine/hematology/faculty_member_blajchman.htm) a Professor Emeritus at McMaster University and is a Medical Director of the Southern Ontario Centres of Canadian Blood Services. He is also an associate editor for the Canadian Medical Association Journal, but curiously doesn’t declare or list (http://www.cmaj.ca/site/pdfs/blajchman.pdf) any conflicts of interest. A past article (http://www.thespec.com/news-story/4432531-hamilton-clinic-at-centre-of-paid-plasma-fight/) also stated that there was/is a second medical director who was also from McMaster University's medical school.

The business development consultant is Dr. Michael Kloft who seems to be tied to German pharmaceutical company and plasma medication maker Biotest AG (https://translate.google.ca/translate?hl=en&sl=de&u=https://de.wikipedia.org/wiki/Biotest&prev=search). This company
is the fifth or sixth largest (depending on the claim) producer and supplier of plasma protein products worldwide and has a presence in Western Europe, in the United States along with 70 other countries. During hearing before the Ontario government Bahardoust stated that Canadian Plasma Resources was hoping to build and operate a fractionation plant with our strategic partner Biotest AG. Curiously, in one of Biotest AG’s supply agreements it states (http://www.sec.gov/Archives/edgar/data/946840/000119312509158200/dex104.htm) that,

“They will never be eliminated.”

Purchaser acknowledges that when Products prepared from human blood or plasma are administered, the potential for the transmission of infectious agents (such as viruses or other infectious particles, and including infectious agents that may not have been discovered or characterized at this time) cannot be totally eliminated, despite stringent controls applied in the selection of blood and plasma donors and prescribed manufacturing standards used at blood and plasma collection centers, testing laboratories and fractionation facilities. Accordingly, Purchaser agrees that any claims resulting from or alleging such transmission of infectious agents are NOT intended to be covered by the indemnification provisions of Section 8.2.”

Back to Dr.Kloft. He also appears to have travelled to Iran and presented (http://www.ibto.ir/HomePage.aspx?TabId=4583&Site=ibto&Lang=en-US) at the Iranian Blood Transfusion Organization (IBTO (file:///C:/Users/Michael/Downloads/2nd%20International%20Conference%20on%20Transfusion%20Medicine%5b1%5d%20(2).pdf) “2nd Congress on Transfusion Medicine- Plasma Industry.” Biotest AG and the Iranian company Darou Pakhsh (the largest Iranian pharmaceutical company with a turnover of US$ 400 million) formed (http://www.biotest.at/ww/en/pub/investor_relations/news/newsdetails.cfm?newsID=17131) Biodarou (http://biodarou.com/en/) in Tehran in January 2004 with Biotest holding a 49% interest in the Tehran-based company and establishing an initial total of three plasmapheresis stations and test laboratories in Iran. Interestingly, Darou Pakhsh is listed (https://www.gov.uk/government/publications/iran-list) by the British Department for Business, Enterprise and Regulatory Reform (BERR) as a blacklisted end-user (i.e. a belief that they violated terms of their licence and transferred their purchase to other companies with link usually with links to proliferation activities).

It appears (http://www.yatedo.com/p/Mohammad+Reza+Shojaei/normal/994a90e041179e1c46a03bae574f4582) Reza Shojaei was the Pharmaceutical Project Manager at Canadian Plasma Resources (and Examon Industries and Consulting Services Corporation) from 2009 until 2011, and is now the current Quality Systems Manager. Previously he worked (http://www.coldchainpharm.com/reza-shojaei-speaker) at BioDarou.

In Saskatoon, the Quality Systems Associate is Pauline Delgado (https://ca.linkedin.com/in/pauline-delgado-berthier-a2547847) who graduated two years ago with a Pharmacology masters degree. Her profile highlights her role as including the: set up of a new plant in Saskatoon, implementation of the quality systems, preparation of the Health Canada licensing process and preparation of the ISO certification.

One would be employ is Ramin Fallah who was to serve as vice president and chief operations officer of Canadian Plasma Resources. Fallah has invested (http://news.nationalpost.com/news/canada/would-be-medical-exec-from-iran-barred-from-canada-over-alleged-ties-to-tehrans-nuclear-program) $1.3 million into the holding company EXApharma and had sought a three year visa and work permit for Canada. Instead, the Canada Border Services Agency refused to issue a work permit as they believe he was a security threat and he has barred him from Canada over his alleged links to Tehran's nuclear program. Interestingly, the court documents (http://www.scribd.com/doc/282495199/Exapharma) show that temporary resident visas were issued to him in August 2001, July 2003, and August 2005. The ruling was based partly on classified evidence about the companies Fanavari Azmayeshgahi (Eghlim Sanaate Sabz Co branch of the company it seems (http://webarchive.nationalarchives.gov.uk/20121017180846/http://www.bis.gov.uk/assets/biscore/eco/docs/iran-list.pdf)), an Iranian import firm that Mr. Fallah was the managing director of which, “has been involved with procurement connected to the Iranian nuclear program.” Open source documents show this company has been flagged as in the UK (https://www.gov.uk/government/publications/iran-list/iran-list) and Japan (https://www.google.ca/url?sa=t&rct=j&q=&esrc=s&source=web&cd=6&cad=rja&uact=8&ved=0ahUKEwi2o97_a3LAhWnnYMKHelBoyoQg3MAU&url=http%3A%2F%2Fwww.meti.go.jp%2Fpolicy%2Fapplied%2Ftutatu%2Ft11kaisei%2F140401kaisei_userlist_kohyo.xls) and
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4.2 So where is the money coming from:

There seem to be some deep pockets backing Canadian Plasma Resources/EXApharma Inc. As an important disclaimer, this isn't to denigrate or malign any communities but to try and understand where the financial backing is coming from to get a better understanding of the situation. In Ontario the company spent $3 million from investors, creating a clinic in Hamilton, and another $4 million on two clinics in downtown Toronto despite provincial opposition. The company stated (http://www.lfpress.com/2014/04/22/firm-plans-to-sue-to-recover-75m-investment-if-proposed-ban-on-paying-for-plasma-passes) prior to the ban in Ontario that it was planning sue to recover nearly $7.5 million it's already invested if the ban came into place, but it is unclear if this has occurred. Bahardoust had also stated (http://www.thestar.com/life/2013/04/12/should_federal_and_provincial_regulators_allow_plasmaforprofit_clinics_to_operate_in_canada.html) they had a plan for a $400 million expansion to open 10 plasma collection centres and to build and operate a fractionation plant with Biotest AG (who are not currently in Canada at this point); this obviously isn't the type of money you can just walk into a bank and ask to borrow. Bahardoust had also claimed (http://www.otnia.on.ca/web/committee-proceedings/committee_transcripts_details.do?locale=en&Date=2014-12-01&ParlCommId=9003&BillId=3015&Business=128419) that the company had, "invested approximately $40 million in industrial property for the future fractionation plant, which is now going to be used for development and we don't have that property anymore." The company then had the capital to quickly pick up and set up an operation in Saskatoon.

Looking in the Toronto area there are some medical (http://www.scribd.com/doc/282495199/Exapharma) companies, an investment (http://www.ic.gc.ca/app/ccr/srch/mrgt.do?prtl=1&estblmntNo=123456262403&profile=cmpntPrfl&profileld=984&app=sold&lang=eng) companies, an investment (http://www.salespider.com/b-138628786/p-o-m-investment-group) and security broker (http://businesslistingcanada.com/business-10-144494-0.html), a technology (http://bahardoust.com/) company (http://www.manta.com/ic/m/mt69b52/ca/manco-technologies-inc), and some properties (http://www.toronto.ca/legdocs/mmis/2010/mn/bgrd/backgroundfile-31305.pdf) related (http://www.oaca.info/site/oaca/assets/pdf/omb_board_order_-_131366.pdf) to the last name Bahardoust, but this doesn't look to be the main source of the money backing Canadian Plasma Resources (and could just be a coincidence). In the legal filing (http://www.scribd.com/doc/282495199/Exapharma#scribd) and CBSA document Ramin Fallah does call Canadian Plasma Resources his newly created business, but $1.3 million is a far cry from the amount of money currently in play.

Digging a little deeper it appears that EXApharma is owned and operated by the Riahi family and Canadian Plasma Resources director Yalda Riahi is the president of the EXApharma. A 2013 Toronto Star article (http://www.thestar.com/life/2013/04/12/should_federal_and_provincial_regulators_allow_plasmaforprofit_clinics_to_operate_in_canada.html) stated that the company's owners are, "the Riahi family, who made its fortune in construction and real-estate development, and has experience in the blood business. They once owned three plasma-collection clinics in Austria and currently own a German consulting company that provides expertise on licensing and designing fractionation facilities." Searching for clear construction and real-estate connections for the last name Riahi in Canada doesn't turn up many clues. One of the only hits (http://www.parya.org/index.php/en/our-sponsors) that comes up is for the Riahi Nasser & Company who are sponsors for a Iranian foundation in Toronto.

With the Toronto Star story claiming the Riahi family was the owners and name Nasser Riahi (presumably related to Yalda Riahi the president of EXApharma) the picture starts to get a little clearer. In Austria the EXAMON group (http://examongroup.com/) is, "a privately owned independent group of companies established in 1994. Headquartered in Vienna-Austria and having offices in 4 corners of the world.” In the group there are a variety of different areas included EXAMON PHARMA Handelsges.m.b.H. which handles a number of pharmaceuticals, needing cool chain logistics (i.e. blood products), and EXAMON Handelsges.m.b.H. is specialized in trade and trade-finance for pharmaceutical products and industry. They represent companies including: Merck Serono, Hameln Pharma, Genzyme (a Sanofi company), Fresenius Kabi, Sandoz, Takeda, Leo Pharma, Nestlé Health Science Products, Astellas, B.Braun Melsungen, B Biosyent, Biolyse, and Servier. The also handle the finances for Darman Ara pharmaceutical company in Iran who bring in plasma products from Biotest AG; the company stated (http://www.darmanara.net/BusinessDevelopments.aspx), "under current situation of global sanctions against our country, we do our financial activity via our reputed partner 'Examon Group' to facilitate commerce fellow for other partners." They are also involved (http://www.bartrammedical.com/global/index.php?option=about) with Iranian pharmaceutical importers. In Germany the name Nasser Riahi is associated with a company (https://translate.google.ca/translate?hl=en&sl=de&u=http://firma-24.de/nasser-riahi-advanced-plasma-technology-and-supply-gmbh-gr%25C3%25BCner-weg-aachen&prev=search) called Advanced Plasma Technology and Supply
GmbH. The Darman Ara company is also partnered with Advanced Plasma Technology and Supply GmbH and Bio Darou. In Canada there was a corporation (number 7049781) called Examon Industries and Consulting Services, which was a member of Examon Handelsges.m.b.H. in Austria, that was discontinued in 2011. At the same time EXApharma (the parent company of Canadian Plasma Resources) was founded 2009 and still remains active.

It gets even more interesting. It appears the same Nasser Riahi sits on the board of directors for the Tehran chamber of commerce and his email address is linked to the Darman Ara company in this example. He is also a member of the coalition for tomorrow where his bio highlights he is the head of the Iranian Pharmaceutical Importers Association and that Iran's annual import of drugs and pharmaceutical products currently stands at nearly $1 billion. He is also the founder, shareholder and board member Bio Darou, is on the board of directors for other plasma groups, is shareholder and chairman of the board of directors EXAMON Handelsges.m.b.H Austria, and an entrepreneur through EXapharma Canada, the first plasma collected in Canada. The reach of big pharma is truly global and this is likely the source of the money behind Canadian Plasma Resources while being the possible destination of the plasma they plan to collect. It seems again that this has nothing to do with our domestic market or Canadian self-sufficiency in plasma, but is rather a part of a group of international blood brokers tied to the pharmaceutical sector.

### 5.1 Why Canadian Plasma Resources were run out of Ontario:

Prior to Saskatchewan, Canadian Plasma Resources tried to set up shop in Ontario. Council of Canadians has previously pointed out a major win for public healthcare when a pay-for-plasma operation was stopped in Ontario (there were clinics that had been set up in Toronto and Hamilton), but with
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For those not familiar with the story in Ontario, Canadian Plasma Resources was raided by Ontario Ministry of Health inspectors in its two Toronto clinics (located in near services for or in economically disadvantaged areas). These clinics offered subjects who qualified $25 to give blood for a “research trial” (i.e. blood money). This plasma was to be collected by Canadian Plasma Resources and sold on the international market to the highest bidder. Further, Canadian Plasma Resources CEO Bahardoust has said the plasma collection centre has to collect 30,000 to 40,000 liters of plasma annually to make the operation economically viable, which is a substantial amount (Canada’s last plasmapheresis collection clinic, which recently closed in Thunder Bay, was only hitting a threshold of 15,000 litres a year). Ontario Health Minister, Eric Hoskins, put forward a new bill to ban for-profit plasma centres (Bill 21). Ontario and Quebec now ban for profit plasma centres, this represents well over half of the Canadian population (around 61.2% of Canada’s population).

In contrast Dustin Duncan, Saskatchewan’s minister of health has stated that the province has assured Canadian Plasma Resources it wouldn't pass legislation similar to Ontario's, which effectively bans the paid collection of plasma.

5.2 Who are the patient groups who support Canadian Plasma Resources:

The pharmaceutical and plasma lobby has also created a plethora of front groups and has made millions of dollars of donations to a variety of patients groups. While these ‘patient groups’ tend to seek out media to trumpet paid plasma, what they fail to disclose is the millions of dollars they receive in donations (a vast number of them are non-receipted charitable donations) from big pharma. For example, in the last Ontario provincial election Canadian Plasma Resources / Exapharma created an astroturf group called ‘The Ontario Plasma Coalition’ and contributed $209,060 to them as they were registered as third party advertiser for the Ontario Election.

There are also groups who on first blush look to be in the interest of patient well-being and medicare in Canada. But, digging a little deeper it becomes apparent that these groups are not what they seem. The Canadian Association for Rare Disorders is one of these groups and with a quick glance at the CRA page it shows $516,595 (79%) non-receipted donations last year with 0% expenses for fundraising. At the same time their corporate leaders section is the who’s who of big pharma. Their ED, Derhane Wong Rieger, was appointed to the board of Canadian Blood Services but resigned in 1999 claiming CBS was being too cautious. She also supposedly supports the Ontario Plasma Coalition according to this article. In the past she was the president of the Canadian Hemophilia Society and is involved with many other projects (for a somewhat dated but still interesting expose from 2008 see here). The Canadian Hemophilia Society is also another group which may raise some eyebrows. In 2014, they received a total $1,850,991 corporate support (public donations were $306,152). Their national executive director David Page has also written in support of Canadian Plasma resources in the PTTA’s magazine. These two groups are charities, but they also belong to a not-for-profit umbrella organization called The Network of Rare Blood Disorder Organizations which is again sponsored pharmaceutical industry.
Interestingly though, not all of the provincial hemophilia societies seem to agree with the position taken by the national organization. Recently, the British Columbia Chapter of the Canadian Hemophilia Society (BCCHS), wants to (http://www.newswire.ca/news-releases/bc-chapter-of-the-canadian-hemophilia-society-calls-upon-the-bc-government-to-enact-legislation-to-prevent-private-companies-offering-payment-for-donations-of-blood-and-plasma-asks-the-federal-government-not-to-56970288),

“ensure that BC continues to enjoy a safe supply of quality blood products and therefore we are calling on Premier Clark and Health Minister Dr. Terry Lake to enact legislation to effectively ban private-for-profit clinics... We are a society of patients and families of those who need medications made by plasma to survive and to have a higher quality of life. We have listened to our membership, done extensive investigations into this matter and for three years our board has not wavered on our commitment to stop the commercialization of our voluntary donor system. We want to be clear and reassure the public that there are no shortages in medications. Allowing private-for-profit clinics in Canada will in no way add to any supply levels for Canadian patients.”
6.1 Paid plasma companies take advantage of low-income, racialized, and vulnerable communities:

In Canada's tainted blood scandal, for-profit blood brokers purchased blood from high risk population in places like Haiti, skid row in Los Angeles, Arkansas prisons and Russian funeral homes. Products made from Arkansas prisoners' were plasma based and were directly implicated in Hepatitis C outbreaks in Canada, France, Iran, Iraq, Ireland, Italy, Japan, Portugal, Spain, Scotland, Switzerland and the USA. The blood merchants knew that high risk populations offered the cheapest source of paid blood despite the innate danger. This is one of the main reasons the Krever Commission recommended an end to a private, for-profit blood donor system in Canada, citing these five basic principles regarding how the blood system should be governed: 1. Blood is a public resource; 2. Donors should not be paid; 3. Sufficient blood should be collected so that importation from other countries is unnecessary; 4. Access to blood and blood products should be free and universal; and 5. Safety of the blood supply system is paramount.

The business model for for-profit plasma companies follows the predatory and inexcusable model that lead to the tainted blood scandal; time after time, they are set up to take advantage of people's poverty (especially in regards to racialized communities). In the U.S. these clinics are most often found within close proximity to low income neighbourhoods (and in some cases close enough to the Mexican border for people to cross over and sell their plasma). In 1990’s, “China attempted to develop a plasma market to compete with Western companies by touting money for plasmapheresis in China's most impoverished province, Henan. Villagers that were too poor to afford condoms soon realized they could earn more money by selling plasma than by farming the land, but the facilities offered substandard sterilization techniques, needles, and blood bags. By 1995, Henan Province had become a blood farm built on a criminalized plasma economy. Thousands of Chinese donors became infected with AIDS and Hepatitis C.” In 2007, China had to recall IVIG that was tainted with Hep C. that wasn't supposed to be possible through the fractionation process.

While the above situations may seem exceeding egregious, what Canadian Plasma Resources has does is no different. When they attempted to set up in Ontario, Canadian Plasma Resources set up one clinic beside a methadone clinic and another by a homeless shelter. Their business model is the same as their international counterparts. In their newly opened clinic in Saskatoon they are located, “on Quebec Avenue, which is a few blocks away from the predatory loans and pawn shops that are along Idylwyld.” For their part, the Saskatchewan government doesn't seem to care that the company is targeting people (largely indigenous people) from disadvantaged areas. This is a recipe for disaster and should not be permitted on medical and ethical grounds. By licensing the clinic, Health Canada the Saskatchewan government is displaying the same arrogance and short sightedness that the Canadian Red Cross had when the tainted blood scandal occurred under their watch.
As Dr. Ryan Meili, a noted front line physician and health expert from Saskatoon, stated in regards to the issue, “I think it causes us to really reflect on what kind of a province we want to be... We have a poverty reduction strategy, and our work is towards getting people out of poverty. Or do we want to be the place where people are allowed to live in poverty as long as they can sell some of their blood or plasma, then that's how they can scrape by.” Further, we know repeated plasma donation poses health risks when the protein-rich plasma extracted from the blood of a donor. Regular donors in the U.S. (driven largely out of fiscal necessity) have reported weakness, black outs, chronic headaches, numbness, muscle contractions, seizures and a plethora of other problems. The anti-coagulant used during plasmapheresis is often the chemical sodium citrate, or other similar citic-acid derivatives, which bonds with the calcium in your blood and afterwards the calcium is not longer available in your body. For regular donors this calcium depletion can lead to serious long term health issues and in the worst case extreme hypocalcaemia which can be fatal (see this well researched article [http://www.theatlantic.com/health/archive/2014/05/blood-money-the-twisted-business-of-donating-plasma/362012/] for stories from regular plasma donors in the U.S.).

6.2 Who are the targets in Saskatoon:

As a result of the Harper government’s elimination of the long form census it is more difficult to find robust information on the area around the clinic. But, pulling together available data a picture can still be painted on the area in Saskatoon where Canadian Plasma Resources has their operation. Looking at the federal election data [http://www12.statcan.gc.ca/nhs-enm/2011/dp-pd/prof/details/page.cfm?Lang=E&Geo1=FED2013&Code1=47012&Data=Count&SearchText=Saskatoon%20West&SearchType=Begins&SearchPR=01&A1=A&II&B1=All&Custom=&TABID=1], the riding on the west side of Saskatoon is: 66.9% White, 18.1% Aboriginal, 5.5% Filipino, 2.0% South Asian, 1.8% Chinese, 1.5% Southeast Asian, 1.2% Black, and has a median income of just $29,326. Further, Saskatchewan has a higher rate of poverty than the national average and a child poverty average [http://www.cwp-csp.ca/wp-content/uploads/2012/05/Province-Poverty-Profiles_SK.pdf] of 25.5% (the national rate being an equally disturbing 19.1%). For First Nations children, studies show [http://cjme.com/article/186204/ckom.com/content/half-first-nations-kids-living-poverty] that nearly two out of three children live in poverty. At the same time, Saskatchewan has the second-lowest minimum wage in Canada. The picture should be pretty clear at this point that there are major poverty and health issues on the west side of Saskatoon. This is the area Canadian Plasma Resources is located in as its business model is to prey on and take advantage of the needy. A study by the department of justice stated [http://www.justice.gc.ca/eng/rp-pr/csj-sjc/crime/rr06_6/rr06_6.pdf], “For the objectives of this study, a ‘disadvantaged’ area is defined as any neighbourhood having more than 20% of its families living in low-income...a socio-economic divide does exist in Saskatoon with 13 of the 16 ‘disadvantaged’ neighbourhoods located in a relatively tight cluster in the west side of the city, particularly in and surrounding the core area.”
So what are Health Minister Dustin Duncan and the Brad Wall government doing about this? Well, the Saskatchewan Ministry of Social Services recently ordered cuts to one of Saskatoon’s major homeless shelters (the Lighthouse) located on the west side of the city; as a result, 50% of requests for shelter have been turned down. Stable housing is one of the key determinants for the health outcomes and well-being of vulnerable populations. Instead, the Saskatchewan government has brought in austerity to the health care system and decided to waste public money American austerity ‘LEAN consultations.’ The Sask Party government has spent, spent $40 million on John Black (one of these snake oil salesmen), $20 million per year on LEAN promotion, untold more on promotion staff and rental halls, $3,500 a day on “the senseis” costs and increased top health care executives salaries as much as 46% more. A new report published in a medical journal has shown that for every dollar saved by Lean, Saskatchewan spent $1,511. This is just a small sample of the ineptitude in health care being displayed in Saskatchewan (championing paid plasma donations is another disaster being spearheaded by the Brad Wall government). In regards to poverty reduction the government is now in full austerity mode blaming low resource prices, which as Dr. Ryan Meili points out, “ignores studies of governments around the world which show that social investment begets resilience...Your economy bounces back faster and you have fewer problems in that difficult period.”

People in poverty are at high risk of illness and research has shown that residents living in six low income neighbourhoods in Saskatoon (all located on the west side of the city where Canada Plasma Resources has their operation) are: a) 1458% more likely to attempt suicide, b) 1389% more likely to have Chlamydia, c) 3360% more likely to have hepatitis C, d) 676% more likely to have gonorrhoea, e) 154% more likely to have a teenager give birth to a child f) 448% more likely to have an infant die in the first year in comparison to higher income residents in Saskatoon. The Saskatoon Regional Intersectoral Committee (SRIC) which conducted the research stated that, “For example, the infant mortality rate in Saskatoon’s low income neighbourhoods was 448% higher than the rest of the city, which is worse than war torn nations like Bosnia.” As a result the least affluent residents in Saskatoon will die nine years earlier than the most affluent citizens in the city.
6.3 Saskatchewan has the highest rates of HIV and Hepatitis-C in Canada:

In [2015](http://thestarphoenix.com/news/local-news/two-hiv-positive-babies-born-in-sask-third-case-under-investigation), two HIV-positive babies were born in Saskatchewan with a third case under investigation. The high rates of poverty and blood borne illnesses in the inner-city of the west side of Saskatoon where the for-profit plasma clinic is operating is a major cause for concern (Saskatchewan has the highest rates of HIV and Hepatitis-C in Canada). While Minister Duncan took the time to attend the opening of this plasma clinic, the Saskatchewan government recently [cut](http://thestarphoenix.com/news/local-news/two-hiv-positive-babies-born-in-sask-third-case-under-investigation) the Saskatoon Health Region's $200,000 community grant program which helped AIDS Saskatoon, as well as mothers at risk and inner city nutrition programs. This program had a direct effect on improving the health conditions of the residents who Canadian Plasma Resources (and the government) are now targeting. By providing a financial incentive to donate plasma while placing the clinic in an area with high poverty rates and health issues, the clinic is attempting to incentivize high-risk donors from vulnerable populations.

![Figure 2. Number of new HIV cases by year, Saskatoon Health Region and Other Saskatchewan Regional Health Authorities (RHAs), 2001-2013.](image)

Not only are the Saskatchewan government and Canadian Plasma Resources joining together to exploit vulnerable populations on the west side of Saskatoon, these populations include large numbers of Indigenous people who face significant, and additional, barriers to health and wellbeing. Recognizing the inherent issues the constitutional term Aboriginal (which includes First Nations, Metis, and Inuit people) for the remainder of this article, this constitutional language will be used for uniformity as it is the common terminology used in health reporting and statistics. Saskatoon's medical officer of health, Cory Neudorf has [stated](http://www.cbc.ca/news/canada/saskatoon/effects-of-poverty-in-saskatoon-are-illness-and-death-1.2685727) that there is big challenging in trying to close the health gap between rich and poor in the city is finding culturally sensitive ways to reach out and meet the needs of the urban aboriginal population. Further, “There is institutionalized and systemic racism that's in place. That contributes to inequitable access and outcomes in services.”

That Saskatoon Health Region has acknowledged in reports ([https://www.saskatoonhealthregion.ca/locations_services/Services/Health-Observatory/Documents/Reports-Publications/2014_shr_series5_hsrfull.pdf#search=hiv](https://www.saskatoonhealthregion.ca/locations_services/Services/Health-Observatory/Documents/Reports-Publications/2014_shr_series5_hsrfull.pdf#search=hiv)) that, "Despite efforts to improve Aboriginal health, in general, there remain substantial inequties in the health of Aboriginal peoples in Canada compared to the rest of the population. Saskatoon has the second highest percentage of Aboriginal residents of all major cities in Canada at just over 9% of the population, and this population is expected to increase. Unfortunately, over 45% of the Aboriginal peoples living in Saskatoon are living in poverty (below the Low Income Cut-Off) and likely in areas of highest deprivation where health inequities are most persistent [The Deprivation Index]." A deprivation index is a material and social index used as a tool used to monitor socio-economic inequalities in health which [is used often](https://secure.chihi.ca/free_products/Reducing_Gaps_in_Health_Report_EN_081009.pdf) in health research to highlight socio-economic or geographical inequalities in health status or in access to health services. While Canada has no official figure to define poverty, Statistics Canada uses the concept of low income cut-off (LICO) to indicate an income threshold below which a family will likely devote a larger share of its income on the necessities of food, shelter and clothing than the average family. [In Saskatoon](http://www12.statcan.gc.ca/health-sante/82-228/details/page.cfm?Lang=E&Tab=1&Geo1=HR&Code1=4706&Geo2=PR&Code2=47&Data=Rate&SearchText=Saskatoon%20Regional%20Health%20Authority&SearchType=Contains&SearchPR=01&B1=All&Custom=&B2=All&B3=All), almost half of the Aboriginal peoples in Saskatoon are living in poverty below the LICO. Further, over 60% ([http://www.homelesshub.ca/sites/default/files/SOHC2014.pdf](http://www.homelesshub.ca/sites/default/files/SOHC2014.pdf)) of the homeless population in Saskatoon is Aboriginal.
At the same time, the Public Health Agency of Canada has recognized, "HIV risk among Aboriginal people is closely linked to a variety of determinants of health that influence vulnerability to infection, including poverty, unstable housing and homelessness, mental health and addictions, traumatic childhood experiences, racism and the multi-generational effects of colonialism and the residential school system." Outside of the list from the Public Health Agency, it is worth noting that Saskatchewan's prison system (colloquially called Alabama North) has been characterised as the 'new residential school system' (for a worthwhile read see this article [http://www.macleans.ca/news/canada/canadas-prisons-are-the-new-residential-schools/]). As a result of these many intertwined factors, Saskatchewan has nearly twice the HIV rates of Canada, and the highest in Canada (around 19 people per 100,000). Margaret Poitras, CEO of All Nations Hope AIDS Network, has highlighted that, "The way that HIV is being spread in this province is through injection drug use and I can say we're not doing a good job of reaching people that are most at need here... When we talk about indigenous people, we have an epidemic going on here with HIV that hasn't been addressed." We know at the same time that, paid plasma clinic don't turn away injection drug dealers; a 2009 study [http://www.ncbi.nlm.nih.gov/pubmed/19230645] has found that, "only one-third of injected drug users who reported selling their plasma in our study were potentially deferred as high risk donors the last time they sold their plasma."

Dr. Alex Wong (an infectious diseases physician, researcher and a clinical director of the HIV provincial leadership team) has found [http://www.macleans.ca/news/canada/saskatchewans-hiv-epidemic/] that the infection rate for Saskatchewan's non-Aboriginal population is below the national average. Yet, while First Nations and Metis account for about 16 per cent of Saskatchewan's population, they represented about 80 per cent of all new cases of HIV diagnosed in 2011, and that "The incidence rate in our Aboriginal population is about 88 per 100,000 [population], which is 14 times the national average, on par with various African countries." Worse yet, little testing has been done outside of the city on Saskatchewan's reserves where the federal government (Health Canada) is responsible for public health. A recent article [http://www.cbc.ca/news/canada/saskatchewan/hiv-rates-on-sask-reserves-higher-than-some-african-nations-1.3097231] pointed out that in Saskatchewan, "about 70 [reserves] don't know what their HIV rates are and don't have any care programs." In regards to Hepatitis-C, looking at data from a study Regina (which would likely correlate to Saskatoon), Wong stated [http://www.macleans.ca/news/canada/saskatchewans-hiv-epidemic/], "So, two in five individuals basically walking the streets of Regina, if you are Indigenous, you're hepatitis C-positive...Those numbers, to me, are absurd."

Unfortunately, Health Canada also does not consider the location of these plasma facilities, or many other important factors, when granting licenses. It is important to consider the sources of donation and the ethical concerns regarding targeting vulnerable populations who live in poverty. As recommendation 2b of the Krever report stated that, "Donors of blood and plasma should not be paid for their donations, except in rare circumstances," further noting that "blood and plasma from unpaid donors are safer than blood and plasma from paid donors."
This isn't to vilify the population who may be donating to these paid facilities for a variety of purposes but, rather, to have a realistic perspective on the possible issues that will likely arise. Further, if there is anyone who should be vilified as predacious company Canadian Plasma Resources and the government of Saskatchewan who actively choose to set up un-ethical facilities in the areas that are targeting people who live in poverty, and specifically who are Aboriginal. This is the underlying issues the media is not reporting but is at the heart of the issue.

7.1 Canadian Plasma Resources is planning to expand into other provinces:

Now that Canadian Plasma Resources has set up their beachhead in Saskatchewan, they are quickly trying to expand to the other provinces in Canada where they haven't been run out of. According to a recent article (http://thestarphoenix.com/opinion/letters/op-ed-plasma-donation-system-needs-vigorous-debate) the company has licensing pending in Alberta and British Columbia (and while the article also lists Manitoba sources say that while they have contacted the government there isn't a license pending [they are likely awaiting the results of the upcoming election]). Canadian Plasma Resources has been active lobbying Liberal governments in BC (http://www.lobbyistsregistrar.bc.ca/index.php/whos-lobbying-who-in-bc/2014-monthly-snapshots-1/265-who-s-lobbying-who-october-2014) and Nova Scotia (http://www.novascotia.ca/sns/lobbyist/consultant/confirmation.asp) according to the provincial registries.

In both cases they are using the same consultant lobbyist they hired in Ontario, Jim Pimblett who is a partner at the Toronto based Beaconsfield Group, to arrange lobby meetings (http://www.lobbyistsregistrar.bc.ca/index.php/whos-lobbying-who-in-bc/2014-monthly-snapshots-1/265-who-s-lobbying-who-october-2014) with the provincial, “Minister of Health and Premier's Office staff on behalf of Exapharma operating as Canadian Plasma Resources with respect to the establishment of a plasma-based pharmaceutical business.” They seem to be using Jim Pimblett to lobby Liberal governments due to his deep ties with the party. He was a former executive assistant to Prime Minister Martin, served as a senior advisor to former Premier Dalton McGuinty, executive assistant to former Liberal leader Michael Ignatieff. He is also a consultant for ATMA Capital Markets which along with advisory services claims to have a ‘global network of contacts’ to be able to source ‘investment capital, off-take, deal origination.’ As stated (http://www.atmacorp.com/) on this website, “Jim has served three leaders of progressive Canadian political parties in senior roles and has extensive knowledge of government, including many of its most senior officials across Canada.” While we can only speculate on the influence this high level Liberal insider is having with the Trudeau government, Health Minister Philpott and Health Canada, it is safe to say that he is being heard.

8.1 Has the federal Liberal government forgotten the tainted blood scandal:

The question you're likely asking at this point is where is the federal government on this issue and why are they not acting to stop the trade of body parts. Previously the Harper government, through their influence in Health Canada, (http://www.canadians.org/content/profit-blood-collection-have-your-say) passed the regulations and responsibilities (http://www.hc-sc.gc.ca/dhp-mps/consultation/biolog/plasma-consult-disc-eng.php) onto the provinces to allow or disallow payment for plasma. In a textbook example (https://impactethics.ca/2013/08/06/policy-laundering-and-payment-for-plasma/) of policy laundering, they went so far as to claim in a Machiavellian policy that compensation to donors of plasma is a non-safety “corporate decision” outside of Health Canada's authority. So far the new Trudeau government seem to be playing the same tune and are showing no leadership on this major health issue. Despite calls by myriad of groups to close the plasma operation, Health Minister Philpott has (http://www.ctvnews.ca/health/saskatchewan-nurses-latest-to-oppose-
Blood money: why are the federal Liberals ignoring the findings of the tainted blood scandal? | The Council of Canadians

8.2 Looking for real change and leadership:

The safety and viability of Canada's blood and blood products supply is ultimately a federal responsibility. The federal government, through Health Canada, has the authority (and obligation) to ban the practice of private blood product collection across the country and stop private plasma/blood brokers. The decision to allow or disallow compensation clearly falls within Health Canada's mandate to regulate the safety and quality of plasma products as drugs under the Food and Drugs Act. Further, instead of abdicating its duties to the health of Canadians like we saw under the Harper government, our new government and Health Minister Philpott must take responsibility for their statutory duties to enforce the Food and Drug Act. There is no justification for the government's inaction which is resulting in a fundamental shift in policy that benefits the interests of plasma businesses at the public's expense.

The government must deny the license to Canadian Plasma Resources, and any other companies that propose to pay donors for blood, plasma or other blood products. They must also immediately instruct Canadian Blood Services to develop a real strategy to increase unpaid plasma clinics in Canada and move toward self-sufficiency in plasma supply. We must ensure that the blood system moves towards more voluntary plasma collection which is in the public interest.

Michael McCarthy, tainted blood survivor an infected hemophiliac, has explained that, “This company is here to exploit our most vulnerable population and export blood out of the country, this is not what people died for. We have no business introducing a competitor into blood collection, it does not work in Canada and I am proof of how this has gravely failed before.” Allowing licenses to Canadian Plasma Resources has no benefit to Canadians and is all risk and no reward. Plasma must be treated as a public resource and health issue; trading body parts as a commodity to profit off of is morally corrupt. Too many people have fought too hard and too long to have the truth be ignored again just so the pharmaceutical industry can make a big profit by controlling this public resource. There is no reason jeopardize the safety our voluntary blood system. We've been here before and know the outcome, so why is the Liberal government making the deadly mistakes of the past again?