Culture, Commerce, and Control: The Ethics and Regulation of Plasma and Plasma Donation in the Life Science Industry

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Abstract

The global plasma industry sits at the intersection of commerce, healthcare, and ethics, raising enduring questions about how human biological materials are valued, exchanged, and regulated. This paper critically examines the ethical and policy dimensions of the plasma market, focusing on the U.S. model of paid plasma donation and its implications for international health equity. While the commercialization of plasma has expanded access to life-saving therapies, it has also presented structural inequalities: wealthier nations rely heavily on plasma sourced from economically vulnerable donors, primarily in the United States. Through analysis of current regulatory frameworks, donor compensation practices, and cross-border plasma trade, the paper explores how financial incentives blur the boundary between altruism and exploitation, and evaluates strategies for achieving more equitable and sustainable practices. It argues that the global dependence on commodified plasma undermines the ideal of voluntary donation and places disproportionate burdens on low-income populations. The final sections evaluate policy responses aimed at achieving a more ethical balance, emphasizing the need for stronger oversight, transparency in supply chains, and equitable participation in plasma production worldwide. Ultimately, the paper suggests that maintaining both the supply of plasma and the dignity of donors requires treating plasma not as a commodity to be extracted, but as a contribution that binds global health communities together.

Introduction

Most people are familiar with the whole blood donation market. Think about the American Red Cross, Blood Connection, or Vitalant, all of which are companies that use whole blood donations from the civilian population for transfusions or other medicinal purposes. Yet, few people realize that whole blood is only made up of about 45% red blood cells, and the other 55% is made up of plasma. Plasma is the liquid base of whole blood, and contains 8-9% solids, including medicinally valuable proteins such as albumin and globulin, coagulants such as fibrinogen, electrolytes, and immunoglobulins such as IgG and IgM. (Mathew et al., 2025)

These plasma-derived proteins, unfortunately, cannot be synthetically manufactured by life science companies. Thus, for patients who lack these proteins and are afflicted with blood-clotting disorders, immune deficiencies, or burn wounds, plasma donation is not just for the public good. Instead, it is key for survival and a high quality of life.

The issue explored in this paper lies behind the ethical dilemma of where this life-saving plasma comes from, as well as what conditions it was given under. In some countries, plasma donation is a paid transaction, while in others, it is an altruistic act. The tension between market forces, cultural values, and public health needs lies at the center of global plasma therapeutics. Understanding the regulatory systems and business models that govern these ethical boundaries will reveal whether this mix of culture, commerce, and law is sustainable or a recipe for donor exploitation. This literature review will explore articles and publications from approximately the past 10 years with information regarding plasma donation, incentives for donation, government regulations on plasma donation, and the use of donated plasma in both public and private sectors.

In order to fully understand the issue at hand, one must be familiar with the need for plasma in the biotechnology industry, as well as the demand and current state of the market.

According to a 2018 paper by Burnouf, the fractionation of human plasma is still the only biotechnological approach to make essential medications to treat several human diseases. Some examples of valuable plasma products are Fibrinogen, Factor VIII, Factor IX, and Polyvalent IgG, used to treat congenital deficiency, Hemophilia A, Hemophilia B, and infections in immunodeficient patients, respectively. (Burnouf, 2018) All of these products are considered plasma-derived medicinal products (PDMPs), and they play a critical role in treating rare and often genetically inherited conditions. In recent years, the use of these products has greatly increased due to the more rapid approval of them through regulatory agencies, gaining approval for additional use cases, and some increased off-label use. Many of these products (PDMPs) have been labeled by the World Health Organization (WHO) as essential medicines. This leads to increasing demand, constrained by the availability of donated human plasma. (Belmonte et al., 2025)

Plasma can be obtained in one of two ways. The first is through what is known as recovered plasma, where plasma is extracted from whole blood donations, and the second is source plasma, which uses a process known as apheresis to extract only plasma while the other cellular components are returned to the donor at the time of donation. The company Grifols also uses a technique called plasmapheresis to pull only plasma from its donors. (Belmonte et al., 2025) The United States is currently the major global supplier of plasma, as it holds 80% of the world's plasma donation sites, and supplies almost 70% of the plasma used worldwide. (Belmonte et al., 2025; Burnouf, 2018) Beyond the biological and clinical aspects, plasma donation is deeply shaped by cultural values and societal norms, which in turn influence who donates and why.

Cultural Foundations of Plasma Donations

The cultural frameworks that govern how societies view plasma donation differ significantly between the U.S., the European Union, and other parts of the world. In the US, plasma donation is often framed as a hybrid of altruism and compensation. This means that people donate plasma and are paid for it, but the narrative surrounding donation invokes feelings of helping others and personal autonomy, and motivation. This model aligns with cultural values emphasizing individual choice, free markets, and rewarding labor. The US is one of the few countries that has private plasma collection, meaning that financial compensation and other incentives are provided to donors. Out of the countries explored, which included Australia, Austria, the Czech Republic, France, Germany, Italy, the Netherlands, New Zealand, Spain, the UK, and the US, only the US and 3 others (Austria, the Czech Republic, and Germany) offer private, compensated collection methods for plasma in addition to the public and not-for-profit donation centers. (Belmonte et al., 2025)

In studies exploring the motivations of paid plasma donors in the US and Hungary, it was found that university students donating plasma were significantly motivated by the monetary incentives, often using the money for activities previously outside of their budgets. Paid plasma donors in Hungary stated that they would not continue to donate if the payment ceased. Overall, these donors had less altruistic motives than voluntary whole blood donors. (Berger et al., 2023) Another study performed in the US found that university students' willingness to donate plasma rose over 40% when informed that they would be compensated. (Berger et al., 2023)

In many European countries, donors are not monetarily compensated for plasma donation, but may receive other incentives. Take Italy, for example: Donors here are not compensated with cash, but instead are rewarded with a day off from employment. Donors still

receive full pay for work that day, adding a burden of unpaid labor to employers. For this reason, the Italian government sets aside a fund to help offset the cost of these donations for employers, making them indirectly the group that compensates the donors. (Penrod & Farrugia, 2015) European countries adhere to the ethos of "solidarity-based altruism." Under this model, donating plasma is viewed primarily as a civic responsibility and moral duty rather than a financial transaction. Due to the lack of compensated donations, many countries outside of the US are not able to be "self-sufficient" in plasma collection. These countries require imported plasma in addition to domestic plasma in order to meet their demand for PDMPs. According to a 2025 paper, European "domestically collected plasma meets only about 63% of the demand for PDMPs, with the remainder predominantly imported from the United States." (Belmonte et al., 2025)

These divergent logic systems set up different expectations for what a plasma donation means. The question remains of whether plasma is a gift or a good, whether the donor is a co-producer of therapy or a supplier, and how the public and regulatory authorities understand donor motivations.

Cultural norms heavily influence perceptions of safety, fairness, and legitimacy in plasma donation. In regions with voluntary donation systems, public trust might often be rooted in transparent oversight and the appearance of altruism. European countries that do not offer financial incentives tend to emphasize public sector oversight of collection, rigorous regulations, and donor protections. All of these contribute to public confidence in the plasma collection system. (Belmonte et al., 2025)

Conversely, in areas where plasma donation is compensated, sometimes concerns may be brought up regarding whether financial incentives may coerce donors, especially where

vulnerable or low-income populations may be encouraged to donate for a bit of extra cash. There is also sometimes a question posed of whether donor and patient safety is compromised under the pressure to collect more plasma, or whether the altruistic motivation of donation is actually overshadowed by the profit motives of large companies such as CSL. One interesting finding from the studied literature was that donors given the opportunity to pay their monetary reward for donating plasma forward to a non-governmental organization were more willing to donate. (Berger et al., 2023)

The perception of legitimacy also shifts with how plasma donation is framed. When an unpaid donation is the norm, paying donors may be seen as morally inferior or even exploitative. In markets like the U.S., private sector donation centers often attempt to evoke altruistic narratives even as they pay donors, presenting a dual message that can sometimes lead to confusion or mistrust among the public and among donors themselves. However, these motivations intersect unequally across socioeconomic groups.

Understanding the connections between donor demographics and economic motivations is essential to understanding the ethics behind compensated plasma donation. In many cases, donors who receive compensation for plasma donation are disproportionately from lower socio-economic backgrounds. For these individuals, compensation for plasma donation may represent a necessary source of income, not just an extra influx of cash. (Ochoa et al., 2021) Based on a review from 2021, “The rate of residents [around plasma donation centers] between 50 and 100% of poverty was 51 percent higher in tracts with a plasma center than in tracts without plasma centers.” (Ochoa et al., 2021) In these areas, donors may get used to having additional income if they begin donating plasma and using the compensation money for essential items. Because of this, what begins as a voluntary act may become a financial necessity, raising

concerns about economic pressure or exploitation. These disparities extend beyond income, potentially influencing donor health and even product quality.

Furthermore, socioeconomic inequities may intersect with health disparities. Under-resourced communities, if participating in donations more frequently, may have less access to healthcare, nutritional support, or rest. This could exacerbate potential health risks. A 2010 study discussed in a 2021 paper revealed that plasma collected from more frequent donors yielded lower quality proteins and less abundance of medically valuable components. (Ochoa et al., 2021) One 2024 study found that very high frequency plasma donation led to clinically significant decreases in IgG levels, as well as a decrease in ferritin. They did not observe any decreases in exercise-related parameters. (Mortier et al., 2024)

While many donation centers enforce screening and donor safety protocols, some reports suggest that frequency and compensation structures in some jurisdictions may push donors toward donation schedules that are not always optimal for long-term health. In some areas, donors can give plasma up to 2 times a week, leading to approximately 100 donations a year. (D'aes et al., 2024) This leads to questions of decreased donor health as well as the quality of proteins harvested from this donated plasma. Would there be enough of a singular donor's plasma to lessen the effectiveness of a drug when the plasma is pooled? Some of these implications will be explored in more depth later.

One of the more striking paradoxes in plasma donation is the way many European nations, and others with voluntary/unpaid models, simultaneously have to depend on plasma that originates from compensated donors abroad. Much of this plasma originates from the US, with about 37% of plasma used in Europe being imported. (Belmonte et al., 2025) Due to bovine spongiform encephalopathy (BSE), the UK has had to outsource all of its plasma until 2021.

They hope to be 30% self-sufficient with their plasma supply by the end of 2025. In another example, Canada is the second-highest consumer per capita of traditional PMDPs, specifically IVIg products, and yet they are only able to cover approximately 20% of their plasma needs with their own donations. They end up spending approximately 66% of their funding for blood-based therapies on outsourcing plasma from other countries. (Belmonte et al., 2025)

This dependency creates what could be coined as ethical outsourcing. On the one hand, European policy regularly affirms the virtue of unpaid donation and civic altruism. On the other hand, their health systems rely, at least in part, on the commercial systems of other countries, where compensation is standard. This dynamic raises questions about consistency in moral policy, trust, and equitable global access. It also introduces potential vulnerabilities: if exporting countries change compensation practices, restrict exports, or face supply disruptions, there is a risk to importing nations. One critique that can be presented on this issue is that high-income European nations outsourcing plasma are benefiting from biological material sourced from low-income Americans.

These cultural and ethical divides shape not only how plasma is collected but also how it circulates as a global commodity. This dynamic becomes especially visible in the business models and regulatory frameworks that sustain the industry.

Business Dynamics of the Plasma Industry

Having explored the cultural foundations of plasma donation, we can now turn to the business dynamics that shape the global plasma economy. The global plasma-derived therapeutics market can be considered one of the fastest-growing segments of the biopharmaceutical sector. The PMDP market has grown at a rate of 7.6% annually since 1996, leading to a value of approximately $26.6 billion USD in 2020. (Belmonte et al., 2025) This

value is expected to continue to grow steadily, due to rising demand for immunoglobulins, albumin, and clotting factors such as Factor XIII and Factor IV. The IVIg products alone represent approximately 47% of the PMDP market, with an expected growth to a value of $24.98 billion USD by 2032. (Belmonte et al., 2025) In 2014, the IVIg market alone required almost 40 million liters of plasma donations to supply these products, which is the equivalent of as many, if not more, donations. Each donation equates to a bit less than a liter of plasma, so as the demand for IVIg products continues to rise, so does the need for more donations. (Grabowski & Manning, 2016; von Bonsdorff et al., 2025) Additionally, the global supply of plasma for fractionation was estimated at 51.2 liters in 2016. (Hotchko & Robert, 2018) Four multinational corporations dominate the market, collectively controlling a large fraction of global plasma fractionation capacity. These companies are CSL Behring, Grifols, Takeda, and Octapharma. Their vertically integrated structures allow them to manage the full value chain, from donor recruitment to final therapeutic production, giving them substantial market leverage and control over global supply.

As described by a 2025 paper, it has been recognized that changes in regulation are needed to prevent and manage IVIg shortages. In response to this, the European Commission approved a new regulation in April 2024 to enhance the quality and safety standards of human-origin medical substances. This new regulation “aims to ensure a more reliable and sustainable plasma supply across Europe by encouraging member states to develop effective plasmaphaeresis programmes and expand plasma collection and fractionation capabilities. It also seeks to foster collaboration among public, private, and non-profit sectors to boost plasma collection efforts.” (Belmonte et al., 2025)

The majority of plasma used in fractionation is collected in the United States, where compensated plasma donation is legal and widespread. About two-thirds of the total source plasma used for PMDPs worldwide comes from the United States. (Hotchko & Robert, 2018) The donation centers in the US are particularly concentrated in the south, in states such as Texas, Florida, and Alabama, where regulatory conditions and cost structures are a bit more favorable. (Ochoa et al., 2021) This expansion of plasma centers has been driven by growing global demand for plasma for fractionation, as well as a consistent domestic donor pool motivated by financial compensation. (Hotchko & Robert, 2018) While these trends support the industry's economic strength, they also expose its dependence on the socioeconomic conditions of US donors and the ethical tensions that come with such reliance. Increasing worldwide demand for plasma will require incentives for donors to become motivated to supply more donations. (Belmonte et al., 2025)

The commercial plasma economy operates while balancing the dichotomy between extraction and efficiency, where biological material from donors is converted into high-value therapeutics sold at premium prices worldwide. This is a market where value is created through the commodification of biological substances. Plasma is a particularly lucrative material because it can be donated much more frequently than whole blood, with some donation centers allowing up to 2 donations per week without significant medical risk, according to recent studies. (Mortier et al., 2024) This donation frequency, coupled with financial incentives typically ranging from $30 - $50 per session, enables companies to maintain a steady supply of plasma material. Countries where more than one organization collects plasma present more diversified incentives for donors to participate in plasma donation, whether that be monetary incentives or non-monetary incentives. (Koch et al., 2024)

However, this incentive structure introduces more ethical complexities. Companies are financially motivated to maximize donation frequency and retention, which raises questions about donor autonomy and health protection. While corporate safety standards and FDA regulations set limits on donation volumes and intervals, the economic incentives can indirectly pressure donors to push those limits. This is particularly true for those from lower-income backgrounds for whom plasma income may be essential (Ochoa et al., 2021). The industry thus embodies a paradox: while it depends on altruistic narratives and claims of saving lives, it is sustained by profit-driven strategies that often rely on the economic vulnerability of its donor base.

The core tension that the plasma industry presents is between profit and ethics. The business model's dependence on frequent, repeat donors creates a system where financial need becomes the primary recruitment tool. Many donor centers offer even higher compensation for the second plasma donation, as a singular donation produces what is known as an "orphan batch" and cannot be used to produce any therapeutics. Testing must be done on repeat donors to ensure that the plasma is safe for use in manufacturing. (Ochoa et al., 2021) The reality that donors cite financial necessity as a main motivation leads critics to question whether donor consent is fully voluntary, or whether participation is driven more by economic precarity than choice.

Even further, market concentration exacerbates these ethical concerns. The plasma industry's concentration under a few multinational corporations leads to monopolistic tendencies. This allows these companies to influence pricing, regulatory lobbying, and global trade flows. (Belmonte et al., 2025) Concentration of the market leads to unequal access to PMDPs, particularly in low and middle-income countries, where treatment costs remain relatively high. Some industry leaders justify the high costs as necessary for innovation and safety, but the issue

remains that the source of value in plasma donation is not a patented molecule or an industrial process, but instead the bodily labor of typically economically disadvantaged donors. (Burnouf, 2018; Farrugia et al., 2015; Ochoa et al., 2021) In addition, the repetitive nature of plasma donation raises health concerns that are still significantly under-researched. While most clinical research suggests that plasma donation is safe when monitored appropriately, the long-term physiological effects of donating plasma twice weekly for years remain insufficiently documented, as well as the potential effects on the quality of the plasma itself. (D'aes et al., 2024; Fransen et al., 2023; Mortier et al., 2024) Ethical debates arise around the adequacy of informed consent in plasma donation, and whether donors truly understand the cumulative effects of frequent donation, and even whether the data is substantial enough for doctors to understand the effects.

Even as the plasma industry is inherently globalized, it is also deeply imbalanced. As mentioned previously, the US supplies almost two-thirds of the world's plasma used for fractionation. (Hotchko & Robert, 2018) The US market depends heavily on compensated donors to continue to show up and provide their time and bodily resources to allow this industry to continue functioning. Even as much of Europe and parts of Asia rely heavily on imported US plasma to sustain their domestic production of PMDPs, they continue to prohibit paid donation in their own countries. (Farrugia et al., 2015) Despite this prohibition of paid donation for altruistic and ethical reasons in their own countries, they continue to benefit from the compensated donations from places such as the US. While obviously raising ethical concerns, this dependency also raises supply chain risks. If policy changed in the US and donors were to decline giving due to the lack of financial incentives, the global plasma supply could contract, thus disrupting the availability of essential medicines such as immunoglobulins and clotting factors. Therefore,

while the current system sustains global health needs for now, it does so on a precarious foundation, one that monetizes vulnerability under the guise of medical progress.

Legal and Regulatory Frameworks

In the United States, the regulation of plasma donation and PDMPs is primarily under the authority of the Food and Drug Administration (FDA) through the Center for Biologics Evaluation and Research (CBER). Source plasma collected for fractionation is regulated as a biologic under the Public Health Service Act, and must comply with current Good Manufacturing Practices (cGMP) and donor requirements outlined by the FDA in 21 CFR Part 630. (Weinstein, 2018) The FDA requires testing for transmissible infections, labeling that ensures traceability of plasma pools, and recordkeeping to guarantee donor and product safety. The FDA classified plasma as a manufacturing input rather than a direct transfusion product, allowing source plasma donations to be compensated monetarily. (Weinstein, 2018) This legal distinction allows commercial operators to offer financial incentives to donors, enhancing the supply chain for fractionation of plasma into immunoglobulins, albumin, and clotting factors. Having fewer legal hurdles to jump over allows the US to account for about two-thirds of the world's plasma supply, making its regulatory framework central to the global plasma economy. (Hotchko & Robert, 2018)

Despite its regulatory structure, the US system reveals several ethical and procedural gray areas. First, the FDA establishes minimum intervals between plasma donations, typically twice within seven days, but there is no federally mandated cap on annual donations. This loophole in regulatory oversight leads to frequent plasma extraction from economically vulnerable or disadvantaged populations, raising health and equity concerns. (Fransen et al., 2023; Weinstein, 2018) In some areas, donors can give upwards of 100 times a year, leading to bodily effects that

are not well understood. Some studies report minimal implications for donors, while others show reports of fatigue, depleted protein in the plasma, and potential long-term effects on the immune system. (Fransen et al., 2023; Mortier et al., 2024) While the FDA oversees product safety, donor health monitoring largely falls outside federal purview and is inconsistently handled by private plasma collection centers or state agencies. (Weinstein, 2018) The Centers for Disease Control and Prevention (CDC) plays a limited role, focusing mostly on infectious disease surveillance rather than donor well-being. Consequently, a gap persists between product-centric regulation and human-centered ethics, reflecting broader tensions between commerce and public health.

Regulatory philosophies differ sharply between the US and other countries. Within the EU, voluntary and unpaid donation is the ethical standard, with the assumption that paid donation risks compromising donor safety, leading to exploitation or reduced quality of plasma. (Weinstein, 2018) In contrast to the United States, most EU countries prohibit compensation for plasma donation beyond minimal expense reimbursement. This commitment to non-commercial ethics creates tensions mentioned previously throughout this paper, as many European nations depend heavily on US plasma to meet domestic demands, effectively outsourcing the ethical risks of paid donation. This dependency demonstrates the interlinked nature of regulatory regimes in the plasma landscape, where national ethical choices can have global consequences.

The differences between US and EU plasma regulation should prompt increasing calls for regulatory harmonization. Without some level of international coordination in donor protections, plasma testing standards, and donor compensation limits, the plasma market will continue to rely on ethically inconsistent practices. A hybrid regulatory model that combines the US commercial-driven framework with the EU's concern for ethical solidarity could show promise. The issue remains that achieving harmonization in regulation could lead to other complex

questions. Stricter regulation could decrease the potential for donor exploitation, but could also disrupt fragile plasma global supply chains. This could lead to lost access to PDMPs for vulnerable populations worldwide. But, maintaining the current framework perpetuates inequities between donor and recipient populations, as wealthier nations importing plasma from the US benefit from biological material sourced from lower-income donors, who, in some cases, may not be able to afford the exact medications they are helping manufacture.

Together, these frameworks reveal a fragmented regulatory landscape. The US prioritizes supply stability through commodification, while the EU prioritizes ethical purity and public trust. Neither system alone ensures long-term sustainability: the U.S. model risks exploitation, while the EU model risks chronic shortage. The global plasma industry thus operates in a liminal space, which is governed by law but shaped by economic necessity. These contrasting regulatory philosophies reveal the broader challenge, which is maintaining a stable plasma supply while respecting ethical boundaries. How culture, commerce, and law interact in practice will determine whether the system operates as a sustainable model or a precarious arrangement.

A Useful Mix or a Recipe for Disaster?

The global plasma system operates as a complex balance between cultural values, economic imperatives, and regulatory philosophies. This balance has proven remarkably effective, as it provides life-saving therapies to patients worldwide while sustaining a multi-billion dollar sector of the biopharma market. Yet, as discussed throughout this review, the same forces that keep this system functioning expose deep ethical and structural vulnerabilities.

The US plasma landscape is a good representation of how economic and cultural norms can reinforce each other, as the belief that bodily materials can be exchanged for payment normalizes the commercial nature of the industry. This belief creates a permissive legal

environment, where, as long as safety and labeling standards are met, compensation is seen as an exchange between consenting adults rather than coercion. The legal minimalism of this approach, sustained by the FDA's limited jurisdiction over donor compensation, enables the expansion of private plasma collection networks but has left little room for public debate about fairness, health equity, or moral limits. (Belmonte et al., 2025; Weinstein, 2018)

The pragmatic benefits of this hybrid model are undeniable. Paid plasma donation centers in the United States, and limited compensation in countries such as Germany and Austria, have ensured a steady global supply of source plasma. This stability has enabled the rapid growth of the plasma-derived therapeutics industry, valued at $26.6 billion globally in 2020. (Belmonte et al., 2025) Commercial incentives for companies have also driven technological innovation in fractionation efficiency, pathogen screening, and product diversification, indirectly improving patient outcomes. Moreover, the globalized plasma market allows nations that cannot achieve self-sufficiency in source plasma supply to meet clinical needs without diverting public health budgets toward donor recruitment. In this sense, the system demonstrates something of a moral efficiency, where the willingness of some societies to monetize plasma supports the altruistic ideals of others. The arrangement is functional, even if ethically asymmetrical.

The same forces that make the system efficient also make it precarious. Overreliance on compensated plasma donation risks establishing socioeconomic inequalities, as financial vulnerability becomes a prerequisite for participation in the donation process. When the market value of bodily materials becomes normalized, the line between autonomy and exploitation blurs, especially when repeat donors may face health risks from frequent donation. (Fransen et al., 2023) Ethical dangers also extend to the international scale. Countries that do not offer paid plasma donation import plasma for PDMPs from systems where donors are compensated,

transferring the moral burden of commodification abroad while retaining the medicinal benefits. This dependence reinforces global inequality, as wealthier importing nations rely on poorer donors elsewhere to sustain their healthcare systems.

If public awareness of these contradictions grows, the industry could face reputational backlash. The trust that sustains both donors and patients depends on the perception that plasma donation serves a collective good, not commercial exploitation. Should that perception erode, political pressure for restriction could destabilize the global plasma supply chain. Addressing these vulnerabilities requires policy interventions that reconcile economic incentives with ethical safeguards. The following recommendations explore how national and international frameworks might stabilize the plasma system while protecting donor welfare.

Policy Implications and Recommendations

The sustainability of the plasma and PDMP supply chain depends on regulatory evolution that preserves supply without sacrificing ethics. National and international reforms must therefore pursue ethical harmonization with a balanced framework that allows limited compensation while ensuring donor welfare, transparency, and public trust.

In the US, regulatory agencies should strengthen the oversight of donor health and donation center operations. Current FDA guidelines permit donations up to twice weekly, yet some studies suggest that frequent donors experience higher rates of fatigue and lower levels of medicinally valuable proteins in the plasma. (Mortier et al., 2024) Implementing stricter frequency caps and mandatory medical follow-ups for repeat donors could mitigate these risks. Additionally, governments should require plasma centers to provide full disclosure of compensation practices, recruitment methods, and donor retention data to prevent predatory targeting of low-income populations. Transparency should also extend to the product labeling.

Clearly identifying whether plasma-derived products originate from compensated or voluntary donors would allow patients to make informed ethical choices if they had a preference.

At the global level, harmonization remains the central challenge. The World Health Organization and the European Medicines Agency could collaborate to establish an international code of practice for plasma collection, integrating donor safety, compensation limits, and traceability standards. This framework should not aim to impose uniform altruism, but to ensure that compensation does not become coercive.

The future of plasma collection lies in reframing it as a public–private partnership, one that recognizes the shared responsibilities of the state, the corporation, and the donor. Ultimately, plasma donation should be governed by a principle of mutual accountability, where donors provide a vital biological resource, corporations profit from its processing, and governments hold both parties accountable for maintaining safety. This allows for biological materials to be treated as shared assets of both economic and moral significance. Taken together, these suggested reforms outline a vision for a plasma industry that is both efficient and ethically grounded, but their success will depend on sustained commitment across governments, corporations, and donor communities.

Conclusion

The plasma industry sits at the intersection of culture, commerce, and control. Each element sustains the others, but without stronger ethical and regulatory alignment, the balance risks tipping toward exploitation rather than global health equity.

The core insight emerging from this review is that sustainability cannot be measured solely in liters of plasma collected or profits earned, but in the ethical stability of the system that

produces them. Global health equity depends on maintaining this balance and ensuring that donors are protected, patients are served, and profit never outweighs principle.

Looking forward, the challenge for policymakers and industry leaders will be to institutionalize transparency, strengthen ethical harmonization, and foster cultural understanding across national boundaries. Only by aligning economic necessity with human dignity can the plasma industry fulfill its promise as both a profitable enterprise and a genuinely humane one.

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