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The Impact of International Pricing Index / Negotiated Pricing on the Plasma Sector

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Why is the Plasma Industry Different than Biopharma?

The plasma sector is very different than Biopharma:

- According to our recent [H.R.3. research](#), in 2020, biotech now requires \$5 bil. of investment to have a 50/50 probability of market entry.
- Biopharma's level of risk requires enormous upfront investments before market entry with a failure rate in excess of 90%; once a product is approved, the raw material costs are only a small fraction of the total revenue of the new therapy.

In contrast, the plasma sector has very high costs per liter of plasma collected to produce every gram of final product:

- Roughly 1/3rd of all costs are compensation payments to donors
- Production costs are traditionally more than half of all revenue
- The sector relies on its ability to collect plasma in the USA, which accounts for 60-80% (depending on the company) of all plasma collected globally.

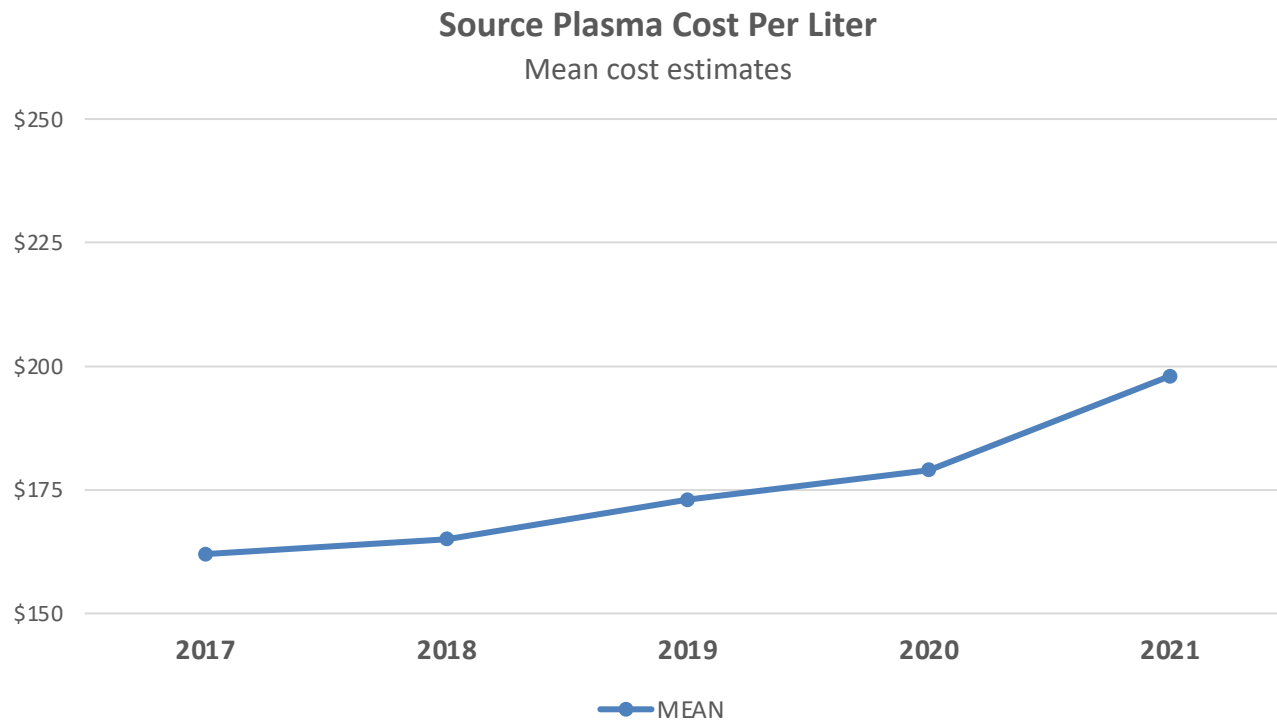
The entire production process, due to the high cost of raw materials relative to revenues, is dictated by the clinical need for IVIG:

- The economics and nature of the manufacturing process means the industry cannot produce other plasma protein therapies (PPTs) such as Fibrinogen and Albumin unless it can produce and sell IVIG; IVIG is the base for the entire value chain for all PPTs. Impacting the production of IVIG will negatively impact all PPT products in the portfolio.

The current economic climate for plasma manufacturers

- 1) The plasma sector's costs have risen by 35% - 50% since 2019, depending on the company, due to several key factors:
 - COVID-19 has caused people to avoid making donations, this has caused an historic, unprecedented increase in costs associated with donor compensation.
 - The Biden Administration's Customs and Border Protection agency has restricted the ability for cross-border donations from Mexico. This change has radically cut donations and caused companies to both divest existing facilities and invest in new facilities away from the US/Mexico border, further increasing costs of production.
- 2) Because of the unprecedented increase in the cost of plasma acquisition, the percentage of total revenue it represents – already almost 49% pre-covid – is now substantially higher.
- 3) In an historically low margin industry, these higher costs have already raised serious patient access concerns, even BEFORE any implementation of the negotiated cost controls now being proposed.

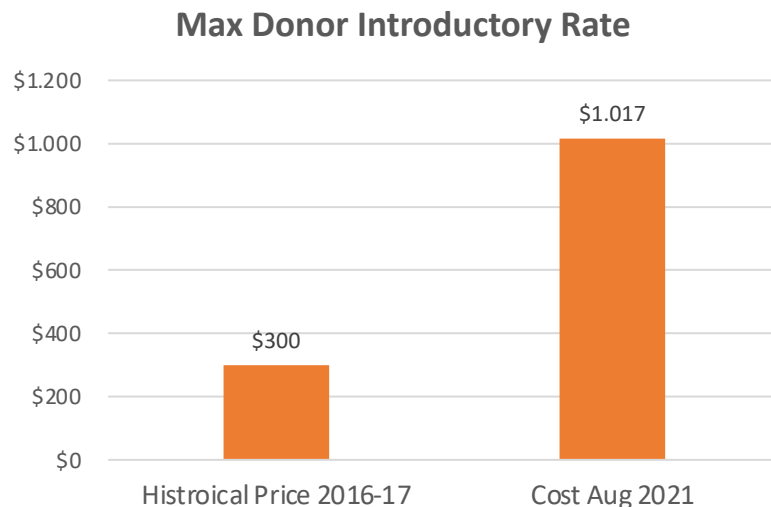
Rising Source Plasma Acquisition Cost per Liter



Recent Jump in Plasma Collection Costs 339%

Sample - August 2021 vs Historical Price – Advertised Max Monthly Plasma Donor Compensation

Website Archive	Date of Capture	Introductory Compensation
Link	7-May-21	\$1,000
Link	14-Apr-21	\$1,100
Link	9-Aug-21	\$1,000
Link	26-Aug-21	\$1,000
Link	18-Aug-21	\$1,000
Link	10-Aug-21	\$1,000
Link	8-Apr-16	\$200
Link	25-Oct-16	\$400
Link	13-May-16	\$400
Link	18-Sep-17	\$300
Link	29-Mar-16	\$200



Conclusions

- As the cost of raw materials in the plasma sector are a high percentage of the total operational costs, it is very different than the biopharma sector and operates more like traditional manufacturing, even though its 'final products' are for regulated therapeutic use.
- Unprecedented cost increases – in an industry that already experienced serious patient access challenges in 2019, pre-US border policy and pre-COVID-19 – have put manufacturers under considerable strain worldwide.
- As a majority global plasma donations come from the United States, poorly considered, on-size-fits-all reimbursement decisions will substantially increase the risk of patient access concerns and negatively impact the sector globally.
- As IVIG is the volume leader for ALL of the sector's plasma derived products, reimbursement framework changes that do not differentiate IVIG, or account for its uniqueness, threaten the sector's ability to supply ANY and ALL plasma derived products, with dramatic impacts on all patients. A cursory glance at many [drug supply websites](#) already indicates shortages of IVIG.
- The plasma industry is subject to many of the same pressures of other industries. As ingredient costs rise and reimbursement falls there must be a point where the viability of that industry is in jeopardy.

Data Appendix

Estimating the share of plasma collection costs in COGS (2017 data)

- 1) Liters of IVIG sold = kilograms of IVIG sold x 1.024 liters per kg
- 2) Plasma collected (liters) = liters of IVIG sold/0.004 (0.004 = IVIG yield per liter of plasma)
- 3) Donations needed = Plasma collected/0.7725 (0.7725 = plasma yield per average donor)*
- 4) Total collection cost = Plasma acquisition cost x Donations needed
- 5) Estimated share in COGS = Total collection cost/COGS \approx 48.73%

*Based upon plasma yield by individual donor weight & size.

Disclosure

- Vital Transformation, an internationally based real-world evidence, health economics and healthcare strategy consultancy, was asked to conduct an analysis of the impact of proposed CMS price negotiations and reductions on the therapeutic plasma sector.
- This analysis is based upon publicly available data from SEC 10-K filings, private market research data, and confidential interviews with industry finance professionals.
- The opinions included in this work are those of Vital Transformation LLC, and are not necessarily those of the project's funders.
- The analysis was performed by Vital Transformation's Consulting Economist Dr. Harry Bowen and Vital Transformation's Managing Director Duane Schulthess.
- This project was funded by the Plasma Protein Therapeutics Association (PPTA).