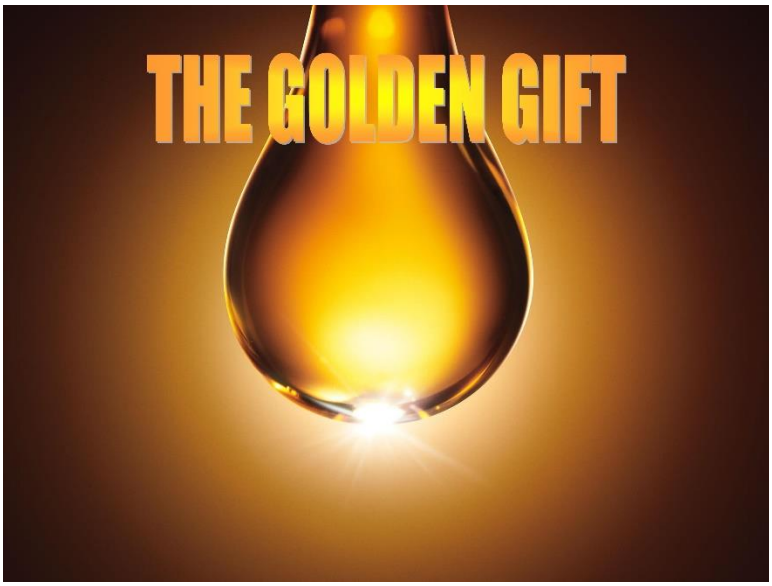
Plasma Facts



Plasma contains an organically perfected mix of over 10,500+ individual proteins (different fractions of albumins, fibrinogens, immunoglobulins, alpha-2-Macroglobulin, eNAMP, VPS35, etc.), 5K different peptides (including LL-37 antimicrobial peptide, GDF-8, GDF-11 growth and differentiation factors), 45 cytokines (including Interferons), 1.84 billion exosomes per ml, 50 different sex specific hormones, enzymes and minerals. Plasma is the most versatile component of human blood.

- According to the Plasma Proteome Database (ver. 06_2015) [19], 10.5 thousand blood-plasma proteins have been detected: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4889822/

- Composition of the peptide fraction in human blood plasma: repeatedly detected masses suggests that approximately 5000 different peptides were recorded: https://pubmed.ncbi.nlm.nih.gov/10348167/

- Approximately 93% of amplifiable DNA in plasma is localized in plasma exosomes. Normal blood plasma contains 1,840,000,000 exosomes per ml (184 × 107particles/mL plasma): https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5574584/

- Scientists reliably predict people's age by measuring proteins in blood: https://www.sciencedaily.com/releases/2019/12/191205130543.htm

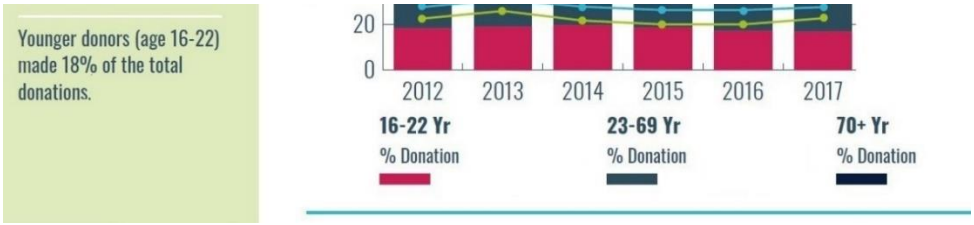
The 100-year life-saving history of blood plasma

- 1628 - Plasma was already well known when described by William Harvey in de Mortu Cordis, but knowledge of it probably extends as far back as Vesalius (1514–1564).
- March 1918 - The use of blood plasma as a substitute for whole blood and for transfusion purposes was proposed in the British Medical Journal.
- 1920s – Plasma becomes first used in US surgical procedures.
- 1938 – Plasma becomes an approved biologic whose use is restricted only to the issuance of a prescription by a licensed prescriber (The Food, Drug, and Cosmetic Act of 1938).
- 1938 – 1947 - Control of biological products, including regulation of the blood supply, under the supervision of the director of the Hygienic Laboratory of NIH.
- February 1941 - Red Cross responds to a request by the U.S. government to begin a Blood Donor Service to produce lifesaving plasma for the armed forces in anticipation of America's entry into WW II.
- 1942 - College units were added to the Junior Red Cross at a time when virtually every campus in the country hosted some type of Red Cross activity organizing student groups that included, for the first time, the recruitment of blood donors.
- November 1943 - "Six thousand units of plasma went ashore at Tarawa [and] 4,000 of them came back in the veins of wounded marines. At least half of the seriously wounded owe their lives to plasma." – Captain French R. Moore, Navy doctor in the Pacific.
- Junior Red Cross membership grew to almost 20 million during WW II.
- 1947 – The Red Cross joins with other blood banks to form the American Association of Blood Banks (AABB).
- 1948 – Biologic products become part of the NIH National Microbiological Institute.
- 1955 - NIH Division of Biological Standards (DBS) for regulating biologics was created.
- July 1, 1972 - the responsibility for implementing the Biologics Act was transferred from the DBS to the FDA. The FDA's Bureau of Biologics was given lead responsibility for overseeing blood collection, processing, testing, and marketing. It was at this point that all blood banks became federally regulated in addition to being state licensed.

Regulatory Considerations

Plasma is regulated by the FDA under rules delineated in 21 CFR 640. Plasma has been in continuous use since the 1920s, and its general safety and efficacy has long been proven. The Food, Drug, and Cosmetic Act of 1938 required only that a new medication be safe. The use of plasma in the United States is restricted only to the issuance of a prescription by a licensed medical provider.

Establishing the legal age of blood donation is the responsibility of each state, often in association with organizations such as the AABB. Donors 18 years or older are accepted nationwide. Approximately 20% of all blood donations since 1942 have been made by young donors, which presently amounts to 1,300 units per day:



The current role of the FDA is to control which medications are available commercially. The FDA does not limit or control how medications are prescribed by physicians once the medications are available on the market. Off-label drug use is common, ranging from 21% for common medicines, to becoming predominant treatments for a given clinical condition. The predominant use of young Fresh Frozen Plasma (yFFP®) collected from healthy volunteer sex-identified donors between the ages of 18 – 25 to treat age-related conditions is off-label.

July 2000, due to significant advancements in testing, the United States FDA reported that our blood supply is the safest in the world and is now safer than it has ever been. That has been annually documented to be true for the twenty-two years since, an incredible record of success:

- https://www.webmd.com/a-to-z-guides/news/20000713/us-blood-supply-among-safest-in-world

- https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/transfusiondonation-fatalities

With AD and age-related neurodegeneration soon projected to be one out of every three dollars spent, a series of encouraging and potentially profoundly beneficial research has been released specific to safely and successfully treating neurodegeneration and other age-related diseases:
October 3, 2014, Stanford's PLasma for Alzheimer SymptoM Amelioration (PLASMA) human trials with young Fresh Frozen Plasma (YFFP), blood plasma collected from donors 18 – 30, commenced. On October 29, 2018, the PLASMA study concluded "The yFFP treatment was safe, well tolerated, and feasible."

November 18, 2016, the Stanford Parkinson's Disease Plasma Study (SPDP) infused young plasma (donor ages 18-25), concluding that "Young fresh frozen plasma was safe, feasible, and well tolerated in people with Parkinson's disease (PD), without serious adverse effects and with preliminary evidence for improvements in phonemic fluency and stigma."

February 19, 2019, the same year the FDA reported that "Due to advances in donor screening, improved testing, automated data systems, and changes in transfusion medicine practices, the risks associated with blood transfusion remain low", former FDA Commissioner Scott Gottlieb, M.D., and the still current Director of FDA's Center for Biologics Evaluation and Research, with regulatory authority over blood plasma, Peter Marks, M.D., Ph.D., stated:

"The FDA has recently become aware of reports of establishments in several states that are offering infusions of plasma from young donors to purportedly treat the effects of a variety of conditions. The conditions range from normal aging and memory loss to serious diseases like dementia, Parkinson's disease, multiple sclerosis, Alzheimer's disease, heart disease or post-traumatic stress disorder. We have significant public health concerns about the promotion and use of plasma for these purposes. There is no proven clinical benefit of infusion of plasma from young donors to cure, mitigate, treat, or prevent these conditions, and there are risks associated with the use of any plasma product."

Alzheimer's disease (AD) and Parkinson's disease (PD) are fatal diseases, with AD sufferers dying on average only 7 – 9 years after becoming diagnosed. Currently, the United States has 86 million individuals with heart disease, 40 million people suffer from neurodegenerative diseases such as Alzheimer's, Parkinson's and multiple sclerosis, 30 million have diabetes and 24 million struggle with immune system disorders.

In calendar year 2019 the FDA reported that 10.8 million whole blood and red cells, 1.9 million apheresis platelets, and 2.1 million plasma components were transfused. Of the 2.1 million plasma transfusions, there was only one plasma-related and entirely avoidable fatality, Transfusion Related Acute Lung Injury (TRALI) that rarely occurs from providing a male with female HLA positive plasma. Spectrum Plasma sex identifies all donors and tests all female donors for HLA. In 2019, there were 2 cases of anaphylaxis out of 14.8 million transfusions, with no attribution to any specific blood product, with it also being known that surgical general anesthetics are one of the five leading causes of anaphylaxis.

On August 7, 2019, The Neurology Center in Houston made public the concluding six-month results of their IRB approved and placebo-controlled investigation of intravenously administering sex-identified yFFP. Over the following six months, patients were evaluated for the outcome measures, with patients who had received the plasma doing better on the outcome measures than those who received placebo. The comparison was statistically significant and as with Stanford's studies, there were no reported adverse effects.

In 2020 and 2021, the FDA reported NO fatalities from plasma transfusions.