PLASMA PROTEIN
THERAPEUTICS
ASSOCIATION

2025 MID-YEAR IMPACT REPORT

LETTER FROM THE PRESIDENT & CEO

Dear Readers,

As we reach the midpoint of 2025, I want to reflect on the incredible progress the Association and its membership has made so far, and where we're headed next.

In the U.S., we've significantly grown the Plasma Caucus, from 26 to 40 bipartisan members. Our annual Congressional Fly-In in May allowed us to connect directly with lawmakers on the unique needs of the plasma community, ensuring our voice is heard within the halls of power.

On the state level, the CalPlasma Coalition has made strides in California, supported by thoughtful testimony, strong media outreach, and growing grassroots support. Nationally, we're pushing for regulatory policies that protect both donors and patients, and have actively engaged with regulatory bodies to encourage the efficient and safe operations of plasma centers.

Globally, the Association's work with EU institutions continues to gain ground.

Whether it's contributing to SoHO Regulation implementation, hosting nearly 300 stakeholders in Warsaw at IPPC 2025, or advocating for donor safety improvements in national registries, we are reinforcing the value and importance of plasma-derived medicines at every level.

Many challenges — geopolitically in particular — will continue to impact the industry. But our purpose remains the same: protecting and improving the lives of patients who rely on plasma-derived therapies. With your partnership, we are ready to meet the moment.

Thank you for your ongoing support and trust. Let's carry this productivity and commitment to patients forward into the remainder of the year and beyond.

Warm regards,
Anita Brikman
President & CEO
Plasma Protein Therapeutics Association (PPTA)

Anita Brikman

EXECUTIVE SUMMARY

PPTA made significant progress across regulatory, legislative, advocacy, and public affairs efforts during the first half of 2025. Key achievements include increasing membership of the Plasma Caucus, advancing national and European Union (EU) regulatory engagement on plasma supply continuity, and launching major initiatives such as a longitudinal cohort donor health study.

PPTA's proactive advocacy in both North America and Europe has positioned the Association to address emerging challenges and strengthen access to plasma-derived therapies globally. Priority initiatives for the remainder of 2025 include implementation of the Substances of Human Origin (SoHO) Regulation, donor health research execution, and continued regulatory collaboration with the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the European Directorate for the Quality of Medicines and HealthCare (EDQM).

North America

BIGGEST WIN – PLASMA CAUCUS GROWTH

The Plasma Caucus has grown from 26 to 40 bipartisan members, thanks to the coordinated efforts of PPTA and member companies. This membership boost was highlighted during the May Congressional Fly-In, where members met with 40 congressional offices. Education and outreach will continue through 2025 with planned briefings and events.

The Plasma Caucus has grown from **26 to 40** bipartisan members.

Members met with **40 congressional** offices.

STATE LEGISLATION

California remains a legislative priority. Assembly Bill 725 passed the Assembly Health Committee in a unanimous vote in April, but was held in the Appropriations Committee after a prohibitively high price tag for bill implementation was provided to the Committee by the California Department of Public Health (CDPH). PPTA is working to secure a meeting with CDPH to understand what changes can be made to reduce the bill's estimated implementation cost and to see if the Department could make some of the reforms contemplated by AB 725 at the regulatory level while legislation progresses. Passage of the bill is supported by CalPlasma, a coalition of stakeholders activated by PPTA.

In Louisiana, Governor Landry signed HB 115 on June 5, following its unanimous passage in both of the state's legislative chambers. The law, which takes effect August 1, will remove the requirement for a lengthy and burdensome licensing process for donation center personnel in the state.

Legislation is also advancing in New Jersey, and PPTA is having discussions with legislators and regulators in Connecticut and Washington regarding our policy priorities.

CALPLASMA PARTNERS

ALPHA-1 FOUNDATION · California Rare Disease Access Coalition · Immune Deficiency Foundation · GBS|CIDP Foundation International · Patient Advocates United In San Diego County · ALBIE AWARE Breast Cancer Foundation · CIBD · Bleeding Disorders Council of California · National Bleeding Disorders Foundation · Jeffrey Modell Foundation · Liver Coalition · CalRare · Lupus and Allied Diseases Association, Inc. · BACC Bay Area Cancer Connections · Kawasaki Disease Foundation

CLINICAL LABORATORY IMPROVEMENT ACT REGULATIONS

PPTA successfully advocated for the Centers for Medicare and Medicaid Services (CMS) to allow greater flexibility in training requirements on plasma center staff. Thanks to our effort, CMS will be allowing "enforcement discretion" for the remainder of 2025 as it revisits the entire regulation. PPTA wil continue to push for full exemption from CLIA.

OTHER FEDERAL REGULATIONS

In May, PPTA submitted comments to the Office of Management and Budget (OMB), urging regulatory relief for the plasma collections industry, which were also shared with CBER. PPTA will also submit comments in response to the Executive Order 14293, which aims to streamline pharmaceutical manufacturing barriers. Both these submissions are ongoing and PPTA will continue to follow up throughout 2025.

NAVIGATING TRUMP 2.0

PPTA is monitoring the April 15 executive order titled "Lowering Drug Prices by Once Again Putting Americans First." The order directs the Department of Health and Human Services (HHS) to develop payment models for high-cost drugs not subject to the Medicare Drug Price Negotiation Program requirements. The proposal may revive elements of the previous Trump administration's Most Favored Nation (MFN) pricing strategy. PPTA is closely reviewing the potential impact and will advocate to safeguard patient access to plasma-derived therapies (PDTs).

Furthermore, PPTA has been actively working to secure exemptions for PDTs, plasma and intermediates in future potential pharmaceutical tariffs or retaliatory tariffs. In comments and meetings with official stakeholders, PPTA has stressed that imports of these products do not represent a national security threat, and trade friction could have a grave impact on the complex supply chain for these products. PPTA will continue to advocate for policies that support this supply chain and patient access to these therapies.

PPTA HOSTS 2025 CONGRESSIONAL FLY-IN

In May, PPTA hosted its annual Congressional Fly-In, where almost 40 attendees met with key Members of Congress to educate them about the unique nature of PDTs and the importance of preserving patients' access to these lifesaving medicines. Attendees met with members of the influential House Ways and Means Committee, House Energy and Commerce Committee, and Senate Finance Committee and urged members to remember that plasma is different when considering policies that impact the industry. Members of the House were also asked to join the Plasma Caucus. The timing of the Fly-In could not have been more auspicious, as two of those committees were marking up legislation that could have had significant impact on the plasma community.

With all the activity related to tariffs, trade, drug pricing, and domestic manufacturing, it is critical that lawmakers understand the unique plasma ecosystem and the role of the policy landscape in allowing it to thrive. We thank this year's attendees for their help in making sure that our issues are top-of-mind as Congress grapples with these important issues.

PPTA Congressional Fly-In attendees meet with Members of Congress in Washington, D.C.

Europe

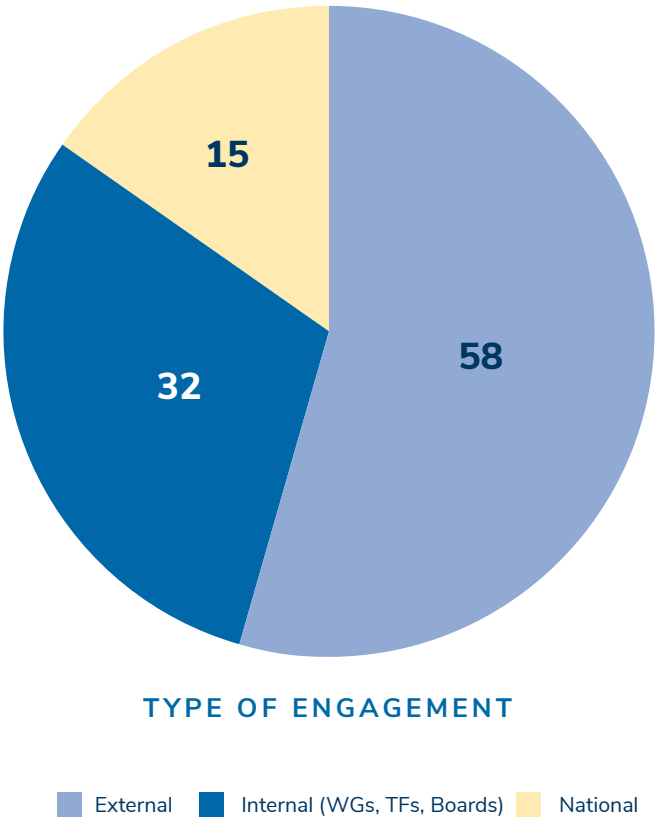
PPTA continues to engage in key EU-level initiatives and regulatory discussions to promote the availability and safety of plasma-derived medicinal products (PDMPs).

HIGHLIGHTS FROM THE FIRST HALF OF 2025 INCLUDE:

- **January:** Building on its meeting with the European Commission's SoHO Unit late last year, PPTA continues to engage in EU and national discussions on the implementation of the **SoHO Regulation**. By securing meaningful participation, PPTA can reinforce recognition of efficient practices already in place, while contributing to the development of practical and regulatory changes.
- **January 17:** PPTA participated in the European Commission's webinar on the upcoming **SoHO** digital platform.
- **January 23-24:** PPTA Europe, in collaboration with the European Plasma Alliance (EPA), reached stakeholder consensus on two key documents at the Platform of Plasma Users (PLUS) conference: a joint letter to the Directorate-General for Health Emergency Preparedness and Response Authority (DG HERA) and a public statement on plasma-derived medicinal product (PDMP) safety.
- **February:** PPTA published a position paper on stockpiling, submitted feedback to the Critical Medicines Alliance (CMA), and provided input to the European Commission's **Critical Medicines Act** consultation.
- **March:** PPTA submitted letters to Turkish authorities and presented preliminary findings on cost-containment measures and shortages to the PPTA EU Board of Directors.
- **March 4:** The first cross-functional Work Plan for Europe was adopted. The plan prioritizes all projects to align with both European and global objectives. It includes a comprehensive inventory of all projects, categorized using a dynamic Prioritization Matrix based on urgency, impact and strategic significance to ensure effective resource allocation. The plan is designed to be adaptable as the political and regulatory environment evolves, enabling swift adjustments to resource allocation as needed.

PPTA Europe Team Engagement Overview:
January – May 2025

106 TOTAL MEETINGS



Strengthening our outreach and our voice through purposeful engagements and nurturing trusted relationships

- **April 3:** PPTA sent a letter to European Commissioner for Trade Maroš Šefčovič and the European Commission president regarding the impact of U.S. trade policy on medicine availability in Europe.
- **May 20-21:** PPTA held its annual International Plasma Protein Congress (IPPC) in Warsaw, gathering nearly 300 attendees, including industry members, health care providers, patient and donor representatives, and members of regulatory and government agencies.
- **May 22:** PPTA met with the office of European Commission President Ursula von der Leyen to highlight the industry's economic footprint and the unique nature of plasma-derived medicinal products (PDMPs) supply chain. PPTA advocated for a tailored and holistic legislative approach for PDMPs and sustained dialogue with the Commission.
- **May 22:** PPTA met with the EC President's Cabinet, emphasizing the industry's strong economic footprint in Europe and the importance of PDMPs. PPTA urged continued strategic dialogue to address trade tensions and ensure uninterrupted patient access. The Cabinet welcomed these calls and committed to conveying the messages to relevant Commissioners and DGs.
- **June:** The European Plasma Alliance (EPA) welcomed the Czech government's implementation of its new donor registry as a critical step in ensuring donor safety. A well-managed, centralized registry prioritizes donor safety by enhancing medical oversight so that legally approved donation frequency limits are upheld.

IPPC2025 drew attendees from 32 countries to learn more about innovation in the plasma industry, donor health, securing a global plasma supply, and more.

- **Publication of EDQM Blood Guide:** PPTA commends EDQM's efforts to advance standards and align practices to enhance donor and patient safety laid out in the 22nd edition of the "Blood Guide," which was published in May 2025. For future editions, PPTA believes that further focus is needed on source plasma donation for fractionation guidance, especially where donor eligibility, testing, and deferral criteria differ to other blood and transfusion sectors, which is mainly due to PDMP safety and quality. PPTA encourages greater collaboration with the PDMP industry in future editions to ensure guidance continues to evolve alongside scientific advancements.
- **Ongoing:** PPTA continued to support political commitments to plasma collection reforms in Greece, with two high-level meetings held in March and April. Media coverage raises awareness on plasma donation and the lifesaving nature of plasma-derived medicines.

  Additional updates from Hungary, the Czechia, and Germany reflect PPTA's work in national registry alignment, data protection, and joint advocacy initiatives. A joint German industry position paper will be published later in 2025.

Regulatory

PPTA's regulatory engagement spans international regulatory agencies and focuses on plasma supply continuity, donor health, and harmonizing inspection and quality standards.

KEY MILESTONES:

- **January 14-15:** PPTA contributed to Q&A sessions at the EDQM Blood Conference and was invited to the EDQM Plasma Supply Continuity Stakeholder Meeting.
- **February 17:** PPTA, alongside member companies, met with the FDA to advance a CLIA waiver for the total protein test at plasma centers.
- **March 5:** PPTA participated in the EMA Haematology Working Party workshop and shared industry feedback on the SCIg/IMIg guideline.
- **March 13:** PPTA advocated for updates to Annex 14 during the EMA Good Manufacturing Practice/Good Distribution Practice (GMP/GDP) Inspectors Working Group meeting.
- **March 14:** PPTA held the inaugural Emergency Preparedness Task Force meeting to plan an FDA-PPTA pandemic preparedness workshop and develop an International Quality Plasma Program (IQPP) emergency standard.
- **March 26-27:** PPTA representatives presented on donor health studies, registries, and plasma supply at the EDQM Plasma Supply Continuity meeting.
- **March 28:** PPTA contributed to cross-industry feedback at the EMA Industry Standing Group (ISG) meeting regarding the Critical Medicines List.
- **April 7-11:** PPTA participated in the Plasma Protein Biotechnology conference in Dubrovnik, Croatia, presenting on international regulatory alignment and patient access.

- **April 11:** PPTA and the International Plasma Fractionation Association (IPFA) presented on PDMP supply chains to the EMA Single Point of Contact (SPOC) Working Party.
- **April 16**: PPTA submitted its Longitudinal Donor Health Study protocol to an institutional review board (IRB).
- **April 17:** PPTA's research on U.S. Source Plasma donor demographics was presented at the American Society for Apheresis (ASFA) annual meeting.
- **May 14-15:** PPTA attended the IPFA/Paul-Ehrlich-Institut (PEI) Workshop on Blood-Borne Pathogens in Heidelberg, Germany.
- **May 31-June 4:** PPTA's research on donor health and marketing was presented at the 35th Regional Congress of the International Society of Blood Transfusion (ISBT) in Milan, Italy.

NATIONAL MILESTONES:

Joint Position Paper, SoHO Task Force ARGE

PPTA - EPA jointly endorsed donor registry and engaged with local plasmapheresis associations on donor safety

Close alignment calls with local plasmapheresis association in advocating for registry implementation

Build trusted relations with Governmental officials and local stakeholders

Plasma Caucus growth; Engagement with state legislators in California, Louisiana, New Jersey, and Connecticut; CLIA waiver advancement; Donor Health Study submitted to IRB

Upcoming Priorities for the Remainder of 2025

PPTA'S FOCUS AREAS FOR THE SECOND HALF OF 2025 INCLUDE:

- National and EU-level implementation of the SoHO Regulation.
- Continued engagement/advocacy on the EU Critical Medicines Act, EU and national stockpiling strategies and the revision of the EU Pharmaceutical Legislation.
- Active collaboration with the EMA on shortages prevention, regulatory updates, and revision of the variations regulation and guideline.
- Finalize protocol and launch the longitudinal cohort donor health pilot study.
- Advance discussions on epidemiology data requirements and updates to the Plasma Master File.
- Continued bilateral engagement with the FDA and EMA to advocate for patient access and regulatory harmonization.
- U.S. and EU continued alignment and engagement on geopolitical and trade tensions.

Key Dates on the 2025 Calendar

- **September 10–12:** Present donor health and communications research at the 6th European Conference on Donor Health and Management (ECDHM), Wijk aan Zee, the Netherlands.
- **October 25–28:** 2025 AABB Annual Meeting, San Diego, California.
- **November 2025 (to be confirmed):** Bilateral meeting with the EMA.
- **Throughout 2025–2026:** Ongoing political and regulatory outreach, along with broad stakeholder engagement.
- **Q4 2025:** BWP workshop on epi-data & Interested Parties meeting with Haematology Working Party.

PPTA's proactive work ensures the plasma industry remains strong, agile, and focused on patient needs globally.

PPTA Events

Visit pptaglobal.org to learn more

OCTOBER 6–10, 2025
International Plasma Awareness Week (IPAW)
www.plasmaweek.org

OCTOBER 14–15, 2025
PPTA Plasma Protein Forum (PPF)
Alexandria, Virginia, U.S.
www.pptaglobal.org/forum

OCTOBER 16, 2025
PPTA Business Forum
Alexandria, Virginia, U.S.
www.pptaglobal.org/businessforum

APRIL 21–22, 2026
PPTA International Plasma Protein Congress (IPPC)
Milan, Italy
www.pptaglobal.org/ippc