PPTA MID-YEAR UPDATE & IMPACT REPORT 2024 JANUARY - JUNE
INTRODUCTION

The Plasma Protein Therapeutics Association (PPTA) and its members are already making a global impact this year. Read about efforts spanning the globe to improve plasma collection policies, protect donor health and patient access, and more.

STATE ADVOCACY

Connecticut Governor Ned Lamont signed Public Act Number 24–7 (Senate Bill 368) on May 9, 2024. This legislation eliminates the requirement that a registered nurse or an advanced practice registered nurse be on-site at a source plasma donation center. It also requires that the source donation center regulations allow a responsible physician as defined in federal law to serve as the source plasma donation center director. Finally, it exempts someone who performs apheresis on a healthy donor from needing a nursing license.

PPTA’s State Working Group initiated this legislation in response to regulatory proposals released earlier this year by the Connecticut Department of Public Health that required the center director to be a physician who has received a minimum of one year of specialized training in blood banking, or has equivalent experience and training acceptable to the department. Members had difficulty finding candidates for the center director position under the proposed regulations. Passage of this law requires the Connecticut Department of Public Health to follow federal law regarding the center director. PPTA is hopeful this effort will allow members to see cost savings, as other states have noted when similar measures were introduced. For instance, in California, a bill introduced just a few years ago has already allowed members in the state to save millions of dollars in operational costs.

In Pennsylvania, clinical lab laws exceed federal requirements in the areas of lab director and lab supervisor qualifications, on-site supervision of clinical lab tests, and the number of labs a director may oversee (state limit is two, federal limit is five). PPTA’s State Working has been working since 2022 to remove the state requirements that make operating source plasma donation centers difficult in Pennsylvania. Finally, after ongoing efforts, in mid-April, House Bill 1795 was signed into law by Pennsylvania Governor Shapiro. This bill adds source plasma donation centers that only perform hematocrit and total protein testing to the list of entities exempt from Pennsylvania Clinical Laboratory requirements. Starting this June, source plasma donation centers in Pennsylvania will no longer have to meet state clinical lab requirements, including state clinical lab licensure.

NORTH AMERICA FLY-IN

On June 5, 35 attendees from PPTA member companies and allies from the American Plasma Users Coalition (APLUS) participated in the Association’s annual legislative fly-in. The six teams participated in a total of 34 meetings, including 10 in the Senate and 24 in the House, an increase of more than 20% compared to the 2023 Fly-In event. All of PPTA’s Global and North America members were well represented, with participation from member companies and APLUS patients and staff members up more than 60% from the previous year.

North America Fly-In 2024
LOS ANGELES GROUNDBREAKING EVENT

PPTA President and CEO Anita Brikman represented the Association at a groundbreaking event for a new Takeda facility in Southern California. There, she also provided remarks around the role the plasma sector plays in local communities by promoting investment, creating jobs, and stimulating economic development.

RECENT EVENT RECAP: PPTA & PNS EXHIBITS

The North America patient exhibit team recently interacted with various patient and physician communities at gatherings like the Hemophilia Federation of America meeting in Indianapolis and the Immune Deficiency and Dysregulation North America Conference hosted by the Clinical Immunology Society in Minneapolis. Later this summer, PPTA will be attending and exhibiting at several conferences, including: Alpha-1 National, National Bleeding Disorders Foundation, IgNS, and Immune Deficiency Foundation.
SOHO GETS A GREEN LIGHT

This spring, the European Parliament approved revised EU rules to protect donors and recipients of treatments/therapies deriving from a substance of human origin (SoHO). PPTA welcomes these policy changes and looks forward to collaborating with all stakeholders, policymakers, and members to ensure a reliable supply of plasma for fractionation. On May 27, the Council of the EU then finalized the agreement. See PPTA’s statement on the adoption here.

CRITICAL MEDICINES ALLIANCE COLLABORATION

In April, PPTA participated in the inaugural meeting of the EU’s Critical Medicines Alliance (CMA) Forum in Brussels, which focused on its role in delivering the EU mission on a health union and addressing medicines shortages. PDMPs were included on the EU Critical Medicines List, which was published in late 2023. Learn more here.

OECD REPORT & INTERACTION

In early 2024, PPTA participated in the “Organisation for Economic Co-operation and Development (OECD) high-level conference on building resilient medical supply chains.” During this conference the OECD introduced its new report, “Securing Medical Supply Chains in a Post-Pandemic World,” which emphasizes the importance of plasma collection and the vulnerability of supply chains. After the report was released, PPTA participated in the second OECD Conference on Medical Supply Chains in Paris. The conference provided an opportunity to assess medicinal supply chain disruptions and bottlenecks as well as discuss possible solutions and information needed for optimal decision-making.

PPTA EXECUTIVES VISIT MEMBERS IN ITALY

Anita Brikman, President and CEO of PPTA, along with Maarten Van Baalen, Executive Director of PPTA Europe, visited PPTA member company Kedrion in Italy. This mid-March visit was filled with productive discussions on public affairs, regulatory updates, patient and donor relations, and a tour of Kedrion’s Bologna fractionation plant. The visit emphasized PPTA member collaboration, united partnership, and a healthy exchange of ideas.
**RECENT EVENT RECAP: IPPC**

The International Plasma Protein Congress (IPPC) was held in Athens in April. The event brought together plasma professionals from around the world to connect, share ideas, and drive progress. The event featured engaging and thought-provoking sessions and discussions, networking events, a panel on donor health, as well as an exciting announcement from Adonis Georgiadis, Greece’s Minister of Health. At IPPC, he announced an upcoming bill that proposes a national framework for the collection of source plasma in Greece. See more scenes from IPPC here.

![Adonis Georgiadis, the Minister of Health for Greece, speaks at IPPC](ippc_photo1.jpg)

![Attendees applaud during a presentation at IPPC 2024](ippc_photo2.jpg)

**RECENT EVENT RECAPS: FUTURE PLANNING ACROSS THE GLOBE**

**PPTA EUROPE 2024 ONWARD STRATEGY / PLANNING MEETING**

On March 13–14, PPTA Europe members gathered with staff to develop priorities, compatible with the recently developed PPTA Global three-year strategy, that require a “multidisciplinary” assessment from the membership and decision-making on the objectives. Priority topics included the optimization of plasma collection model post-substances of human origin (post-SaHO), donor protection (including monitoring and frequency of donation), supply chain issues, and inspections. Member representatives from the EU Board of Directors, EU Advocacy Working Group (WG), European Plasma Alliance, Regulatory WG, Global Communications WG, and Pathogen Safety WG participated in a brainstorming session under Einstein’s axiom: “Insanity is doing the same thing over and over again and expecting different results.”

![PPTA staff, member representatives from the EU Board of Directors, EU Advocacy WG, European Plasma Alliance, Regulatory WG, Global Communications WG, and Pathogen Safety WG participate in strategic workshop.]( workshop_photo.jpg)

**PPTA PLASMA BOARD OF DIRECTORS PLANNING MEETING**

On May 20–21, PPTA Global Plasma held a planning meeting in Washington, D.C. More than 60 participants representing the full breadth of PPTA’s membership and staff came together to exchange and align visions for the next five years of Global Plasma activities. Focus groups discussed key topics including communications, donor health, IQPP standards, regulatory affairs, supply chain resilience, and technology, as well as provided prioritized recommendations for committee and PPTA Plasma Board of Directors consideration. The group also heard from subject matter experts including David Cho with the U.S. Food and Drug Administration on emergency preparedness, Johan Prevot with International Patient Organisation for Primary Immunodeficiencies (IPOPI) on the patient perspective, and Richard Wilner with Takeda on sustainability.

Over the coming weeks and months, these projects will be refined and molded into a concrete vision and work plan for 2025 and beyond. PPTA extends its gratitude to all of the participants who took the time to join us in this valuable exercise.
GLOBAL PLASMA

IQPP REBRAND

PPTA has initiated a rebranding effort designed to revitalize the look and feel of IQPP and maximize the program’s appeal to stakeholders and utility to members. The effort began with a refreshed logo and continues with an in-depth review of the standards themselves.

APSID CONFERENCE IN TOKYO

PPTA participated in the Asia Pacific Society for Immune Deficiencies (APSID) annual meeting and IPOPI Regional Asian PID Patients Meeting in Tokyo on March 22–25. Participation in the event cemented relationships with a broader stakeholder base in the region, allowing us to advocate in a more informed way for access to therapies and increased plasma collection worldwide.

UNITAR - GENEVA

PPTA participated in a breakfast roundtable — “Bridging the Gap in Access to Plasma and PDMPs (plasma-derived medicinal products)” — with the UN Institute for Training and Research (UNITAR) Plasma4Life initiative and a stakeholder meeting on the sidelines of the 77th World Health Assembly in Geneva on May 27. This event was designed to raise awareness among other WHA member countries and stakeholders of the Plasma4Life initiative, which PPTA is proud to support.

EDQM

The European Directorate for the Quality of Medicines & Health Care (EDQM) released a draft of the 22nd edition of the Blood Guide for public consultation. PPTA and its members provided commentary, and PPTA’s regulatory team will continue to provide further updates to members.

PPTA RESEARCH PRESENTED AT ASFA AND ISBT

PPTA’s research titled “Hypotensive Adverse Events Among US Source Plasma Donors” was presented by Dr. Janet Hershman, Takeda, at the American Society for Apheresis (ASFA) Annual Meeting at the Resorts World, Las Vegas, Nevada, April 17–19, 2024. The ASFA is the premier organization of physicians, scientists, and allied health professionals whose mission is to advance apheresis medicine for patients, donors, and practitioners through education, evidence-based practice, research, and advocacy. View the poster here.

PPTA’s donor health research was presented during the 38th International Congress of the International Society of Blood Transfusion (ISBT), held in Barcelona, Spain, on June 27, 2024. The presentation titled, “Hypotensive Adverse Events Among U.S. Source Plasma Donors – Plasmavigilance II” was in the session “Getting to know you and your health” and the abstract is published in Vox Sanguinis. More than 3300 delegates and 84 exhibiting companies from 115 countries participated in the five day meeting.

SCABB MEETING IN FLORIDA

In June, PPTA participated at the South Central Association of Blood Banks (SCABB) Annual meeting in Orlando, Florida. The mission of SCABB is to provide opportunities for members to enhance their abilities to deliver quality blood services. PPTA Medical Consultant, Toby Simon, M.D., presented “Plasma/Paid Donors/Cell Therapy” on a panel discussing programs in blood centers to pay donors for plasma for transfusion and for further manufacturing and for mononuclear cell collection for non-injectable use.
This June, Anita recorded an episode of the Bloodstream Podcast that will air in the fall to promote IPAH.

At #IPPC2024, Marilena Vrana Director, Lead Public Affairs Europe, served as PPTA’s spokesperson for Greek media and provided commentary around the Minister of Health’s announcement.

PPTA partnered with the Brussels Times to highlight a donor and a patient. Haema was also featured in the article.
WHAT'S AHEAD

Here's a look at just some of what's ahead in the latter half of 2024.

**July**

With the aim to improve patient access to care and become as a trusted resource, PPTA continues its engagement in China and builds on the contacts established during the past year by meeting with the authorities and stakeholders in July.

**September**

In September, keep an eye out for more information on an important awareness event on Capitol Hill that will also culminate with the official opening of the new PPTA Washington, D.C. office! And, later in the month, the Business Forum heads to Chicago on Sept. 26.

**October**

This fall, International Plasma Awareness Week (IPAW) is debuting a new look! This annual celebration of plasma donation — which this year will fall from Oct. 7–11 — is receiving an aesthetic refresh featuring a new logo, new colors, and new materials to share. Stay tuned for more opportunities to bring greater awareness to the importance of donating plasma by celebrating IPAW and its new look later this year.

**November**

The annual Plasma Protein Forum returns to Washington, D.C. from Nov. 19-20. Registration information will be shared in the coming months.

LEARN MORE

Already a PPTA member? Learn more about how to get the most out of your membership benefits by emailing rherndon@pptaglobal.org. Not yet a PPTA member? Scan this QR code for the membership application.