



2019 ANNUAL REPORT

Saving and Improving Lives



6 Global
Members

33 Staff



IQPP-Certified Plasma Centers

746 in North
America

88 in
Europe

Mission

PPTA'S MISSION IS TO PROMOTE THE AVAILABILITY OF AND ACCESS TO SAFE AND EFFECTIVE PLASMA PROTEIN THERAPEUTICS FOR ALL PATIENTS IN THE WORLD.

We will strive to achieve our mission by:

- Fostering the collection of high-quality plasma from healthy donors;
- Establishing standards for the manufacturing of lifesaving plasma protein therapies at the highest levels of safety and quality;
- Breaking down artificial barriers on trade and compensated donors that limit patient access to therapy;
- Supporting government reimbursement practices that reflect the unique nature of plasma protein therapies;
- Educating all stakeholders about the value of the therapies; and
- Adhering to the PPTA Code of Ethics.



Globally, PPTA works to:

- Advocate for access to therapies for patients;
- Engage in constructive dialogue with regulatory agencies;
- Collaborate with patient advocacy organizations; and
- Administer standards and programs that help ensure the quality and safety of plasma collection and manufacturing and protect donors and patients.
- Standards and programs include:
 - International Quality Plasma Program (IQPP)
 - Quality Standards of Excellence, Assurance & Leadership (QSEAL)
 - National Donor Deferral Registry (NDDR)
 - Patient Notification System (PNS)
 - North America Data Program
 - European Distribution Data Program



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Letter From the President

2019 was an extraordinary year of challenges and successes for the plasma protein industry and the patients we serve. Around the world, patients often face challenges in accessing plasma-derived therapies. Our industry collected record levels of plasma, the raw material for the critical medicines necessary to treat patients living with certain rare diseases. PPTA has worked diligently to challenge barriers to collecting plasma, to address regulations that govern the manufacture of plasma protein therapies, and to ensure patients have access to the therapies prescribed by their physician. This year's achievements are a testimony to PPTA's commitment to our mission of promoting the availability of and access to safe and effective plasma protein therapies for all patients.

PPTA's advocacy centers upon the patients who rely on access to plasma protein therapies. We were instrumental in challenging regressive clawback efforts in certain markets, and in promoting awareness campaigns about plasma, whether through our "How Is Your Day?" campaign or in cooperation with governments. We participated in, and sponsored, numerous meetings around the world in service of raising awareness and educating stakeholders including regulators, providers, policymakers, researchers, patients, and others about the importance of plasma collection and access to plasma-derived therapies.

Last year was also memorable as PPTA's longtime President and CEO, Jan M. Bult, retired after 23 years of service to the organization. His time at PPTA was marked with significant accomplishments as the industry grew significantly during his tenure. Jan is an institution in the industry and continues to offer counsel and guidance to PPTA.

As we tackle fundamental issues that will impact the industry for years to come, including plasma collection standards, laws, regulations, and geography that challenge patients' access to medicines, the need for a united industry is essential. PPTA remains committed to serving our members as the source of that united congregation. The following pages will demonstrate how PPTA is helping the industry do just that. •



Amy Efantis, *President & CEO*

Access to Care

STRATEGIC GOAL: Ensure access to care through advocacy, education, and appropriate reimbursement policy.



EUROPE

BULGARIA



PPTA submitted letters to the Bulgarian Ministry of Health and the National Health Insurance Fund (NHIF) requesting that, because of their uniqueness, all plasma-derived medicinal products (PDMPs) should be exempt from a payback tax in Bulgaria. The tax known as “Mechanism Guaranteeing the Predictability and Sustainability of the NHIF’s Budget,” states that any (additional) costs for the state budget caused by a company’s increase of PDMPs distributed in Bulgaria compared to the previous year’s forecasted budget threshold must be borne by the Marketing Authorization Holders/manufacturers, who would be required to pay back the difference to the NHIF. The feedback received over Summer 2019 from both authorities was encouraging; in the authorities’ view, the entire group of PDMPs, not only for emergency treatments but also those intended for outpatient treatment, should be provided with funding. The authorities also stated that they will propose the “necessary legislative changes” to ensure patients needing PDMPs have full access to these therapies, out of NHIF budget funds.

GERMANY: IMPACT ON COAGULATION FACTORS



The bill for more safety in the supply of medicines (Gesetz für mehr Sicherheit in der Arzneimittelversorgung, GSAV), including the abolition of the exceptional distribution pathway for coagulation factor products, passed despite the advocacy efforts of PPTA and the German Hemophilia community and will go into effect in August 2020.



EU ROUND TABLE



PPTA hosted a Round Table (RT) in the EU Parliament on February 21. The objective of the event, “The Growing Need for Plasma Derived Medicinal Products in the EU — How to ensure appropriate patient access to PDMP treatment,” was to raise awareness among policymakers.

This successful event was hosted by three key Members of the European Parliament and was attended by 50 participants, including several patient associations, medical treaters/academia, representatives from the German Ministry of Health and the Belgian Regulatory Agency, five EU Member States Permanent Representations (Embassies), the European Commission, and industry.

FOCUS ON PLASMA DONATION

In 2019, the German Ministry of Health allocated a budget for a blood donation campaign of the “Bundeszentrale für Gesundheitliche Aufklärung” (Federal Agency for Health Education). The campaign includes updating the website www.einfachlebenretten.de with special focus on the need for blood and plasma donation.



PLUS MEETING

PPTA staff again participated in the annual stakeholder conference of the Platform of Plasma Protein Users (PLUS), offering the association an opportunity to more fully understand the priorities of those relying on access to plasma protein therapies and to reassert PPTA's commitment to partnering with stakeholders. PLUS represents, among others, patient organizations such as:

- Alpha-1 Federation Europe
- European Haemophilia Consortium
- Guillain-Barré Syndrome | Chronic Inflammatory Demyelinating Polyneuropathy Foundation International
- Hereditary Angioedema International
- International Patient Organisation for Primary Immunodeficiencies
- Immune Thrombocytopenia Support Association
- World Federation of Hemophilia

INTERNATIONAL SYMPOSIUM ON INTENSIVE CARE AND EMERGENCY MEDICINE

In March, PPTA sponsored the 39th International Symposium on Intensive Care and Emergency Medicine (ISICEM) held in Brussels, Belgium. The PPTA Albumin Task Force suggested five speakers for the symposium, and, as a result, there was a session dedicated to albumin. The ISICEM, which attracts more than 6,200 participants from around the world, is open to all physicians, nurses, and other health professionals with an interest in critical care or emergency medicine.

NORTH AMERICA



PUBLIC WORKSHOP

PPTA staff attended a public workshop jointly hosted by the Alpha-1 Foundation, the U.S. Food and Drug Administration (FDA), and the National Institutes of Health in September. The purpose of the workshop, “Developing Therapeutics for Alpha-1 Antitrypsin Deficiency,” was to foster the development of therapeutic products for the treatment of the disease. The event featured presentations and discussions by experts on several topics, including the current needs in AAT drug development, a patient perspective on available treatments, and potential outcome measures for use in clinical trials.

U.S. FOOD AND DRUG ADMINISTRATION

In July, PPTA staff attended a public workshop organized by the U.S. Food and Drug Administration (FDA), titled “Perspectives on In Vitro Diagnostic Devices Regulated by the Office of Blood Research and Review.” The FDA provided comprehensive information covering various aspects of submissions, including requirements, guidance, and recommendations. The presentations are available on the FDA website.

CREUTZFELDT-JAKOB DISEASE FOUNDATION FAMILY CONFERENCE

PPTA staff attended the 18th annual Creutzfeldt-Jakob Disease (CJD) Foundation Family Conference, held in Washington, D.C. This is an exceptional opportunity to meet with families, receive updates on CJD surveillance in the U.S., learn about scientific developments in disease detection and treatment, and hear from the regulatory representatives (Centers for Disease Control and Prevention, FDA). The incidence of sporadic CJD in the U.S. remains unchanged (approximately one case per million population per year), and no new cases of variant CJD have been reported worldwide.

CLINICAL IMMUNOLOGY SOCIETY MEETING

PPTA attended the annual Clinical Immunology Society (CIS) meeting in Atlanta, Georgia. CIS is the multidisciplinary organization for the field of clinical immunology and is dedicated to fostering developments in the science and practice of clinical immunology. This year’s meeting set attendance records, and most participants were scientists or physicians treating immunodeficiencies and diseases of immune dysregulation. Scientific presentations covered difficult to diagnose clinical cases, progress in genetic testing, basic science and its practical applications to personalized patient care, and successes in hematopoietic stem cell transplantation and organ transplantation, as well as in gene therapy. PPTA member companies and the Immune Deficiency Foundation presented posters and exhibited during the meeting.

PPTA ATTENDS BPAC MEETING

On March 20 –21, the 120th Meeting of FDA’s Blood Products Advisory Committee (BPAC) was held in Silver Spring, Maryland. Topics included Zika testing and blood donation policies regarding men who have sex with men (MSM). PPTA delivered a statement regarding the MSM topic with respect to concerns about an individualized risk assessment study that the FDA proposed and a blood center’s request for a variance to allow donors with MSM risk to donate platelets if pathogen-reduced.

MEDICARE PART B CONGRESSIONAL BRIEFING

PPTA and member companies attended a congressional briefing on a change to Medicare Part B reimbursement that allows Medicare Managed Care organizations to begin using step therapy for Part B drugs. Congressional staff heard from providers and a patient affected by this interventional technique and how it has denied access to prescribed drugs that have effectively treated the patient. PPTA has objected to these “fail first” schemes that impede access to appropriate therapies.

CALIFORNIA

In California, an individual who works in plasma collection centers and performs certain tests must be licensed to perform a moderate complexity test. Last year, PPTA effectively worked with California authorities to establish a pilot program that created an exception to the licensing requirement for individuals performing the total protein test using a digital refractometer in licensed plasma collection centers. The pilot is testing whether a trained but unlicensed individual can perform the total protein test using a digital refractometer as well as a licensed individual. PPTA staff began meetings in Fall 2019 with the California Legislature and Department of Public Health to discuss removing the pilot status and making the exception permanent.

FLORIDA

PPTA staff met with Florida legislators, legislative staff, the Governor's office, Florida Medicaid, and several other Florida state offices and organizations throughout the year to discuss using the Spirit Analyzer developed by the Jeffery Modell Foundation. The Spirit Analyzer software identifies patients who are at high or medium risk of a PI, based on historical claims in the last 12 months, with the anticipation that it will lead to earlier diagnosis of PI. PPTA staff believes the Spirit Analyzer will assist the state in providing proper health care to Floridians while saving the state money.

NEW YORK

PPTA advocated to change New York state laws to improve plasma donation. Meetings were held with the State Education Department, the State Department of Public Health, and the New York Legislature. PPTA staff suggested that changes in the laws would result in more plasma donation centers in the state that would benefit the communities where the centers would be located, as well as the patients who rely on donated plasma as the starting material for plasma protein therapies.

ENGAGEMENT WITH MEDICAID PHARMACY DIRECTORS

PPTA staff attended the regional Southern, Western, Eastern, and American Medicaid Pharmacy Administrators Association meetings. These meetings provide excellent opportunities for the Association to interact with key state decisionmakers as well as officials from the Centers for Medicare and Medicaid Services. The conferences feature presentations on various pharmacy topics as well as reports from individual states to share new or upcoming initiatives on which they are working within their Medicaid programs. Of note, PPTA learned that states may pursue cost-savings policies within the blood clotting factor and immune globulin therapeutic classes.

ADVOCACY AGAINST LIMITING ACCESS TO PPTS IN THE STATES

In 2019, several states proposed policies that would limit beneficiary access to the full range of FDA-approved plasma protein therapies (PPTs). In support of stakeholders and in collaboration with the State Affairs Steering Committee, PPTA submitted comments in several states highlighting the importance of patient access to the most medically appropriate therapy. Some engagement efforts were successful and exclusions for plasma protein therapies remained. The outcome of others remain yet to be decided or implemented. PPTA will continue to monitor outstanding and new restrictive proposals in 2020.

In support of stakeholders and in collaboration with the State Affairs Steering Committee, PPTA submitted comments in several states highlighting the importance of patient access to the most medically appropriate therapy.

ENGAGEMENT WITH STAKEHOLDERS

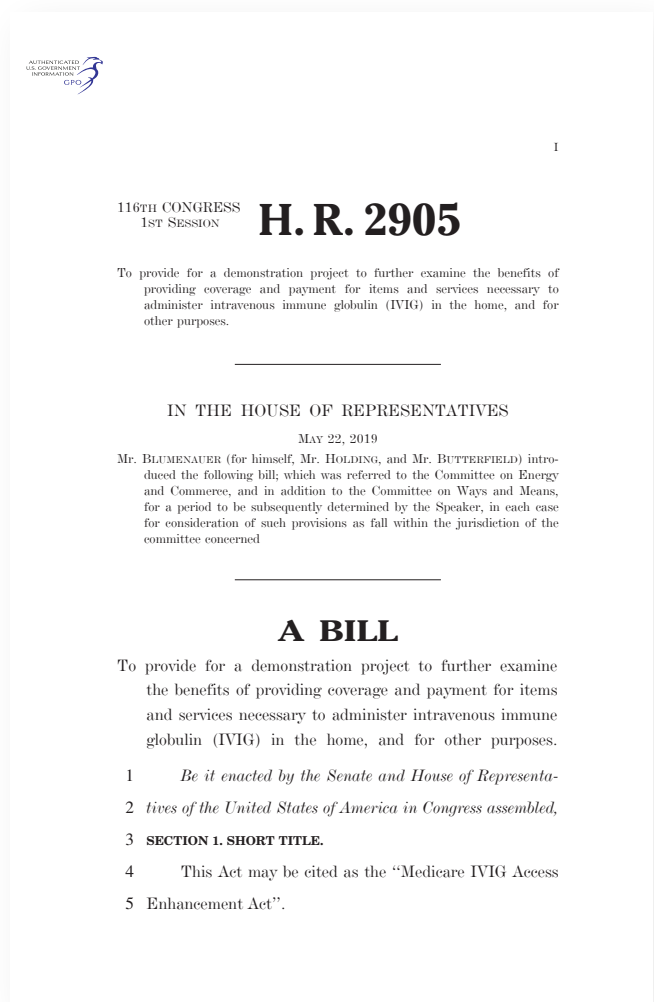
The Association hosted its two annual stakeholder meetings, attended by representatives from the Alpha-1, GBS|CIDP, hereditary angioedema, immune deficiency, and bleeding and platelet disorder communities, as well as member company staff. During the meeting, advocacy organizations identified common objectives and priorities, including patient protections, plasma supply, education and awareness, and patient access factors. The meeting was held in conjunction with the Plasma Protein Forum and featured presentations on — and discussions about — changes to the North America data program, industry actions on plasma collection, and plans to expand manufacturing facilities, advocacy organization surveys, access to care priorities, and opportunities to engage with the “How Is Your Day?” campaign.

ADVOCACY FOR PATIENT PROTECTIONS ON THE HILL

On May 16, PPTA hosted its annual Fly-In in Washington, D.C. Individuals who rely on plasma protein therapies, as well as representatives from patient advocacy organizations, manufacturers, and PPTA, attended approximately 50 meetings with congressional offices. Participants emphasized the importance of ensuring patient protections in any legislative efforts. PPTA used the dedicated hashtag, #AdvocateforPPTs, on Twitter throughout the day to increase our visibility and to continue building awareness of plasma protein therapies.

SUPPORTING PATIENT-LED CONGRESSIONAL LEGISLATIVE EFFORTS

The GBS|CIDP Foundation International is actively working on H.R. 2905 – The Medicare IVIG Access Enhancement Act. This bill would create a three-year demonstration to expand Medicare coverage of IVIG therapy for the treatment of Chronic Inflammatory Demyelinating Polyneuropathy and Multifocal Motor Neuropathy to the home setting. PPTA submitted a letter to the committees of jurisdiction highlighting the Association’s respect for the foundation’s efforts on behalf of its membership.



RESPONSES TO FEDERAL RULE-MAKING PROPOSALS

On behalf of its membership and in collaboration with the Federal Affairs Steering Committee, PPTA submitted comments on two proposed rules issued by the Centers for Medicare and Medicaid Services.

In response to the Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of Certain New Safe Harbor Protections (RIN 0936-AA08) proposed rule, PPTA expressed support for the reforms outlined and recommended the Department of Health and Human Services Office of the Inspector General finalize its proposals to amend the discount safe harbor to remove protection for rebates paid by pharmaceutical manufacturers to Part D plans, Medicaid-managed care organizations, and pharmacy benefit managers for Part D and Medicaid MCO business; create a new safe harbor for discounts provided to beneficiaries at the point of sale, which should be protected even if such discounts are related to formulary position or other conditions that make it easier for beneficiaries to access their critical therapies; and create a new safe harbor for certain PBM service fees paid by manufacturers.

In response to the Hospital Outpatient Prospective Payment System for calendar year 2020 proposed rule, PPTA recommended that CMS should continue to pay Average Sales Price + 6% for separately payable, non-pass-through drugs and biologicals in CY 2020 and that CMS should continue its long-standing policy for payment of the furnishing fee for blood clotting factors administered or dispensed in the hospital outpatient department at the same level as in the physician office setting.

REST OF WORLD

LATIN AMERICAN SOCIETY FOR IMMUNODEFICIENCIES

PPTA staff attended and presented at the biennial Latin American Society for Immunodeficiencies meeting in Cancun, Mexico. The meeting addressed primary immunodeficiency issues relevant to Latin America, including inborn errors of immunity, newborn screening, malignancies, autoinflammation, and autoimmunity, as well as secondary antibody deficiencies resulting from cancer treatments. Delays in detection of many conditions were highlighted and emphasis was made on developing new approaches for providing timely and relevant patient-centered treatments. ●

Communication & Advocacy

STRATEGIC GOAL: Be the trusted resource
for plasma protein therapies.

IMMUNOGLOBULIN ACCESS

In response to reports on immunoglobulin (Ig) access, PPTA created a range of materials and made them available on the Patient Information Resources page on its website. Materials include a description of the issue, a document listing manufacturer toll-free numbers that offers health care professionals the ability to inquire about specific brands of IG therapy for their patients, and an infographic showing the global journey of plasma. The materials note there are multiple variables that impact patient access to subcutaneous- and intravenous-administered Ig products, including manufacturer issues, distributor issues, government policies, physician and pharmacy protocols, and/or growing clinical need. While PPTA does not have the ability to isolate the cause of any access challenge, the Association does provide valuable data regarding plasma collections and Ig therapies.

MEDIA

GERMAN DOCUMENTARY REGARDING PLASMA DONATION

A German television network, ARD, released a 45-minute documentary in October called “Blood Trade: Health vs. Dollars,” which focused heavily on plasma donations made at the U.S.-Mexico border. PPTA engaged with the reporters for more than a year and provided significant information describing the donation process, regulations that permit Mexican citizens to cross the border to donate, and the importance of plasma donation for people living with rare and serious conditions. Though there were aspects of the documentary that were inaccurate or presented unfairly, PPTA agrees with the producers’ overall contention that European countries need to do more to encourage plasma donation wherever possible to provide therapies for patients. Ultimately, what matters most is that enough plasma, donated by healthy and committed donors, is available so those who rely on access to plasma-derived therapies can live normal and healthy lives. PPTA and its member companies are grateful for every plasma donor, whether in the United States or Europe, and their dedication to saving lives around the world.

PPTA RESPONDS TO AMERICAN RED CROSS OPEN LETTER

The American Red Cross published an open letter to the health care community that did not present plasma donors or plasma donation positively. PPTA’s response, published on the Association’s website, was intended to be educational about the value of our therapies.

INTERNATIONAL PLASMA PROTEIN CONGRESS

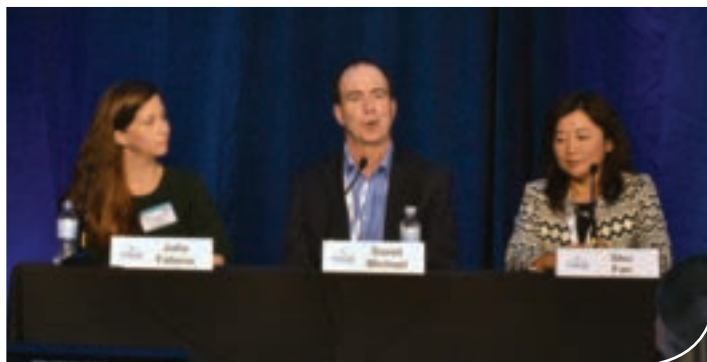
PPTA hosted the 2019 International Plasma Protein Congress in Amsterdam, which was attended by more than 320 industry representatives, public officials, patients, and patient organizations. During the Congress, the 2019 Hilfenhaus Award was presented to Prof. Isabella Quinti, Head of the Primary Immunodeficiencies Unit at the Sapienza University of Rome, Italy.

PLASMA PROTEIN FORUM

PPTA hosted its 2019 Plasma Protein Forum at the Hyatt Regency in Reston, Virginia, on June 18 and 19. More than 270 people attended the Forum, including representatives from PPTA’s membership, patient advocates, academics, public officials, and others. The 2019 recipient of the Dr. Otto Schwarz Award was Ileana Carlisle, President & CEO of Biotest Pharmaceuticals Corporation.

BUSINESS FORUM

In October, nearly 80 PPTA members gathered in San Diego, California, to attend the annual PPTA Business Forum. The PPTA Source Board of Directors and staff present the PPTA Business Forum to the membership, allowing members to become better informed and more involved in PPTA activities. During the forum, Roger Brinser, head of the BioLife Plasma Services’ regulatory organization, was named as the recipient of the Robert W. Reilly Leadership Award.



COMMUNICATION

INTERNATIONAL PLASMA AWARENESS WEEK – OCTOBER 7–11

PPTA again celebrated International Plasma Awareness Week (IPAW) by convening “IPAW on the Hill” with members of Congress, their staff, patient representatives, and industry stakeholders. This year, 43 states and the District of Columbia recognized IPAW. In addition, Congresswoman Doris Matsui (D-CA) submitted a statement for the Congressional Record asking her “colleagues in the House of Representatives to join me and rise in commemoration of International Plasma Awareness Week, honoring those committed donors and collection centers that make and collect needed and lifesaving contributions.”

The following week, a Parliamentary evening took place in Berlin, hosted by MP Katrin Helling-Plahr (Free Democratic Party), with members of the German parliament, parliamentary staff, representatives from the German Federal Ministry of Health, and payer groups, as well as representatives from participating plasma collectors and manufacturers. During the discussion, patients living with a range of diseases described issues impacting their access to treatment. The key topic, however, was the need for more plasma in Europe and what Germany could do to collect more plasma, both in-country and in Europe. All participants agreed that although the situation in Germany is much better than in other countries, more needs to be done, starting first and foremost with education about and advertisement for plasma donation.

ESID CONGRESS IN BRUSSELS

PPTA staff participated in scientific sessions and continued promoting the “How Is Your Day?” campaign by exhibiting at the Congress of the European Society for Immunodeficiencies (ESID), held in Brussels, Belgium. The ESID focuses on improving knowledge in the field of primary immunodeficiency by encouraging research, developing educational programs, and fostering cooperation among all those involved in the diagnosis, treatment, and management of these diseases. PPTA took the opportunity to provide information on the importance of plasma donation and how plasma donors contribute to saving and improving the lives of patients worldwide.

7TH ALPHA-1 GLOBAL PATIENT CONGRESS

PPTA staff participated in a panel discussion at the 7th Alpha-1 Global Patient Congress. The presentation focused on an overview of source plasma donation and manufacturing, with an emphasis on advocacy and the “How Is Your Day?” awareness campaign. PPTA’s animated video describing plasma donation, introduced in conjunction with IPAW 2018, was also shown to attendees.

HEMOPHILIA FEDERATION OF AMERICA’S ANNUAL SYMPOSIUM

PPTA staff attended the Hemophilia Federation of America’s Annual Symposium in San Diego, California. Staff attended sessions on advocacy and research, participated in the policy preconference, exhibited the Patient Notification System, presented the “How Is Your Day?” campaign, and interacted with and learned from advocates in the bleeding disorders community.

PPTA STAFF ATTENDS GBS/CIDP MEETING

PPTA staff attended an Annapolis, Maryland Chapter meeting of the GBS/CIDP Foundation International. In addition to highlighting the “How Is Your Day?” campaign, PPTA provided educational materials on plasma donation and the important role of plasma donors. Association patient access initiatives were also discussed.

NATIONAL HEMOPHILIA FOUNDATION CONFERENCE

PPTA staff attended the National Hemophilia Foundation’s 71st Bleeding Disorders Conference in Anaheim, California, held October 3–5. Drawing approximately 2,500 attendees, the three-day conference is an educational experience for all ages. PPTA staff provided information about the Patient Notification System as well as the “How Is Your Day?” campaign, which emphasizes the importance of sharing the voices of donors and patients. •

**HOW IS
YOUR DAY?**

Plasma Donors Save Lives

“How Is Your Day?” brings together people around the world who are interested in plasma protein therapies, aiming to inform and educate policymakers and the public of their unique, lifesaving value.

ASSOCIATION MANAGEMENT



PPTA'S NEW PRESIDENT & CEO ANNOUNCED

Amy Efantis joined PPTA as its new President & CEO in January 2019. She brings extensive experience in government affairs and health policy to her new position. Previous to her role as Vice President, Global Public Policy & Government Affairs at Biogen, she held roles with Boehringer Ingelheim, PhRMA, and she worked on Capitol Hill as a Congressional Legislative Director, and advised Congressman Thomas Barrett (D-WI) on various House Energy & Commerce Committee issues, primarily in the health care policy areas. David Bell, Chairman of PPTA's Global Board of Directors and General Counsel and Chief Innovation Officer with Grifols SA, stated: "We are very pleased that Amy has agreed to take on the leadership for the PPTA at a time of unprecedented change in health care. Continued progress in the development of vital and lifesaving treatments through the development of plasma protein therapies is critically dependent on the support needed from global stakeholders around the world."



PPTA WELCOMES NEW EXECUTIVE DIRECTOR, EUROPE

Maarten Van Baelen joined PPTA on September 2 as the Executive Director of its European division. Mr. Van Baelen has more than 10 years of experience in the life science arena and has represented the pharmaceutical sector's interest in public forums, strategic policy development, and advocacy on key issues with the European Commission, National Competent Authorities, and other stakeholders.



Free Trade

STRATEGIC GOAL: Eliminate trade barriers and other discriminatory practices to achieve open access to plasma protein therapeutics globally.

FOREIGN TRADE BARRIERS

On October 31, PPTA submitted comments to the U.S. Trade Representative to compile the 2020 National Trade Estimate Report on Foreign Trade Barriers. This report enumerates existing barriers to U.S. exports in goods and services. PPTA highlighted some of the more egregious barriers to our industry that exist worldwide, including Article 49 in China, which prevents the importation into China of any foreign plasma protein therapy besides albumin from the U.S.; the four Canadian provincial bans on compensated plasma collection; and the Japanese preference for domestically-sourced plasma. ●

Plasma

STRATEGIC GOAL: Ensure the availability of safe, high-quality plasma for fractionation.

ASIA

PLASMA PROTEIN INDUSTRY SUMMIT

On September 5 –6, PPTA co-organized and participated for the third year in a row in the Plasma Protein Industry Summit at the Parenteral Drug Industry Congress (PDI) in China. Two half-day sessions featured speakers from PPTA, member companies, representatives from international patient groups, as well as U.S. and Chinese regulators. The audience consisted of Chinese officials, representatives from PPTA member companies, Chinese industry members, and others.

Prior to the summit, PPTA met with representatives of several key Chinese agencies, including the National Medical Authority and Chinese Pharmacopoeia. The meeting was part of ongoing engagement in advance of the release of the newest edition of the Chinese Pharmacopoeia, expected to be published in 2020, and was attended by approximately 30 Chinese regulators.



The ongoing engagement over the past three years has contributed to a softened stance by the Chinese interlocutors on a number of critical sticking points, including the importance of Nucleic Acid Tests, inventory hold vs. the Chinese quarantine-recheck system, and the merits of centralized testing. PPTA has been able to build a reputation in China as a trusted partner and will continue to pursue opportunities to engage with stakeholders at every appropriate opportunity.

EUROPE

ARGE

On November 22 –23, PPTA organized and participated in the annual Congress of the German Arbeitsgemeinschaft Plasmapherese (ARGE) that took place in Kassel, Germany. The ARGE congress is the only platform in German language where collection center staff from the Red Cross, community hospital blood banks, industry, and private collectors come together and have an open exchange. This year's congress featured current topics such as how new potential infectious diseases could impact donor selection, the complicated European regulatory landscape including the challenges for the fractionators, how to measure plasma quality, and Europe's contribution to plasma for fractionation, among others. The congress was attended by nearly 200 persons including regulators from regional regulatory bodies as well as the Paul-Ehrlich-Institut and the Robert Koch Institut.

EUROPEAN PLASMA ALLIANCE

The European Plasma Alliance (EPA) welcomes a new chair. Dr. Matthias Gessner from Takeda took over from Dr. Stephan Walsemann. The EPA is part of PPTA Source and represents the interests of private sector source plasma collectors in Europe. The EPA focuses on establishing credible and constructive relationships with European and national regulators, organizations, patients, and physicians. It also provides expertise to European governmental organizations regarding plasma, plasma donation, and plasma-related disorders.



NORTH AMERICA

CANADA

BILL S-252, VOLUNTARY BLOOD DONATIONS ACT

On April 4, the Canadian Senate's Standing Committee on Social Affairs, Science and Technology (SOCI) unanimously voted to recommend against Bill S-252, the Voluntary Blood Donations Act. The bill, introduced in May 2018, would have amended Canada's Blood Regulations to ban compensated



plasma donation in all Canadian provinces and territories, with an exception for Canadian Blood Services. Prior to making its recommendation, the SOCI received briefs and heard testimony from witnesses, including PPTA staff and members who delivered compelling, and ultimately winning, messages

against the proposed ban.

The bill was officially quashed when the government prorogued (finished the business on its calendar) in mid-June to prepare for Canada's next election.

VOLUNTARY DONATIONS ACT, ALBERTA

On Thursday, October 24, PPTA submitted a letter to Alberta Health Minister Tyler Shandro, respectfully urging that efforts be made to repeal the 2017 Voluntary Donations Act, which banned the compensation of plasma donors. A new conservative government is in place and has been working to repeal a number of policies put in place by the previous government, creating a potential opportunity to reverse this ban.



UNITED STATES

DISABLED DONOR CASES

A number of recent cases have raised the issue of whether a plasma collection center is a “place of public accommodation” under the Americans with Disabilities Act (ADA). The question is not whether plasma centers need to install ramps or handicap accessible restrooms, as industry has routinely made these types of accommodation. Rather, the issue centers on health-related donor deferrals. At times, individuals interested in donating plasma have been deferred based on pre-established, medically vetted center policies due to such conditions as schizophrenia, post-traumatic stress disorder, or the need to use a service animal to manage an anxiety disorder. Some of these individuals have filed suit, alleging that barring them from donating plasma constitutes an act of unlawful discrimination based on disability under the ADA.

In 2019, a number of these cases moved beyond the trial court level to the court of appeals. Two such cases were *Silguero v. CSL Plasma*, in the U.S. Court of Appeals for the 5th Circuit, and *Mathias v. CSL Plasma*, in the Court of Appeals for the 3rd Circuit. A related case filed under the Texas Human Resources Code — a state law similar to the ADA — was heard by the Supreme Court of Texas. PPTA participated in all these cases by filing amicus or “friend of the court” briefs supporting the defendant plasma collection center. In the Mathias case, PPTA also participated in oral argument before the 3rd Circuit.

PPTA made similar arguments in each case. The central argument is that a plasma collection center is not a “service establishment,” the only category that would arguably fit under the ADA’s definition of “place of public accommodation.” Rather than a customer paying to receive a service that benefits him- or herself, which is typically how “service establishments” operate, the reverse is true for a plasma collection center (i.e., a donor is paid to provide a service that benefits patients). PPTA also argued that allowing legal challenges to donor deferrals would interfere with the existing framework, consisting of both FDA regulations and PPTA voluntary standards, that protects donor health and the safety of the collected plasma.

The PPTA and industry position prevailed in the 5th Circuit but was rejected by the 3rd Circuit and the Supreme Court of Texas. On November 7, a petition for a writ of certiorari — a request to take up the case — was filed with the U.S. Supreme Court. It remains to be seen whether the court will grant the petition.

ABC ANNUAL MEETING

PPTA attended the annual meeting of America’s Blood Centers (ABC), and of interest to our sector was the presentation by Drs. Bill English and Peter Jaworski, both of Georgetown University, who have conducted a study supported by PPTA member companies and ABC blood centers. The presentation, “Does Paid Plasma Crowd Out Unpaid Blood Donation? Evidence from Canada and the U.S.,” provided an analysis of data on donations from areas that include both blood and plasma collection facilities compared to areas with only blood centers. PPTA provided data from plasma collection centers. The macro data do not indicate crowding out is a problem, and, in fact, there may be a slight positive effect for blood centers. However, participants agreed that more data are needed on factors affecting blood centers, such as distributions on gender/age demographics, first time versus repeat donors, blood types, and effects of economic indicators, including increased recruiting costs.

INTERNATIONAL BLOOD SAFETY FORUM

In March, PPTA took part in a panel at the International Blood Safety Forum, sponsored by Global Healing and America’s Blood Centers. During the session — “How Professional Societies Can Contribute to the Development of Blood Centers in Low Resource Countries” — PPTA stressed the need for plasma for manufacturing plasma protein therapies obtained in a regulated environment aided by standards such as the PPTA voluntary standards. PPTA also highlighted its education and awareness initiatives in China and participation in conferences such as those sponsored by the Asia Pacific Economic Cooperation. ●

STANDARDS AND PROGRAMS

“PPTA’s voluntary standards program provides global leadership for the plasma protein industry’s goal of continuous improvement with a focus on safety and quality from the donor to the patient. The Standards Program will be transparent, credible, innovative, and responsive to stakeholder and industry needs.”

– *Mission Statement, PPTA Voluntary Standards Program*



IQPP STANDARDS PROGRAM

PPTA implemented the following revised standards:

- IQPP Personnel Education and Training Standard, Version 5.0 (Revision to Version 4.0)
- IQPP Plasma Collection Facility Standard, Version 4.0 (Revision to Version 3.0)

2019 IQPP CERTIFICATIONS

24 Companies held corporate certification

374 Audits were conducted

6 Countries maintained IQPP centers
(Austria, Canada, Czech Republic,
Germany, Hungary, and the U.S.)

834 Centers had earned IQPP certification

476 Centers were certified for 5+ years

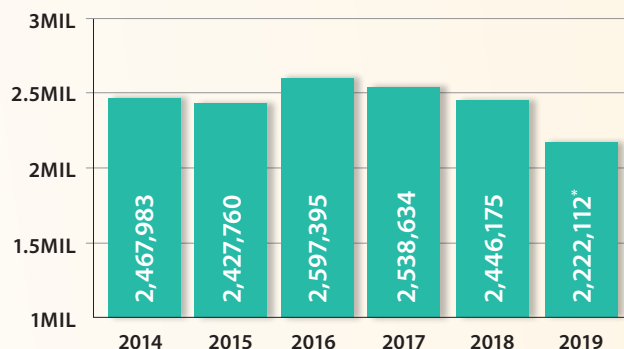
342 Centers were certified for 10+ years

168 Centers were certified for 20+ years

125 Centers were certified for 25+ years

EU – TOTAL UNITS

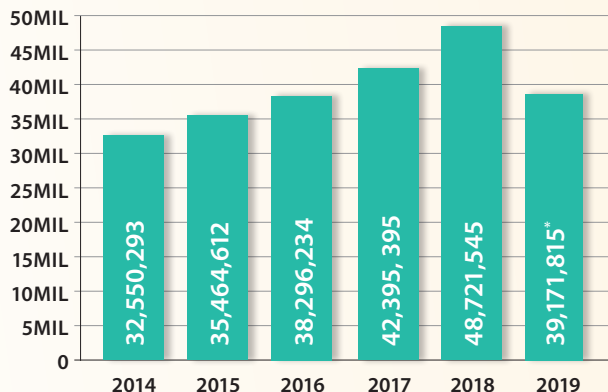
LITERS



*As of September 2019

U.S. – TOTAL COLLECTIONS

COLLECTIONS

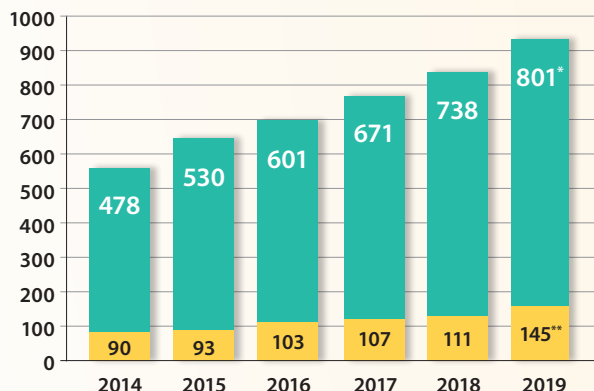


*As of September 2019

EU & U.S. – TOTAL NUMBER OF CENTERS

■ EU ■ U.S.

CENTERS



*As of September 2019

**As of December 2019

Regulatory & Quality Policy

STRATEGIC GOAL: Advocate for regulatory and quality policies that reflect the special nature of plasma protein therapies and promote a harmonized approach.

EUROPE

PPTA ACKNOWLEDGED AS FORMAL STAKEHOLDER AT HMA

In November, PPTA received a confirmation that it will be acknowledged as a formal stakeholder at the Heads of Medicines Agencies (HMA) in the EU. The HMA is a network of the heads of the National Competent Authorities whose organizations are responsible for the regulation of medicinal products for human and veterinary use in the European Economic Area. The HMA cooperates with the European Medicines Agency and the European Commission in the operation of the European medicines regulatory network and is a unique model for cooperation and work-sharing on statutory as well as voluntary regulatory activities.

22ND PLANOVA® WORKSHOP

At the 22nd Planova® workshop in Lisbon, Portugal, PPTA member companies presented the most recent Hepatitis E and A virus filtration from immunoglobulin preparations, the use of UV-C irradiation in combination with nanofiltration, as well as data on the use of specific model viruses to assess the effectiveness of the nanofiltration step in assuring final product safety.

SURVEILLANCE AND SCREENING OF BLOOD-BORNE PATHOGENS

PPTA staff attended the 26th International Workshop on "Surveillance and Screening of Blood-Borne Pathogens" in Krakow, Poland, in May. The keynote, delivered by the U.S. Food and Drug Administration's senior advisor for international blood regulatory affairs, provided a global perspective on current international blood biologics policies and blood safety regulations. This includes established control programs in various regions, as well as operational, scientific, and other challenges. The keynote also included a discussion on global harmonization efforts, such as those led by the World Health Organization. Another PPTA member provided an overview of pathogen inactivation and reduction techniques for non-enveloped viruses in the production of plasma-derived medicinal products.

PLASMA PRODUCT BIOTECHNOLOGY MEETING

The Plasma Product Biotechnology meeting is an important international forum for the presentation and discussion of topics relevant to the plasma industry. In 2019, topics addressed covered: manufacturing, quality, regulatory affairs, clinical development, and technical innovations, among others. While attending the meeting, four PPTA staff members made key presentations in Sicily, Italy:

- "European Medicines Agency's Post-Brexit Implications for Biological Therapies"
- "Perceived or Real Risk from Prions in Plasma-derived Medicinal Products (PDMPs)"
- "Global Sufficiency and the Global Donor"
- "Evolutionary Tale of the Plasma Protein Industry: What has evolved and what has not"

BIOPROCESS INTERNATIONAL EUROPE MEETING

The BioProcess International Europe Meeting was conducted in seven parallel tracks covering a wide range of bio-manufacturing topics (cell culture upstream process development, downstream processing and continuous processing, process characterization and bioassay development strategies, bioprocess analytics and control strategies, vaccines, cell line development, as well as pathogen safety).

PPTA's Pathogen Safety Committee chair opened the pathogen safety track, followed by a regulator question and answer session, which was attended by representatives of the U.S. Food and Drug Administration's Center for Biologics Evaluation and Research and the Paul-Ehrlich-Institut. PPTA member companies presented recent studies on virus inactivation processes (e.g., a novel packed-bed reactor used for continuous virus inactivation process, virus inactivation of human plasma products using UV-C irradiation, and pasteurization). Other topics discussed included an eco-friendly alternative to the Triton X-100 detergent, most recent data on HEV circulation in Europe, and implications for blood and plasma supply, as well as studies around next-generation sequencing for testing of adventitious viruses and biosafety testing of viral vectors and vaccines.

PPTA ENGAGES WITH THE WORLD HEALTH ORGANIZATION

PPTA staff attended the plenary session of the 70th World Health Organization (WHO) Expert Committee on Biological Standardisation (ECBS) meeting in Geneva, Switzerland. During the WHO meeting, PPTA staff and members participated in a hearing on the need for product-specific reference materials for Factor (F) FVIII and FIX. At the meeting, it was agreed that potency of FVIII and FIX products should continue to be labeled in international units and that the WHO International Standards (ISs) for factor concentrates should remain the primary standards. However, for products for which the ISs are not commutable and where there is divergence between manufacturers' in-house proprietary standards and WHO ISs, and discrepancies exist between assay systems (e.g., modified recombinant products), product-specific standards could be an option. For plasma protein therapies (plasma-derived and recombinant), no change is expected for current standards.

EUROPEAN DIRECTORATE FOR QUALITY OF MEDICINES

PPTA staff participated in a three-day Symposium on Plasma Supply Management organized by the European Directorate for Quality of Medicines (EDQM) TS093 Plasma Supply Management Working Group. The purpose of this Symposium was to collect evidence-based data to support the revision of the 20th edition of the Guide to the Preparation, Use and Quality Assurance of Blood Components (Blood Guide) regarding plasmapheresis. PPTA, which had also been part of the scientific organizational committee, was given the opportunity to present on experiences of donor motivation in the private sector, the strategies on protection of iron stores in plasma donors, and the data on donor adverse reactions. Furthermore, representatives from the industry were invited to present on the safety of plasma donation and on efficient collection practices.

It was recognized that human plasma is a crucial component for the manufacturing of the lifesaving therapies that patients with rare and chronic diseases depend on heavily. It was also recognized that the need for plasma has increased in the past few years, and there is a need to foster and support collection systems in Europe. The outcomes of the symposium will be translated into recommendations for the editorial committee of the Blood Guide.

EUROPEAN COMMISSION

PPTA built on its relationship with the European Commission's Directorate-General for Health and Food Safety's B4 unit (responsible for medical product quality, safety, and innovation) in November and had a constructive dialogue on the Mutual Recognition Agreement (MRA) between the EU and U.S. on Good Manufacturing Practice inspections. This follows PPTA's request for inclusion of source plasma as a biological starting ingredient for plasma-derived product (PDP) manufacturing, source plasma collection centers, and PDPs in the scope of the current MRA. Although transitory arrangements are in place for PDPs, and PDP inclusion is planned to be re-evaluated in 2022, this does not guarantee inclusion. Other topics discussed included the uniqueness of the plasma sector as feedback from the commission's conference on the consultation of the revision of the EU Blood Directive (Directive 2002/98/EC), the European Directorate for the Quality of Medicines (EDQM) Blood Guide, and the EDQM's consultation process.

EMA WORKSHOP

PPTA participated in the "EMA Regulatory Science to 2025 Post-consultation Workshop" at EMA's new (temporary) location in Amsterdam. The multi-stakeholder event was opened by EMA's executive director and was attended by the European Commission's directorate-general for health and food safety B5 unit (responsible for Medicines' policy, authorization, and monitoring), patient representatives and health care professionals, health technology assessment bodies, payer organizations, and industry, including PPTA member companies. The workshop shared the outcome and key messages from the public consultation and reported on the prioritization of core recommendations. A final document will be published, containing the outcome of the public consultation, as well as revised/extended actions for all core recommendations.

NORTH AMERICA

DONOR HEALTH AND SAFETY

In 2018, PPTA initiated a study of donor adverse events gathered using the PPTA Donor Adverse Event Recording (DAER) Standard during a four-month period. Three companies participated, representing over 12 million donations (72% of total donations during that time period). In 2019, DAER data collection and analysis was completed. Preliminary results were given at several presentations throughout the year. Results from the study will be published in 2020.

The Donor Health Study (DHS) began recruiting in October 2019 at 14 donation centers across the United States from three member companies. The DHS is a longitudinal cohort study of 4,000 donors consisting of three assessments over a 12-month period. The assessments will examine the functional health and well-being and the occurrence of recent illnesses, infections, and fevers of source plasma donors to determine whether there is any association with donation frequency. Additionally, reasons why donors do not return will be assessed for those who do not return within six months.

ANNUAL PPTA/FDA LIAISON MEETING

The annual liaison meeting between PPTA and the U.S. Food and Drug Administration (FDA) was held in Rockville, Maryland in November. Multiple topics were discussed, including: sharing PPTA's and FDA's current priorities; updates on donor health projects; transgender donor risk assessment; value of behavioral risk deferrals with pathogen reduction; Hepatitis A epidemic in the United States; donor suitability requirements under 21 CFR 630.30 and request for FDA support for U.S. regulatory frameworks for source plasma collection in Europe. Additional topics included PPTA's lessons learned from recent IG availability concerns and updates on current patient access situations and real-world evidence as well as considerations for plasma-derived IgG therapies. Participants agreed that several topics warrant FDA follow-up in terms of guidance, and in the case of behavioral risk deferrals with pathogen reduction, the consideration of sponsoring a public workshop. More than 45 PPTA members, FDA officials, and PPTA staff were in attendance.

AABB ANNUAL MEETING

PPTA was invited to participate in an AABB Blood Center Executive Summit at AABB's Annual Meeting in San Antonio, Texas, in October. The invitation-only event focused on the intersection of blood centers and plasma centers. In addition to PPTA participants, speakers included representatives from the FDA and Centers for Disease Control and Prevention, a representative from Canadian Blood Services, an expert in donor motivation theory, a bioethicist, and a hospital-based physician. Presenters and panelists explored regulatory requirements, existing and needed data on co-existence, and the risks and benefits of different donor models. PPTA focused on patient needs and the goal of global responsibility for plasma to produce lifesaving plasma protein therapies.

COMMENTS

EUROPEAN MEDICINES AGENCY

PPTA submitted comments to the European Medicines Agency (EMA) on the guidelines for clinical investigation and core summary of product characteristics (SmPC) for plasma-derived or recombinant Factor (F) IX products. As in an earlier revision of EMA's FVIII guidelines, the requirement to use previously untreated patients in clinical trials for marketing authorization purposes has been deleted from the FIX guidelines.

PPTA also submitted comments on EMA's discussion paper: "Use of Patient Disease Registries for Regulatory Purposes – Methodological and Operational Considerations." The concept paper specifically discussed opportunities to expand the use of patient registries by introducing and supporting a systematic and standardized approach to registry contribution to benefit-risk evaluation of medicines. PPTA's comments specifically addressed defining requirements for practical implementation using existing registries to support post-authorization observational studies of hemophilia medicines, among other important aspects.

PPTA submitted comments on the Committee for Medicinal Products for Human Use (CHMP) revised draft of the "CHMP position statement on Creutzfeldt-Jakob disease (CJD) and plasma-derived and urine-derived medicinal products." The revision accounted for scientific developments since the statement's last update in 2011; there were no changes in the regulatory recommendations regarding exclusion, potential testing of donors, or the need to evaluate the prion reduction capacity of the manufacturing process and handling of batch recalls. In addition to the comments on the position statement, PPTA also submitted an assessment of the most recent scientific publications on CJD and transmissible spongiform encephalopathies (TSEs).

PPTA submitted comments on the "EMA Regulatory Science to 2025 Strategic Reflection" after the launch of the agency's "Regulatory Science to 2025" strategy in 2018. The strategy delineates EMA's engagement with regulatory science over the next five to 10 years in the areas of human and veterinary medicines. PPTA specifically recommended that EMA include plasma protein therapies in its strategy, pointing out their unique nature and key role in treating a variety of rare and serious medical conditions and rare disease indications.

EUROPEAN DIRECTORATE FOR QUALITY OF MEDICINES

Following up on the European Directorate for Quality of Medicines' (EDQM) plasma management symposium, PPTA submitted comments on the EDQM's "Symposium Recommendations," noting that many of the recommendations drafted did not reflect the symposium presentations or discussions and that some recommendations extended beyond the mandate of the TS093 Plasma Supply Management Working Group and the scope of the Blood Guide. In addition, PPTA objected to the planned referencing of parts of the Blood Guide in the EU Blood Directive (Directive 2002/98/EC) based on an inadequate and non-transparent process for the revision of the Blood Guide, the drafting process and content of the recommendations, and an overall lack of appropriate consultation and participation of all relevant stakeholders in the process.

PPTA submitted comments on behalf of PPTA member companies, the European Plasma Alliance (EPA), and Interessensgemeinschaft Plasma (IG Plasma) on the EDQM's 20th edition of the "Guide to the Preparation, Use and Quality Assurance of Blood Components" (Blood Guide). PPTA commented on donation algorithms, donation volumes, and frequencies set out by different regulatory requirements in EU member states and the United States. Also addressed were clinical parameters for monitoring donor health (iron stores, immunoglobulins), as well as important differences for donor deferrals, mandatory testing, manufacturing steps, requirements for storage, and many others for plasma manufacturing when compared to labile blood components. Other topics addressed by PPTA included donation principles (voluntary and non-remunerated donation practice), reference to various EU directives, and the general scope of the documents, including final products and therapies.

WORLD HEALTH ORGANIZATION

PPTA submitted comments on the World Health Organization (WHO) Working Document, "Draft Action Framework to Advance Universal Access to Quality and Safe Blood and Blood Components for Transfusion and Plasma-Derived Medicinal Products 2019–2023." PPTA pointed out that the growing global clinical need for plasma-derived medicinal products (PDMPs) cannot be met by increasing the amounts of recovered plasma from voluntary, non-remunerated donations, and that the draft action framework does not sufficiently cover actions and strategies related to plasmapheresis/apheresis. PPTA recommended WHO delineate a strategy that would promote and support quality and economically sustainable plasmapheresis programs nationally to increase the amount of available plasma for PDMP manufacturing.

U.S. FOOD AND DRUG ADMINISTRATION

PPTA filed comments with the U.S. Food and Drug Administration (FDA) as a follow-up to the public meeting “Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions,” which was jointly sponsored by the FDA and the Duke-Margolis Center for Health Policy. PPTA’s comments described industry efforts to address shortage preparedness and included an overview of the history, operational details, and stakeholder benefits of the Association’s North America Data Program. The data program is an example of a successful public-private collaboration, which now has a track record of nearly 20 years. With this history in mind, the comments present the data program as both a helpful model to other pharmaceutical sectors and the type of “enduring solution” that the FDA seeks.

PPTA also submitted comments to the FDA draft guidance on the further testing of donations that are reactive on a licensed donor screening test for antibodies to hepatitis C virus (anti-HCV), as required under 21 CFR 610.40(e). FDA’s draft document recommended that if Nucleic Acid Test (NAT) is nonreactive for HCV, further testing is necessary using a second, different licensed donor screening test for anti-HCV. PPTA’s comments suggested the second test was unnecessary and requested an exemption from the guidance. In the alternative, PPTA asked the FDA to include another algorithm choice of using FDA-cleared moderate or high-complexity serology assays (anti-HCV or NAT) to provide additional information concerning the reactive donor’s HCV infection status in addition to assays licensed for donor screening. In its final guidance released in October, the FDA agreed to the alternative algorithm that does not require the use of a licensed donor screening test for additional testing.

PPTA submitted comments to the FDA draft guidance “Principles of Premarket Pathways for Combination Products,” and offered solutions to FDA’s questions on filings to prevent duplicative reviews by FDA Centers involved in the regulation of the combination products.

PPTA provided comment in the open public hearing of FDA’s 120th Blood Products Advisory Committee in March. The statement was in reference to Topic III: Blood Donation Policies Regarding Men Who Have Sex with Men (MSM). PPTA’s comments were two-fold. PPTA first questioned the lack of inclusion in the FDA’s proposed studies, noting specifically, “Without the plasma industry’s participation in the design of the proposed FDA study incorporating an additional donor history questionnaire, the HIV High Risk Questionnaire (HRQ), it is unknown whether the results of such a study could be transferred to the source plasma collection community.” Further, PPTA voiced an objection to FDA’s possible approval of an alternative procedure submitted by a blood establishment to exempt deferral of MSM for the collection of pathogen-reduced platelets. PPTA advised that it encourages a broader discussion of behavioral risk relevance with the implementation of pathogen reduction. The same topic was discussed with the FDA at its November 6 PPTA/FDA annual liaison meeting, with the suggestion that PPTA would support a public workshop on the topic.

PUBLICATIONS

PPTA has submitted an original research manuscript, comprised of data collected over the past 20 years on the important contribution of nanofiltration to viral safety of plasma-derived therapeutics, for publication in *Transfusion*. The manuscript was written by past and present members of PPTA’s Pathogen Safety Steering Committee (PSSC) and represents the most diverse nanofiltration data collection to date, which substantiates the effectiveness and robustness of nanofiltration in virus removal under manufacturing conditions of different plasma-derived proteins. If accepted, it would be the fourth publication of the PSSC on pathogen safety and risk reduction measures of plasma protein therapies in *Transfusion*, following previous articles in 2009, 2011, and 2012. ●

Supporting Organizations

PPTA would like to thank these patient organizations for their support.



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