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Worldwide Initiative for Rh Disease Eradication

WHO Action Framework: A Step in the Right Direction

Key Economic and Value Considerations of Plasma-Derived Medicinal Products (PDMPs) in Europe
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Recognizing the challenges facing healthcare and transfusion medicine, we are on a journey to deliver solutions that are personalized to your goals. Alinity s is Abbott’s next-generation harmonized system purpose-built for blood and plasma screening. Together with AlinIQ, our innovative professional services and informatics enablers, Alinity s has the power to transform your operations, helping you achieve measurably better healthcare performance.

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Oocrates said, “The secret of change is to focus all of your energy not on fighting the old but on building the new.”

It’s challenging enough to ring in a new year — there are resolutions to be met, like getting in shape; there are adaptations to be made, like writing the new year on checks (remember checks?), and there are reconciliations to be made, like filing taxes for the previous year. But 2020 is not just a new year, it’s a brand-new decade, a broad, open doorway of opportunity. We are taking stock of what that means for PPTA.

For us, the new decade began on a bittersweet note. The bitter news was the tragic loss of a dear friend and colleague, Dr. Fabrizio Fabbrizzi, who passed away as the year turned. (See remembrance on page 22). If you were honored to have known Fabrizio, you were privy to his Renaissance knowledge of a myriad of subjects, with an equal measure of passion for medicine, science, antiquities, history, fashion, gastronomy, and the arts. The contributions he made to our industry, and to the patients we serve, are immeasurable, and his departure leaves us at once deeply saddened and utterly grateful for having known him.

The sweet we find is the promise that a new decade brings for PPTA to renew our commitment to our mission: to promote the availability of and access to safe and effective plasma-derived medicinal products (PDMPs) for patients around the world.

As a small organization, it’s essential that we’re strategic and focused. The three pillars of our strategy are collecting enough plasma to meet clinical need, establishing regulations that allow for the safe but flexible oversight of therapies and their journey from raw material to finished product, and, finally, ensuring patients’ ability to access these lifesaving therapies.

In order to collect enough plasma to meet clinical patient need, we will focus our energies on educating stakeholders and decision-makers about the prerequisite for plasma to meet the needs of patients around the world. We will challenge institutional barriers and long-held beliefs that have stifled collection. We are committed to joining other stakeholders in an “all of the above” approach to the collection of blood and plasma, whether compensated, uncompensated, or recovered. After all, we share the same goal — ensuring the donor experience is positive and meeting the clinical needs of patients. Our efforts must be complementary, not adversarial, to make certain that shared goal is met.

On the regulatory front, the new decade means a more rapidly changing landscape that will improve treatment paradigms for patients. PPTA is dedicated to continuous engagement with regulators in making sure vigilance and timeliness are constant themes in delivering safe and effective medicines to patients. We will work closely with stakeholders to ensure the newest and best methods for evaluating therapies are understood and accepted by regulators.

Finally, we know that treatments, whether new or stalwart, can be challenging for patients to access because of payer exclusions, restrictions, denials, etc. PDMPs occupy a unique area of health care, and PPTA will fight to ensure decision-makers understand this distinction. Nearly 60% of the costs of these therapies lies in the precious raw material that is human plasma. One plasma donor at a time, the raw material is collected and processed in an exquisitely complex journey that takes seven to 12 months to produce a finished therapy. From start to finish, our companies are custodians of that process and are thereby intrinsically linked to both donors and patients.

Because of the unique narrative of PPT manufacturers, and the fact that these therapies serve patients who live with rare diseases, we must join hands with stakeholders across the spectrum to advocate for access to these lifesaving therapies.

PPTA is invigorated by the prospect of a new decade and a renewed commitment to our mission. We look forward to a sunny future filled with promise for those we serve.

Amy Efantis, President & CEO, PPTA
Despite regulatory approval in 1968 for the human use of Rh(D) immune globulin to prevent Rh disease of the fetus and newborn, Rh disease still occurs in many parts of the world. During the past 50 years, Rh(D) immune globulin has been approximately 99% effective at preventing Rh disease when women receive the drug both antepartum and postpartum.\(^1\) As a result, Rh disease has virtually disappeared from Western Europe, Canada, the United States, and Australia. Nonetheless, Rh disease remains prevalent in other parts of the world, leading to hundreds of thousands of families affected by repeated miscarriages, stillbirths, and neonates with hyperbilirubinemia-related adverse outcomes.\(^4\) The most severe of these outcomes is acute bilirubin encephalopathy and kernicterus spectrum disorder, which can result in death, cerebral palsy, auditory spectrum disorders, and developmental delay.\(^5\)
Although highly effective prophylaxis exists to prevent Rh disease, a lack of awareness, education, resources, and access to appropriate care have perpetuated the global burden of this disease. For example, it is estimated that approximately 50% of the pregnant women around the world who need Rh(D) immune globulin do not receive it, amounting to roughly 2.5 million women each year. To address the continuing challenges of Rh disease, a new, multidisciplinary organization was founded in 2019: the Worldwide Initiative for Rh Disease Eradication (WIRhE).

WIRhE aims to eradicate Rh disease by “connecting the world to protect mothers and babies.” To this end, the intention is to encourage, enable, and empower the efforts of diverse groups of individuals and organizations; to serve as a clearinghouse for cooperative and collaborative projects; to provide a centralized source of information about Rh disease for patients, physicians, and health care organizations; and to advocate for affordable access to Rh(D) immune globulin. WIRhE has partnered with relevant organizations to achieve these goals, including various academic health care organizations, nongovernmental organizations (NGOs), governmental representatives, regional health care professionals, patient advocacy groups, and industry — the latter to provide Rh(D) immune globulin and point-of-care blood typing tests. In addition, WIRhE is endorsed by the AABB (formerly the American Association of Blood Banks), the International Society of Blood Transfusion (ISBT), and the International Federation of Gynecology and Obstetrics (FIGO).

WIRhE held its first symposium in the fall of 2019 where participants from 21 countries, 15 medical associations, and eight NGOs discussed the current state of Rh disease in their communities and strategies for improvement. The symposium revealed several themes afflicting many geographic locations. First, there is a lack of information about the prevalence of the Rh(D)-negative blood type in many populations, particularly when comparing various tribal, racial, and ethnic subgroups. Second, the availability and affordability of Rh(D) immune globulin varies widely throughout the world. Third, an international consensus guideline is needed, in multiple languages, to facilitate provider education and standardize care with recommendations commensurate with the economic status of the country of interest. Finally, fragmented health care systems often result in delays in care, and, in some instances, prohibit care by trained health care professionals.

Preventing Rh disease requires both blood group testing and the administration of Rh(D) immune globulin. Because great variability exists throughout the world in the treatment and prevention of this disease, WIRhE aims to build the connections needed to standardize care. The barriers to prevention stem from multiple issues, including the lack of an international consensus treatment guideline in multiple languages, problems with drug availability and affordability, lack of recognition and/or prioritization by governments or health authorities, and lack of provider and patient awareness. Success in eradicating Rh disease will require multidisciplinary teams and multidisciplinary approaches to address the unique circumstances that impede care in specific locales around the world.

WIRhE’s short-term goals include the creation of a resource webpage (www.wirhe.org) available in multiple languages and a Twitter feed (@WIRhE_Org) to provide education about the disease and the consensus treatment guidelines, educational tools for public outreach, such as videos and posters, and website links to multiple local initiatives. WIRhE hopes to expand the number of industry partners through engagement with multiple Rh(D) immune globulin and point-of-care blood typing test manufacturers. Through collaborations with NGOs, professional societies, and academic investigators, WIRhE aims to facilitate pilot projects to identify sustainable and scalable solutions. Through these efforts, WIRhE ultimately hopes to eliminate the unnecessary suffering experienced by women, children, and families affected by Rh disease of the fetus and newborn.

References:
WHO ACTION FRAMEWORK:
A STEP IN THE RIGHT DIRECTION

BY DOMINIKA MISZTELA, SENIOR DIRECTOR, REGULATORY POLICY EUROPE, PPTA
On February 27, 2020, the World Health Organization (WHO) launched its “WHO Action Framework to Advance Universal Access to Quality and Safe Blood and Blood Components for Transfusion and Plasma-Derived Medicinal Products 2019-2023” (WHO Action Framework) at its headquarters in Geneva. This follows a public consultation on the framework document held from July to September 2019.

BACKGROUND
The WHO Action Framework resulted after calls for action from various stakeholders to improve blood and blood product quality, safety, and availability in WHO regions and countries. Multiple World Health Assembly resolutions since 1975 have recognized that availability of and access to safe and adequate blood and blood components represent an integral part of every country’s national health care policy and infrastructure. However progress in many WHO regions has been slow due to gaps in policy, governance and financing, insufficient collection and access, and deficiencies in control measures. According to the most recent 2016 WHO Global Status Report on Blood Safety and Availability, vast differences exist between the different WHO regions, as well as within the regions themselves, and there is a marked difference in the level of access to blood and blood components between low- and high-income countries. Over the past few decades, countries in the European Union and the United States have put in place well-functioning, quality blood collection systems and regulations; the inadequacies are most obvious in low- and middle-income countries.

The WHO Action Framework aligns with the 13th WHO General Programme of Work 2019-2023 and the WHO Strategic Plan for WHO Regulatory Support Activities for Health Products (2019-2023). It is based on the implementation of a series of national, regional, and international resolutions and activities and is aligned with the United Nations’ Sustainable Development Goals.

WHO’S STRATEGIC OBJECTIVES AND ACTION POINTS TO ASSURE ACCESS TO PDMPs — PPTA’s VIEW
The current WHO Action Framework is comprised of six strategic objectives, each one designed to improve universal access to quality and safe blood and blood components for transfusion and plasma-derived medicinal products (PDMPs).

These strategic objectives are:
1. Adequate leadership and governance of the national blood system;
2. Functioning blood services ensure efficient, safe, and quality blood and blood components for transfusion and plasma-derived medicinal products;
3. Appropriate clinical use of blood is ensured to improve patient outcomes and patient safety;
4. Blood regulatory bodies and control laboratories are available and have the capacity to regulate and assess blood products and associated medical devices, including in vitro diagnostic devices for blood screening;
5. A functional surveillance system is in place to monitor and assess the blood system, including adverse reactions in blood donors and patients; and
6. Achievement of key priorities through effective collaboration and information exchange.

The current efforts by WHO are commendable. However, PPTA considers that these recommended strategies will not be sufficient to ensure access to safe and efficacious PDMPs unless two key actions are taken by WHO:
1. Delineation of specific strategies and actions to promote and support quality and economically sustainable plasmapheresis programs at a national level; and
2. Recognition and acknowledgment of important differences between labile blood components and PDMPs at various levels, including specific legislation and policies to address sourcing (donor selection, testing), manufacturing, and quality control, as well as distribution. A crucial component is the recognition of the global nature of plasma and the need for global sufficiency and sourcing as opposed to national sufficiency recommended by WHO.

PPTA thus recommends that these are specifically considered in the current proposed strategic objectives:

Strategic objective 1: Adequate leadership and governance of the national blood system
The WHO recommendation to implement national blood regulatory systems across the regions is certainly an important step. However, the need for a separate plasma regulatory framework that highlights the differences between plasma for transfusion and plasma for manufacturing use is a must.
Strategic objective 2: Functioning blood services ensure efficient, safe, and quality blood and blood components for transfusion and plasma-derived medicinal products

In relation to achieving this, WHO states that “a functioning blood service requires the availability of quality and safe blood products for clinical use and sufficient blood donations from voluntary, non-remunerated donors ...” and further suggests that this can be achieved through “100% voluntary, non-remunerated blood donation and increasing the volume and quality of recovered plasma for manufacturing of PDMPs.”

Experience and data clearly demonstrate that the current clinical need for certain PDMPs cannot be met by relying on recovered plasma and voluntary and non-remunerated (uncompensated) donations. WHO needs to recognize the contributions of both the public and private sectors to ensure the adequate collection of plasma for manufacturing use.

Strategic objective 3: Appropriate clinical use of blood is ensured to improve patient outcomes and patient safety

PPTA urges WHO to extend its partnership and collaboration beyond blood for transfusion and include entities and stakeholders with relevant and proven expertise in plasmapheresis and manufacturing of PDMPs. In addition, PPTA recommends WHO draw from already published recommendations on the appropriate clinical use of blood and blood components, such as the Wildbad Kreuth Initiative.

Strategic objective 4: Blood regulatory bodies and control laboratories are available and have the capacity to regulate and assess blood products and associated medical devices, including in vitro diagnostic devices for blood screening

PPTA recommends that information exchange is sought and best practices are adopted from well-established, mature regulatory bodies.

Strategic objective 5: A functional surveillance system is in place to monitor and assess the blood system, including adverse reactions in blood donors and patients

PPTA applauds WHO efforts in this area and considers the WHO Global Database on Blood Availability and Safety an important tool to ensure adequate action is taken to protect the health of future donors and patients. Equally, PPTA and its member companies are committed to assuring patient and donor health and safety. To monitor donor safety, PPTA has undertaken a series of donor health initiatives, including establishing its own PlasmaVigilance (hemovigilance) system. PPTA urges WHO to extend its collaboration and exchange of information to stakeholders with proven expertise in plasmapheresis practice.

Strategic objective 6: Achievement of key priorities through effective collaboration and information exchange

PPTA agrees with WHO that “the overall goal of universal access to safe and quality blood and blood components can only be achieved through effective collaboration and information exchange between WHO, Member States, and a wide network of relevant stakeholders and partner organizations.” As stated previously, PPTA encourages WHO’s engagement with stakeholders with relevant and proven expertise in plasmapheresis and manufacturing of PDMPs.

CONCLUSIONS

PPTA considers that the WHO Action Framework represents an important step by WHO in assuring safety and availability of PDMPs. However, certain key actions specific to plasma and PDMPs need to be considered. To support the Action Framework, PPTA appreciates the opportunity to further engage with WHO in a constructive dialogue and exchange information and expertise in plasmapheresis and manufacturing of PDMPs.

References:
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Upon assignment of PPTA, Vintura made an assessment of the key economic and value considerations of plasma-derived medicinal products (PDMPs) in Europe and developed a White Paper (“EU White Paper”) to better communicate these findings with policymakers. Vintura is a leading consultancy company specializing in health care and life sciences.

This EU White Paper aims to analyze and demonstrate the unique nature and value of PDMPs across clinical, economic, and societal dimensions and focuses on improving Patient Access. The objectives of the EU White Paper are to:

• Create an understanding of the unique value of PDMPs with policymakers, payers, and other decision-makers;
• Create awareness on the needs and solutions to ensure a balanced global sufficiency of plasma; and,
• Decrease inequalities and ensure patient access to safe and effective PDMPs.

“For severe and rare diseases with high patient burden of disease [such as primary immunodeficiency (PID) and hemophilia], the standard measure of cost-effectiveness is often not as meaningful as other endpoints. PDMPs’ potential to recover large number of DALYs [disability-adjusted life years] and at the same time save substantial indirect costs are quite compelling arguments, both from the patient perspective and healthcare ecosystem viewpoint: both are supporting PDMPs’ socioeconomic value.” — Prof. Dr. Lieven Annemans
VALUE PROPOSITION
PDMPs are often the only and/or most effective therapies for the aforementioned conditions, preventing premature death, minimizing disabilities, and promoting patients’ quality of life. Since the introduction of immune globulins, patient survival rates for those living with common variable immune deficiency have increased from 30% in 1979 to an almost normal life expectancy for patients without disease-related complications. In turn, clotting factors have profoundly extended the life expectancy of patients with severe hemophilia A from 19 years pre-1955 to 71 years in 2001. These therapies have consistently achieved significant clinical results against primary endpoints (e.g., 80% reduction in bleeds for hemophilia patients and more than 65% reduction in infections for patients with immune deficiencies). These results positively impact patients’ socioeconomic activity and psychological well-being. They also have a much broader societal and economic benefit: comparing the time before and after the introduction of PDMPs for PID and hemophilia in Europe, treatments have yielded a combined health value gain (the magnitude of the socioeconomic impact of PDMP treatments) of 2 billion euros/year. For PIDs, this is approximately 1 billion euros/year (based on a PID population of 44,000). For severe hemophilia, the figure is at least 1 Billion EUR/year (based on a severe hemophilia population of 47,000). In addition to the health value gains, these treatments can also prevent indirect health care costs in the range of 1.1 billion euros/year and 1.6 billion euros/year. Limiting access to PDMPs often equates with denying patients’ access to the only effective therapy and reduces the concomitant socioeconomic benefits.

CHALLENGES
Formal Patient Access: In Europe, many PDMP treatments are not reimbursed or are only reimbursed for narrowly defined eligible patient populations, resulting in unacceptable inequalities geographically among patients in Europe. IgGs for PIDs are consistently reimbursed, but this is not the case for the same therapeutic class in relation to secondary immunodeficiencies. In many countries, PDMP treatments, such as FX, FXIII, and Protein C, are entirely omitted from reimbursement lists. When PDMPs are reimbursed, patients often face additional economic challenges, including reimbursement issues, the consequences of external reference pricing (ERP model) and/or cost-containment measures such as clawback or payback taxes. Although several countries have lifted, deferred, or reduced application of these taxes in recognition of PDMPs’ unique value, nature, and availability risks, there remain many others that continue to apply them. PDMP manufacturing costs are high and difficult to reduce. Thus the continued cost-containment measures that threaten the already fragile balance of the PDMP industry structure, ultimately limit Formal Patient Access.

Therapeutic Patient Access: Access to optimal treatment is under pressure, particularly from procurement practices such as tendering, where the decision is based on price alone. Tenders can be effective in controlling reimbursement budgets, but they are only appropriate if differences between medicines are negligible (when medicines are bioequivalent). However, this is not the case with PDMPs; they cannot be considered interchangeable because they are not required to prove bioequivalence (unlike generics or biosimilar medicines). Different brands within the same PDMP class have different tolerability profiles. Switching between them for economic reasons rather than clinical need can have adverse effects on patients. Availability of only a single

PDMP brand of each class means not only that physicians will need to switch existing patients’ therapies but also that they will have no choice of customizing naive patients’ treatment regimens, e.g., choosing between differentiated brand properties and routes of administration. When a procurement system contravenes the clinical guidelines and therapeutic need, this system may require adjustments to better serve the patients.

Product Availability: Plasma is a gift from healthy donors. Plasma collection policies and collection volumes directly impact the amount of PDMPs produced. In Europe, availability of source plasma is extremely uneven: Just four countries contribute more than 55% of the total amount of plasma collected in Europe for manufacturing. Additionally, the plasma volume collected in Europe fulfills only around 63% of the European PDMP clinical need; the rest is imported from the United States. It is challenging to attract enough plasma donors in Europe to meet the clinical need for patients. Source plasma donors face greater inconveniences and expenses than whole blood donors, so it is difficult to maintain the necessary donation volumes. Also, in Europe there are fewer plasmapheresis centers than blood collection centers, and the plasmapheresis process takes significantly longer and is more burdensome. In recognition of these factors, the four countries collecting the most plasma per capita have allowed a system of monetary compensation for the donors’ inconvenience and expenses, which has proven to be singularly effective. Since the growing clinical need for PDMPs is a global phenomenon, without an increased European contribution in plasma collection, there is a high risk of falling short of meeting patients’ clinical needs.

RECOMMENDATIONS

The PDMP ecosystem is in a fragile balance as it depends on many variables: often uncertain volumes of donations, complex regulations, strict safety procedures, and lengthy manufacturing processes. Additionally, heterogenous reimbursement across Europe and varied economic measures may further impact its current stability. These challenges negatively impact the end goal of optimal Patient Access and require multi-stakeholder solutions. These four actions demand the most urgent attention from all stakeholders:

1. **Apply effective measures, in collaboration with private industry, to promote and grow plasma donations across Europe to fulfill the clinical need for PDMPs. These measures include:**
   a. Establishing dedicated plasma collection (plasmapheresis) programs and outreach campaigns directed toward plasma donors in all EU Member States.
   b. Permitting the co-existence of public and private sector-owned plasma collection centers.
   c. Allowing compensation for donors’ expenses and inconvenience related to donation.

These items should be implemented and addressed in the most appropriate policy frameworks at the EU Member States level or at the EU level.
2. Ensure the broadest possible reimbursement coverage for all eligible patients to maximize clinical and socioeconomic benefits.

3. Optimize reimbursement policies, considering Value-Based Pricing such as value informed, affordable pricing models, and revise cost-containment measures to maintain the PDMP industry’s sustainability and improve equitable access to treatment for patients in Europe.

4. Revise and align procurement practices with clinical needs to ensure the right treatment for the right patient.

With a strong partnership and open trust-based dialogue among industry, policymakers, patients, and other health care stakeholders, these solutions can be achieved.

“Key Economic and Value Considerations for Plasma-Derived Medicinal Products (PDMPs) in Europe” was authored by:

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Prof. Dr. Lieven Annemans is Senior Professor at the Faculty of Medicine at Ghent University, Belgium, specializing in the economics of health and wellbeing, and is also an external expert to Vintura. He is the former president of ISPOR (International Society of Pharmacoeconomics and Outcomes Research) and was previously adviser to the Belgian Minister of Health, chair of the National Health Council, as well as president of the Flemish Health Council.

He has twice received the Francqui Chair, a Belgian award for academic excellence. He has published more than 300 papers and four books on health economics, among which the newest “Health Economics for Non-Economists: An Introduction to the Concepts, Methods and Pitfalls of Health Economic Evaluations” (Pelckmans Pro, 2018).

Prof. Dr. Annemans was advisor to the Belgian Minister of Health from 2001 to 2003 and president of the Flemish health council from 2003 to 2009.

Prof. Marcin Czech is the head of the Department of Pharmacoeconomics and a professor at the Institute of Mother and Child in Warsaw; a professor and postgraduate course director at Business School, Warsaw University of Technology; President-elect of ISPOR, Poland Chapter; and, former Undersecretary of State/Vice Minister at the Ministry of Health (Poland).

References:
5. Vintura Analysis

Please visit www.vintura.com/en/life-science-consulting/publications/ to download a complete copy of the White Paper “Key Economic and Value Considerations for Plasma-Derived Medicinal Products (PDMPs) in Europe.”
When I was elected earlier this year to lead the Plasma Protein Therapeutics Association’s (PPTA) Global Board of Directors, I was equally honored and humbled.

PPTA’s focus on patients and ensuring they have access to innovative therapies — made possible through the generosity of plasma donors — is very much aligned with the values of my company, CSL Behring, where I’ve been fortunate to spend most of my career.

Through my work, I’ve had the privilege of meeting many donors and patients over the years, and listening to their stories is a highlight of my job. I met a donor at our Knoxville, Tennessee center who has been donating weekly for more than 10 years. In talking to him, I learned that during his first donation ever, he met a patient who relied on plasma therapies. He told me that being able to connect with that patient was all he needed for motivation to return regularly.

There’s also Dee, an alpha-1 antitrypsin deficiency patient, who became a patient advocate for CSL Behring after her own diagnosis so she could help empower others to navigate the everyday challenges that come with having a genetic disorder.

These interactions always leave me feeling grateful, inspired, and motivated. I’m grateful that our donors are so willing to take time out of their day to selflessly help others. I’m inspired that our patients are so resilient in their personal battles against serious and rare diseases. And I’m motivated knowing we’re not only working for today’s patients but also for patients of the future who may not yet have a diagnosis.

To be certain, the work we do is not a choice. It is a moral imperative for our industry to continue to drive scientific innovation and enable access to critical therapies so we can help improve the lives of even more patients and, by extension, their loved ones. They are undoubtedly counting on us, and they deserve nothing less.

Since becoming the head of the PPTA Global Board just a couple of months ago, many of my coworkers have stopped me in the halls at work, and PPTA members I’ve known for years through my involvement with the Association have messaged me with words of encouragement and congratulatory sentiments.

But they also want answers. Understandably my colleagues’ well wishes quickly turn into pointed, albeit polite, inquiries. What is my vision for the future of the plasma protein industry? Where will I focus my initial efforts? How do we balance the cost of innovation while ensuring donor safety and satisfying patient need?
Undoubtedly, we are facing some seemingly daunting challenges that are ever-evolving. But with those challenges come incredible opportunities to join together as an industry and collaborate on behalf of our donors and our patients.

Here are four areas where I know we can have a meaningful impact on the future of our industry and — by leading change together — ultimately make a difference in the health outcomes of the millions of patients who depend on us.

1. **Addressing availability challenges.** As an Association, we must ensure our therapies are readily available to patients. This requires strengthening relationships and having productive conversations with government agencies related to how plasma is collected and transformed into therapies, and especially how new technologies can improve our ability to serve patient needs.

2. **Ensuring patient access.** One-size-fits-all reimbursement models can be especially harmful to the plasma industry, limiting our ability to drive scientific innovation and to ensure adequate access to therapies. We must continue to have meaningful conversations with policymakers globally to ensure they understand the value of our therapies and the challenges of developing and delivering them to patients. These innovations have the potential to be life-changing but only if patients have access.

3. **Advocating in Europe.** We must continue our strong advocacy efforts in Europe as regulators there prepare to undertake a review of the EU Blood Directive. This creates an opportunity for a productive, science-based discussion to ensure an optimal framework for plasma therapies and patient care in the EU.

4. **Working in and with China.** By partnering with stakeholders in China, there is a great opportunity for PPTA to develop a five-year strategy that charts a clear path forward for improving the environment for plasma collection, regulation, and access in Asia’s largest market.

As many of PPTA’s member companies focus on their respective strategies for a new decade ahead, these areas of focus for the Association are not meant to be a final, comprehensive list. I’m looking forward to working with all of our members during my three-year term as Global Board Chair so we can share perspectives, solve problems, and begin to write our industry’s important next chapter together for patients and donors alike.

---

**NAME:**
Karen Etchberger

**NEW ROLE:**
Chair, PPTA Global Board of Directors

**MEMBER COMPANY:**
CSL Behring

**CURRENT TITLE:**
Head of Digital Transformation & Execution Systems

**NUMBER OF CSL EMPLOYEES WORLDWIDE:**
25,000+

**NUMBER OF CSL PLASMA CENTERS:**
230+ across North America and Europe

**YEARS IN THE INDUSTRY:**
28

**EDUCATION:**
University of Maine, Ph.D., Immunology and Virology; Earlham College, Bachelor’s degree, Biology

**FAVORITE PART OF SERVING AS CHAIR:**
“Having the opportunity to meet our donors and patients always drives home why the work we do matters. Thanks to the generosity of our donors, I’m grateful to be able to work in an industry that makes a difference in the lives of so many patients and their loved ones.”
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The newspaper ad reads “U on PrEP?” A U.S. government website shows the plan for ending the HIV (human immunodeficiency virus) epidemic that began in America in the 1980s with this important starting point: “Prevent new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs.” The underlying premise is that U=U or undetectable=untransmittable. The HIV Medicine Association on its website endorses the U=U consensus statement “that when a person living with HIV has an undetectable viral load, they will not transmit HIV.” Supporting this is a quote from Anthony S. Fauci, M.D., the famed virologist from the U.S. National Institutes of Health (NIH): “The body of scientific evidence to date has established that there is effectively no risk of sexual transmission of HIV when the partner living with HIV has a durably undetectable viral load, validating the U=U message of HIV treatment as prevention.” The treatment leading to the undetectable viral load is known as ARV (anti-retroviral therapy). PrEP is used by HIV-negative individuals who are engaging in sexual practices that might put them at risk for acquiring HIV, whereas ARV is treatment taken by individuals who are HIV-positive to eradicate the virus. In both cases, it is felt that U=U applies, i.e., that undetectable virus means untransmittable by sexual acts.

This would all appear to be a great public health success. Why then should there be a concern for blood safety? Unfortunately, undetectable does not mean untransmittable by blood transfusion. The message that it is safe for HIV-infected individuals and individuals at high risk for HIV infection to participate in sexual activities previously known to transmit the disease could be misinterpreted to mean it is safe for them to donate blood or plasma. This concern was confirmed in a paper at the 2019 AABB meeting delivered by Brian Custer, Ph.D., from the Vitalant Research Institute in San Francisco, showing that individuals who are HIV-positive and taking ARVs are donating blood. This could be because such individuals 1) assume that safety for sex equates to safety for donation and/or 2) inaccurately assess their viral load status, stating they are virally suppressed when biomarkers fail to confirm that status, as shown in a recent study in the journal AIDS.

U=U (UNDETECTABLE=UNTRANSMITTABLE): A THREAT TO BLOOD SAFETY?

BY TOBY L. SIMON, M.D., SENIOR MEDICAL DIRECTOR, CSL PLASMA
Beyond the issue of individuals donating who should be deferred based on risk status is the issue of the accuracy of the blood virus screening tests for those using these drugs. It is possible that enough virus could be present to transmit infection by transfusion but be below the detection limits of the nucleic acid amplification (NAT) assays used for blood and plasma donor screening. It is also possible use of the ARV drugs could delay seroconversion (HIV serology turning positive). Thus, we could have a situation in which the utility of both the serology and NAT testing are compromised.

It is not surprising that the U.S. Food and Drug Administration (FDA) has become concerned about these possibilities and, on December 20, 2019, issued a statement warning individuals who ever tested positive for HIV not to donate blood. The statement does not take into consideration high-risk individuals on PrEP, although it seems reasonable to consider the potential danger from donations from both individuals on PrEP engaging in high-risk sexual activities and individuals who have tested positive for HIV but who have suppressed their viral load by ARVs.

The concern for blood safety has also led to action by AABB. The organization is currently considering adding PrEP and ARVs to the medication list for deferral and asking a specific question on the donor history questionnaire as well. This is after more than a year of considering the issue and gathering input from public health officials.

How should the plasma industry react? Our situation is different than the whole blood transfusion industry since our products are subject to pathogen inactivation and removal processes during manufacture of plasma-derived therapies. We are confident these processes would likely result in safe products, even if a donated unit of plasma with low virus levels is included in the manufacturing pool. However if there were more donations with low levels of virus, it might require revision of risk assessments routinely performed for regulatory agencies and of concern to patient groups.

Indeed, the findings of some of the ongoing research would seem to have implications for our testing laboratories. In 1998, Lee et al. in the research laboratory of Michael S. Busch, M.D., Ph.D., now director of Vitalant Research Laboratories, showed that higher levels of HIV-1 were detected in platelets than in plasma. A determination that detection of low levels of HIV in donations requires testing of whole blood rather than plasma could have implications for testing of our plasma donations. An article in AIDS in 2017 showed that PrEP use delayed seroconversion. There was also an article in Clinical Infectious Diseases in 2016 showing that initiation of anti-retroviral therapy during acute HIV infection leads to a high rate of non-reactive HIV serology. Another study in the Journal of Infectious Diseases in 2019 showed that donors found to be serology positive, but NAT negative, were on ARV. These data could result in a push for still more sensitive test systems which could lead to significant changes in our laboratory operations.

In the U.S., more research on this issue is underway with ongoing efforts by the NIH and FDA to assess the safety of the blood supply with shorter donor deferral periods for males who have sex with males (MSM) or alternative deferral schemes for high-risk behavior. Different countries have taken different approaches to deferral of MSM donors, and there is no current global consensus. At this time, the source plasma industry needs to carefully follow these developments, assess the need for any action, and work to anticipate any disruption to our current testing practices.

References:
1. www.HIV.gov
2. www.HIVMA.org

The author gratefully acknowledges Michael S. Busch, M.D., Ph.D., from Vitalant Research Institute for sharing a recent presentation and other materials. The views expressed are those of the author and may not represent the views of CSL Plasma and its affiliates.
Stakeholders Join Together in Portugal

BY AMY EFANTIS, PRESIDENT & CEO, PPTA

As we move through our day to day lives, we sometimes lose sight of the perspectives of others, even when we share a common goal. That is why the act of coming together in community is so vital to our common goals, in this case, the availability of plasma and plasma protein therapies to serve the patients who need them.

The Platform of Plasma Protein Users, or PLUS, held its Stakeholders Consensus Conference in Portugal at the end of January. The charming seaside town of Estoril kindly provided a breathtaking backdrop for the gathering.

The assembly was small but diverse. In attendance were patients, providers, key opinion leaders, donor representatives, members of the blood community, and PPTA representing the plasma industry. The meeting opened by reviewing the principles adopted at last year’s meeting — and the actions taken in 2019 to deliver those principles to pivotal audiences, including the European Parliament.

We learned about the latest data and trends in the plasma market from the Marketing Research Bureau (MRB). The overall conclusion from MRB was not surprising — Europe needs to collect more plasma to meet the clinical needs of patients.

To that end, the group discussed the ongoing work related to the EU Blood Directive and shared perspectives on how to improve and increase collection in Europe. The group also spent time learning about current and foreseen treatment challenges to patient access in different disease states, including primary immune deficiency, hemophilia, alpha-1 antitrypsin deficiency, Guillain-Barré syndrome, and chronic inflammatory demyelinating polyneuropathy.

As an exercise, attendees considered hypothetical situations in which Europe might face a crisis of plasma availability. At the conclusion, it was decided that the group will work cooperatively to develop a strategic plan that will hopefully never need to be used but that will allow for a ready response if necessary.

Though there was some disagreement on how to move forward to achieve the goals, we all agreed that increased collection of plasma for therapies to serve patient need is our shared goal. If our future efforts continue to reflect that shared goal, we will see positive developments in the years to come.
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In Memoriam: Fabrizio Fabbrizzi
APRIL 10, 1955–JANUARY 2, 2020

BY THOMAS R. KREIL, PH.D., ASSOCIATE PROFESSOR OF VIROLOGY; VICE PRESIDENT, GLOBAL PATHOGEN SAFETY, TAKEDA &
DOMINIKA MISZTELA, SENIOR DIRECTOR, REGULATORY POLICY EUROPE, PPTA
ON BEHALF OF PPTA’S PATHOGEN SAFETY STEERING COMMITTEE

On January 2, 2020, PPTA’s Pathogen Safety Steering Committee (PSSC) lost one of its longest-standing and most endearing members, an exceptional colleague, and to many also a very dear friend: Fabrizio Fabbrizzi.

Fabrizio was active in several PPTA industry committees for well over two decades, and together with Elisa Moretti, he represented Kedrion on PPTA’s industry expert committee on global pathogen safety issues for most of that time.

Fabrizio’s contribution to the work of the PSSC on pathogen safety and risk reduction measures of plasma protein therapies has been considerable and spanned a wide range of topics and issues over the years. As part of the PSSC, he contributed to the publication of three industry data collections in the form of scientific, peer-reviewed articles in Transfusion, specifically on the capacity of certain plasma product manufacturing steps for prion removal, the contribution of the cold ethanol fractionation to virus removal, and the effective virus inactivation by solvent/detergent treatments. The fourth in the series of the PSSC publications with Fabrizio’s contribution describes the generic effectiveness of nanofiltration in removing viruses and thus contributing to the safety margins of plasma protein therapeutics and was submitted to Transfusion in November 2019. (See PPTA Group Publications on page 24).

In the words of his Kedrion colleague Elisa Moretti: “Among the most evident and well-known traits, Fabrizio’s generosity in sharing with us his boundless knowledge,
Because of his medical training, he was often able to present genuinely liked and cared about people. Observing his passion and his desire to communicate our commitment to guarantee vital and safe products for our patients has been for me, as I think for many others, a source of inspiration. Fabrizio was both a colleague and a friend; he was a guide for many of us. Fabrizio will be missed!

Another PSSC member describes Fabrizio as a “Renaissance man:”

“He was known as a physician and scientist, but he had so many other interests, including people. His ability to engage with others in a way that was warm and intense, making you feel like you were the only one in the room, made him a favorite of all. Among his passions were the opera and shopping. At most meeting venues, you could spot Fabrizio with shopping bags on his arms and tickets for the local opera in his hand.

“The time he hosted a PSSC meeting in his lovely home built on the city wall surrounding the center of Lucca was epic. The meeting itself was productive and well-planned. Fabrizio ensured that the meeting setup was as business-like as any office or hotel meeting room. But by hosting the event in his home, Fabrizio also revealed more of his interests and talents. His home has a “wow!” factor from an architectural and historical view. The “wow” extended to Fabrizio’s engagement in his home. When complimented on the window treatments, he admitted that he had made them. When an antique sofa and chair were mentioned — yes, he found them at a bargain and had re-upholstered them himself. His unique marble bathroom — he had designed it and supervised the construction. After the meeting ended, he fed the group with a dinner that he had planned and prepared in advance. His talents extended to the after-dinner toasts with limoncello that, yes, Fabrizio had made. For many reasons, this is a most memorable PSSC meeting, not the least of which were the efforts that Fabrizio made to ensure that the meeting was effective and that the experience was special.”

It is difficult to dissociate the personal component from the professional relationship many colleagues had with Fabrizio. As another industry collaborator had put it:

“It was one of Fabrizio’s many qualities and a very endearing one: In the first instance, before addressing any professional topics or issues, Fabrizio always wanted to know how I am, how those close to me are, listening intently, providing encouragement and discussing. He was very personal, empathic, and he genuinely liked and cared about people.”

His opinions were valued and listened to by the PSSC. Because of his medical training, he was often able to present a different angle on the sometimes rather dry and, at least in appearance, “isolated” subjects covered in the committee’s work. Fabrizio still saw patients in his “spare time” next to his other duties because it kept him grounded and he just liked it (according to his own words). The PSSC valued his knowledge and the ability to immediately link our work to possible patient and health impact. His message was always delivered with passion, intensity, and enthusiasm, often also with a great deal of emotion and outspokenness on issues that he felt strongly about.

In 2017 and 2018, Fabrizio and the PSSC chair worked with PPTA on possible impacts of an EU-wide restriction, driven by environmental concerns over its use, of a chemical routinely used for virus inactivation in manufacturing of plasma-derived proteins, Triton X-100. Solvent-detergent (S/D) treatment for virus inactivation, often involving Triton X-100, was developed during the 1980s, after the “HIV crisis” and was key in assuring the pathogen safety margins of plasma-derived therapies against blood-borne viruses. Since then, it has become the gold standard for eliminating the risk of transmission of lipid-enveloped viruses, such as human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV), from plasma-derived medicinal products (PDMPs). Subsequently Triton X-100 has been increasingly implemented also in the production of other human and animal cell-derived medicines. Although alternatives for Triton X-100 have been identified in the meantime, it remains crucial for the production of many PDMPs and is the only viral safety used in the production of S/D-treated plasma, a pathogen-reduced version of fresh-frozen plasma (FFP), which has been developed to reduce the potential risks associated with the use of non-pathogen reduced FFP.

The work on Triton X-100 was part of a much broader industry initiative involving seven other European pharmaceutical industry associations and spanned activities for more than two years. It led PPTA to advocate with key stakeholders involved in the restriction, including national regulatory agencies, the World Health Organization, the EU Commission, a live-streamed discussion in the European Parliament Committee on the Environment, Public Health and Food Safety, as well as the European Medicines Agency and the European Chemicals Agency, ultimately showing our stakeholders how valuable Triton X-100 is for our industry and that certain provisions will be necessary to assure an appropriate phasing out of the agent only after the development of alternatives has been accomplished.
“Working with Fabrizio on many different topics across a large number of years, his passion for just doing the right thing for the patients we serve will certainly stick with me. Beyond his love of life — in a very broad and deeply cultivated way, as well as his genuine liking of people — made him a very special colleague — who will be sorely missed.”

From this, and earlier collaborative projects, another colleague remembers:

“Working with Fabrizio on many different topics across a large number of years, his passion for just doing the right thing for the patients we serve will certainly stick with me. Beyond his love of life — in a very broad and deeply cultivated way, as well as his genuine liking of people — made him a very special colleague — who will be sorely missed.”

Fabrizio’s last official engagement for PPTA prior to his passing was in one of the many other roles he held in addition to his positions at Kedrion: As an enthusiastic and unstoppable advocate for the use of albumin. As chair of the Albumin Task Force, he presented on the clinical use and efficacy of albumin in emergency settings, such as cardiac surgery, acute liver injury, sepsis, septic shock, and liver cirrhosis, during the 2019 Plasma Protein Industry Summit in Shanghai, China, in September. Albumin is currently the only plasma protein that can be imported into China, due to restrictions placed by Article 49 regulation.

In the words of one PSSC member: “He just left us too soon.”

One of us still keeps the last correspondence with Fabrizio: “I am relaxed and ready to fight against the disease. I will do my best!”

We all miss our friend and colleague, an excellent scientist and a doctor!

**INPUT FROM PPTA STAFF**

Larisa Červenaková  
Mary Gustafson  
Dominika Misztela

**PPTA GROUP PUBLICATIONS**


**SHARED SENTIMENTS FROM PPTA PSSC MEMBERS**

Thomas R. Kreil, chair (Takeda)  
Rodrigo Gajardo (Grifols)  
John More (BPL)  
Elisa Moretti (Kedrion)  
Gerhard Poelsler (Biotest)  
Peter Roberts (BPL)  
Nathan J. Roth (CSL Behring)  
Toby L. Simon (CSL Plasma)  
Eleonora Widmer (CSL Behring)
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When my daughter, Ella, was very young, we started noticing a lot of bruises all over her body. Over the course of three years as our family moved and siblings were added, we asked three different pediatricians multiple times if there might be something wrong.

The doctors all said Ella was “just an active kid.” Finally, when she turned 7, the bruises and nightly bleeding on her pillow from her gums and nose just could not be ignored, and we finally found a pediatrician who would listen.

I remember getting a phone call from Physician Assistant Susan Amster that fall morning. She told me to go get Ella at school right away. She said her platelets were so low there must have been a mistake in the test. I hastily ran to school and took Ella for a recheck. Sure enough — still very low. We were immediately referred to a specialist at Yale School of Medicine, and after a very scary week ruling out other causes, Ella was diagnosed with idiopathic thrombocytopenic purpura.

The doctors told us Ella would have to receive a medication called immunoglobulin through an IV. This medicine would prevent Ella’s body from attacking its own platelets for a little while. They told us most kids only have to get it one or two times, and the body just “resets” on its own. We figured life would go back to normal in a few months.

Just a few days later, we drove to the Yale infusion center and Ella spent the first — of what would become many — days hooked up to her IV.

We’ve since learned that Ella does best on intravenous immunoglobulin (IVIg) with a premed cocktail of steroids, Benadryl, Tylenol, and Zofran and that a slower infusion helps with the post-infusion migraine she gets a few days later. IVIg is very successful for her and boosts Ella’s platelets way up into the 250K range for a few weeks before she starts to taper off again until, by week seven or eight, she’s back down to her normal range of 5-10K platelets.

Ella has always been an incredibly wise and mature child, and she always seemed to know getting her IVs was something she just had to endure. She was a model patient. It wasn’t until she got a little older that she told us she thought the medical equipment was scary-looking and that she often felt afraid to look up at the big bags of medicine and think, “That has to go inside of me? All of it?”

We adults focus so much on the getting the IV part (and with good reason!), but we forget that the entire experience can cause fear and anxiety for kids.
So in fifth grade Ella took matters into her own hands. Ella had to create an invention as part of a school project, and the kids were encouraged to think of a problem unique to them. At that time, although she was now a “pro” at getting IVs and had grown used to her IV bags, she hadn’t forgotten how scary the big bags of medicine had been for her, and so she started thinking of ways she could hide them. She cut up a stuffed animal and removed the stuffing. Using a hot glue gun, she made a mesh sleeve on the back. She now had a cute little pouch to slip her bottles of IVIg into and no longer had to look at them all day long during infusions.

Ella’s invention was a hit with her nurses, and while she had success at the local and regional level of an invention competition, she did not advance further. But now the idea was firmly lodged in her brain, and Ella, being Ella, didn’t let it go. In sixth grade, she researched how to write a business plan and drafted a multi-page document that included graphs and cost analysis. She made a marketing video and pitched her idea to a local philanthropist, who gave some advice and encouraged her to keep going.

In spring 2019, with Ella in just seventh grade, we were able to start a company, receive 501(c)3 nonprofit status, file for a patent, and place our first order of 2,000 Medi Teddys! We have already given away Medi Teddys to children and charities in 23 countries and 46 states. We have had several large charities purchase Medi Teddys to help us in our endeavor and have also received two grants to assist us in giving away Medi Teddys to children. We have purchased another 2,000 Medi Teddys but they are going fast!

We know we have only scratched the surface. There are hundreds of hospitals — thousands worldwide — that still have not received any. The feedback from children and parents has been so positive. Medi Teddys really do provide a friendly, familiar face during a scary time and children are reporting real comfort from their special friend.

Ella has endured so much over the past six years. Dozens of blood draws and IVs, missing days of school, post-infusion migraines, missing special trips and activities due to low platelets ... and she just never complains. In so many ways, I think this whole experience has given her confidence and a sense of accomplishment so important to a young girl — especially one who struggles with chronic illness.

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Meet the PPTA Staff:
Timothy Swope
MANAGER, GOVERNMENT RELATIONS

How long have you been with PPTA?
I have been with the Association since May, 2019.

What do you focus on in your role as Manager, Government Relations?
My main objective is advocating for access to plasma protein therapeutics. This includes meeting with congressional staff, organizing the PPTA Fly-In, and leading the International Plasma Awareness Week (IPAW) activities in the U.S.

Tell us about your background.
I have more than 10 years of experience in health care policy. My health care policy career began with nearly five years at the Personalized Medicine Coalition. I also worked with patient advocacy organizations at FasterCures. Before joining the Association, I spent four years with the Bipartisan Policy Center as a senior policy analyst focused on health innovation.

What is your proudest professional achievement?
When 21st Century Cures was signed into law in December 2016, it was the culmination of three years of policy negotiations. At the Bipartisan Policy Center, I had the privilege of working on technical assistance for the Senate Health Education Labor and Pensions Committee on the Cures legislation in 2015. Many of the recommendations I worked on were included in the final Cures bill. I am very proud to have worked extensively on a legislative package designed to improve the discovery, development, and delivery of medicines to patients. The Cures bill ultimately gained sweeping bipartisan support in both the House of Representatives and the Senate.

What is most rewarding about working in this industry?
The plasma protein industry, and the patients whom we serve, are truly unique. It is fulfilling to advocate for an industry whose products have such clear value to patients in improving their quality of life.

What do you see as your biggest challenge?
There is a two-fold challenge in the current political environment for the larger biotechnology industry. First, it is sometimes difficult for policymakers to understand why the plasma protein industry is different. Second, and even more important, it is a challenge to gain policymaker champions for the plasma protein industry who are willing to exclude the sector from policies which could hinder access.

Despite the challenges, I am encouraged by speaking with policymakers and staff because the goals of their policies are not to harm our industry or the patients dependent on it. The dialogue is more about limiting unintended consequences of policy proposals.

What characteristic do you most admire in others?
I am inspired by the perseverance of others, an unwillingness to take “no” for an answer.

Who’s been an inspiration to you in your life?
My 99-year-old grandmother has been an inspiration in her character, courage, and commitment. A lifetime learner herself, she instilled in her five children the importance of education. I strive to live by her personal motto, “no complaints.”
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**April**

17
World Hemophilia Day

22 – 29
World Primary Immunodeficiencies (PI) Week 2020

29 – May 1
World Orphan Drug Congress

**May**

6 – 9
41st American Society for Apheresis (ASFA) Annual Meeting

Austin, Texas, United States

13 – 14
International Plasma and Fractionation Association (IPFA)/Paul-Ehrlich-Institut (PEI) International Workshop on Surveillance and Screening of Blood-borne Pathogens

Porto, Portugal

14 – 17
5th Hereditary Angioedema (HAE) Global Conference 2020

Frankfurt, Germany

**June**

6 – 10
36th International Congress of the International Society of Blood Transfusion (ISBT)

Barcelona, Spain

14 – 17
World Federation of Hemophilia (WFH) 2020 World Congress

Kuala Lumpur, Malaysia

24 – 25
2020 Parenteral Drug Association (PDA) Global Conference

Brussels, Belgium

26 – 28
29th Annual Alpha-1 Foundation National Conference

Dallas, United States

**July**

31 –
Platelet Disorder Support Association (PDSA)

August 2
National Patient Conference

Seattle, United States

**August**

6 – 8
National Hemophilia Foundation’s (NHF) Bleeding Disorders Conference 2020

Atlanta, United States

**September**

1 – 3
Parenteral Drug Industry (PDI) Congress

Beijing, China

**October**

1 – 3
Guillain-Barré Syndrome|Chronic Inflammatory Demyelinating Polyneuropathy (GBS|CIDP) Foundation International Symposium

Alexandria, Virginia, United States

3 – 6
AABB Annual Meeting

Baltimore, United States

5 – 9
International Plasma Awareness Week (IPAW)

August 2
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