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These statements are those of the author and do not necessarily reflect the opinion of PPTA or its members.

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In My View

BY JAN M. BULT, PPTA PRESIDENT & CEO

While I am waiting in Barcelona, Spain for my six-hour delayed flight back to Washington, D.C., there is time to reflect on things happening throughout the world. From the roof of my hotel, I see the calm Mediterranean Sea on one side and the Sagrada Familia on the other side. Looking at this incredible manifestation of architectural beauty, you see one of the spectacular buildings that Antoni Gaudi has left as his legacy in this beautiful city. Only two days ago there were about half a million people protesting the police actions in response to calls for independence in Catalonia. I am not going into the politics or making a statement about who is right or wrong. The only point I want to make is that a lot of taxpayer money is used to deal with political unrest. Money that could be used differently.

During this weekend, I read about other places where there is unrest that is also threatening to so many people. Just think of Myanmar, Syria, the Korean peninsula, and many other areas of social and political unrest. A lot of taxpayer money is used to deal with these conflicts. Money that could be used differently.

Then we see unrest in Europe as a result of other political factors such as Brexit. A lot of taxpayer money will be used to deal with the consequences. Money that could be use differently.

Other examples of questionable use of taxpayer money includes the expensive monthly moving caravan to bring all members of the European Parliament and their documentation from Brussels to Strasbourg and back.

Month after month. Money that could be used differently.

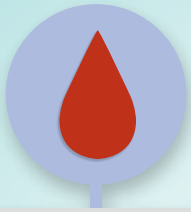
Another recent example is what happened in the Netherlands. After more than six months of negotiations, a new Cabinet was formed. One of the decisions of the new government was to rename the “Department of Safety and Justice” to “Department of Justice and Safety.” Now all letterheads, name cards, envelopes, email addresses and more needed to be changed for many millions, paid for by taxpayer money. Money that could be used differently.

The only good thing about these examples is that there will be an end to it. Nothing will last forever.

The sad thing is that persons with genetic disorders are in the middle of this. They don’t ask for their diseases, they ask for a cure and hope for a normal life. It is very difficult to understand why so much taxpayer money is spent to deal with questionable decision-making. It would be so much better if that money could be used differently.

I will stay away from the political debate and instead focus on helping patients in different parts of the world to have unlimited access to lifesaving plasma protein therapies. The costs for the therapies we deal with only represent 2 percent of the total costs for medication used in the world. The therapies are truly different than the traditional therapeutics made by Big Pharma. Though we are small in comparison, the enormous contribution made to the recipients of plasma protein therapies is the chance for a normal life. Taxpayer money could be much better spent to provide good care to patients, especially those with life-threatening, genetic conditions. ●

CROWDING OUT



THE COEXISTENCE OF COMPENSATED & NON-COMPENSATED DONATIONS

BY JOSHUA PENROD, VICE PRESIDENT,
SOURCE & INTERNATIONAL AFFAIRS

What happens to blood collection when plasma collection increases? What happens to a blood center when a plasma center opens nearby? These questions and others related to it have come up from time to time over the years. In recent discussions, it has come up more frequently—and with greater urgency. In 2016, PPTA member companies in the United States collected more than 38 million plasma donations, nearly quadruple what it had been a decade before.

Throughout the same period of time, the number of plasma collection centers has more than doubled, indicating that while the growth in the industry has been significant, the volume of source plasma collected per center has increased by an even greater rate.

All of this growth has occurred against the backdrop of concerns relating to compensated plasma collection and national self-sufficiency policies. These issues have been covered extensively elsewhere (Penrod, 2016¹; Taylor, 2014²). Some of the specific concerns about compensated donation include the effect that incentives have on donor motivation and potential related issues. Richard Titmuss also put this idea forward in *The Gift Relationship*; however, like so many claims alleged in that work, it was largely unsupported. Other works have also questioned the possibility of “crowding out” occurring, and still others have attempted to better understand the possibility of crowding out when it occurs.

The increasing quantity of plasma collected, and with such unanswered questions and worries articulated even in public policy and news articles, concern has been growing. A recent *New England Journal of Medicine* (NEJM) article indicated that declines in blood collection throughout the past several years have exceeded 25 percent, with a possibility that the declines will continue for at least several more years.³ The authors suggest that the reasons behind the declines, at least in the U.S., have been due to a handful of different factors, including changes in surgical practice and blood-management strategies, among others. The authors argue that the business impacts of the trends of less blood usage are also combined with a strain on blood systems with low reimbursement rates, escalating regulatory costs due to more stringent requirements, and more general health care industry pressures. The article depicts deep public health concerns regarding these trends and the possible problems with it, and we should all share those concerns.

From the standpoint of plasma collection, it’s also important to address these concerns in the face of the increases in plasma collection mentioned earlier. The NEJM authors cite many factors that are increasing the level of challenge within the realm of blood collection in the United States. It may be instructive to look at other countries for their experiences as well.

In the Czech Republic, the Ministry of Health keeps highly accurate records on plasma and blood collection within the country, dating back more than a decade. Using these data, we can see, over the span of 10 years, whether there appears to be an impact on blood collection or not.

Professors Mario Macis and Nico Lacetera, of Johns Hopkins University and the University of Toronto respectively, are in the process of analyzing data from the Czech Republic



As noted by the leadership of Canadian Blood Services, plasma products derived from compensated donors have excellent safety records, and the issue of compensation having any deleterious impact on safety is untrue.

and have offered some preliminary findings from a paper currently in progress.⁴ Profs. Macis and Lacetera assume the presence of three major types of donors: (1) donors who are motivated by economic incentives; (2) donors motivated by social image; and (3) donors who have a different range of motivations and may switch between types of donations (including the altruistically motivated plasma donor who might switch to donate blood in the presence of compensation for plasma). Some of the early results that the authors offer include:

- Blood collection numbers and rates have remained relatively stable over the past 10 years, with neither sharp upticks nor declines.
- This stability in blood collection has persisted despite the opening of 10 plasma collection centers between 2007 and 2010.
- This same stability in blood collection has persisted despite a dramatic increase in predominantly compensated source plasma collection during the same time frame, moving from 6.8/1000 donations per person in 2006 to 63.4/1000 donations per person in 2010.

The authors draw some conclusions from these preliminary results. First, there is little indication that compensation has had any effect on non-compensated donations in the Czech Republic. Second, these figures tend to underscore that donors of plasma and blood come largely from different populations. Lastly, donors have a mix of motivations; as the authors put it, “preferences for altruistic behavior might not be incompatible with preferences for monetary compensation.”

Some of the more prominent recent discussions on crowding out have occurred in several provinces in Canada. While much of the early rhetoric focused on the safety of compensated plasma, this contention is completely unsupported by evidence. As noted by the leadership of Canadian Blood Services, plasma products derived from compensated donors have excellent safety records, and the issue of compensation having any deleterious impact on safety is untrue.⁵

The argument instead turns to concerns regarding a potential crowding out. A recent survey conducted by Profs. Macis and Lacetera in Canada, presented at the American Enterprise Institute on October 20, indicates that more than 72 percent of the population in Canada is in favor of having compensated plasma donation in Canada.⁶ Naturally, these numbers are even higher when survey respondents are asked to consider the need for domestic sources of supply.

Doesn't this give an indication that crowding out would occur in Canada, given the supermajority of the population in favor of donor compensation? First, it is an indication that suggests perceptions about donor compensation are somehow "different" in Canada than they are in a number of other countries in the world are false. Second, the percentages of those in favor of compensated donation done in the United States is only somewhat higher, meaning donors who currently donate in Canada are likely *already* aware of all of the marketing that occurs regarding the importance of blood donation. Any effect of crowding out would seem to be already a part of the numbers. This is further emphasized by the *direct* experience in other countries, which indicates that the donor populations are different, and largely separate.

As another measure of misplaced policy priorities, Canada has national legislation that prohibits payment or advertising of payment for human eggs or sperm. Called the Canadian Assisted Human Reproduction Act of 2004, the legislation has essentially forced importation of gamete cells from donation centers outside of Canada (e.g., the United States.) While some

donors do, in fact, donate for non-monetary reasons, fertility clinics (and hopeful parents) in Canada are generally reliant on importation of the necessary means from the United States. One example of several consistent estimates is that Canada imports approximately 90 percent of sperm cells used by fertility clinics.⁷ Between this and the ongoing issues with compensated plasma donation in several provinces, it would seem to be evident that, rather than concerns about crowding out, Canadian policymakers should recognize that the status quo is crippling their own internal potential.

Given the clear concerns and stark reality involved in whole blood collection in many countries today, it is important to give consideration to public health dimensions of important resources such as availability of whole blood components. It is also important, however, to greet these concerns with evidence and critical thinking, rather than seeking to score political points. After all, patients rely on compensated plasma donation as well—even in territories, provinces, states, and countries where compensation is unlawful. We should all avoid any discussion that stigmatizes compensated donation; instead, we should simply thank *all* donors. ●

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For a better understanding, in the Czech Republic it is common practice to compensate whole blood or apheresis donors. Compensation of the private plasma sector is limited to 5 percent of the legal minimal wage (CZK 550 ~ 25 USD) and is distributed as a lump sum of donor's costs and time connected to the donation. Compensation from the public transfusion sector includes a day off work with full pay (CZK 3000 ~ 136 USD) or a personal income tax deduction (tax base of CZK 2000 ~90 USD). This is considered as a gift for medical purposes. A Czech specificity allows donors to choose which kind of compensation they want independent of where they donate.



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Planning for the Unexpected

BY SONIA BALBONI, ASSISTANT DIRECTOR, SOURCE & STANDARDS

At an industry event in 2011, former PPTA Source Board of Directors Chair, Shinji Wada (Grifols), introduced us to the Japanese term, “*Sou-Tei-Gai*,” which means “beyond what one expected, not foreseen.”¹

Every company has plans for business continuity to guarantee its operations run smoothly even when faced with unpredictable events. These past few months, the United States has faced California wildfires and two catastrophic hurricanes. Additionally, some plasma collectors have experienced an anticoagulant shortage. At the October Business Forum in Las Vegas, we asked members how they manage to ensure the availability of sufficient quality plasma, even when threatened with the most challenging of circumstances, whether it is a national disaster or a product shortage.

Charles Auger (Grifols) shared parts of his company’s business continuity strategy. For Grifols, it is not just about having a plan in place but also ensuring a safe and reliable supply of plasma is also part of the Grifols corporate philosophy. He pointed out that ensuring staff safety during and after an event was paramount. Mr. Auger added that he believes our industry will always be able to withstand events like the ones experienced this year due to a number of factors, including:

- Large geographic diversity provides inherent protection.
- Companies are prepared and resilient.
- Donors remain motivated and are agile.
- Expanding U.S. donor center network continues to shrink the risk.

Dr. Jan Hartmann (Haemonetics) maintained that business continuity planning is a key value driver to any industry, but especially for plasma protein therapies (PPTs). For Dr. Hartmann’s company, business continuity planning includes four main elements: quality and safety assurance; data security; sourcing and supply chain; and enabling the



CHARLES AUGER



DR. JAN HARTMANN



JAMIE SIELATYCKI



CHRISTIAN LEE



EDDIE KUBO

growing demand. Dr. Hartmann outlined the four principles of the Haemonetics approach, which include understanding continuous evolution, utilizing a cross-functional team, adopting a holistic view with third-party assessment, and leveraging people, processes, and technology.

For Jamie Sielatycski (HemaSource), helping customers ensure business continuity is key to his company's mission. For him, understanding the unique needs of our industry and individual customers is paramount. As with the other companies on the panel, redundancy and backup sources are critical to ensuring that we can be prepared for the unexpected. According to Mr. Sielatycski, a company should always consider the "what if?" when developing its plan.

Christian Lee (Abbott), reinforced messages regarding preparation and planning. Business interruptions have an effect on many different aspects of operations, including the reputation of a company and its brand. Prioritization and communication among suppliers, customers, and other partners are important components in business continuity.

Eddie Kubo (Fresenius Kabi) discussed business continuity planning from a supply perspective. For Mr. Kubo, transparency is essential. It is important to maintain regular communications with customers, suppliers, and other stakeholders and to keep customers informed as events unfold. Like others, Mr. Kubo stressed the importance of ensuring employee welfare. He noted that company employees are the frontline when it comes to preparing for an event as well as re-establishing and maintaining production after the event has occurred. He

Our members recognize the importance of ensuring business continuity, even under the most dire of circumstances, so that quality source plasma remains available for the manufacturing of safe and effective therapies to treat patients worldwide.

related his company's efforts during the recent hurricanes in Puerto Rico, where it maintains two production facilities.

The mission of the PPTA is to promote the availability of and access to safe and effective plasma protein therapeutics (PPTs) for all patients in the world. Our members recognize the importance of ensuring business continuity, even under the most dire of circumstances, so that quality source plasma remains available for the manufacturing of safe and effective therapies to treat patients worldwide.

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USAGE OF PLASMA PROTEINS *AROUND THE WORLD*

BY MATTHEW HOTCHKO, Ph.D., VICE PRESIDENT, RESEARCH, AT MARKETING RESEARCH BUREAU

The consumption of plasma products on a per capita basis varies greatly around the world, for numerous reasons. Still, there are commonalities among many places, and a clear trend toward greater usage is seen in most countries. This article focuses on the “core” three fractions: albumin, polyvalent immunoglobulin (IgG), and plasma-derived factor VIII, with emphasis on usage in China and other Asian countries.

Italy has the highest per capita albumin usage in the world with 684 grams per thousand inhabitants in 2014. Albumin is notably prescribed to cirrhotic patients, often monthly, with several units at a time. At the other end of the spectrum, countries such as India used only 19 grams per thousand people in 2015. In these countries, the lack of access to adequate health care, and the affordability of products, are key issues, compounded by lack of funding for plasma-derived drugs. China is close to the world’s average, with 232 grams per thousand inhabitants in 2016. This is higher than the United Kingdom and Switzerland, and not far below Germany. Given the population of China, this country is the largest albumin user in the world, representing roughly one-third global consumption, followed by the United States. However the indications for which albumin is prescribed differ somewhat in China and the United States. In the U.S., albumin is used primarily for cardiovascular surgery, sepsis/infections, and cirrhosis, in this order. In contrast, in China the top three indications of albumin are cancer (mostly lung and liver cancer), cirrhosis, and sepsis/infections, in this order.

In the past 12 years, albumin usage has grown

considerably, particularly in Asia: In China, albumin consumption increased 268 percent between 2003 and 2015 while usage jumped 370 percent in Indonesia and 198 percent in Malaysia. However albumin consumption only increased by 12 percent in Korea in 12 years, and in Japan, it decreased by 26 percent in that time. In Japan, the self-sufficiency policy restricted the market to only include the domestic manufacturers, constraining the albumin supply. In South Korea, the low price of albumin treatment has discouraged imported albumin, causing the market to grow slowly, as the supply was essentially from local recovered plasma.

Regarding IgG, the countries with the highest usage per capita are the United States, Australia, and Canada, each with more than 200 grams per thousand inhabitants. Many European countries report an average consumption ranging from 65 grams to 110 grams per thousand population, while the average usage levels in Asian countries are lower. For instance, the usage per capita in Indonesia is less than 1 gram per thousand inhabitants, and in China, 18. China uses much less IgG than European countries but more albumin, due to cultural and political reasons. Politically, the Chinese government embraces local manufacturing and sourcing policy for the supply of plasma-derived medicines but makes an exception for albumin, which may be imported from foreign companies. In contrast, IgG cannot be imported, and it is not as popular as albumin due to the cost and lower awareness. However IgG usage has increased significantly from 2003 to 2015 in China and several Asian countries: +317 percent in China, +286 percent in Indonesia—which started



level, and +151 percent in South Korea. In Japan the IgG consumption grew at a more modest 39 percent in 12 years or 2.8 percent per year because the self-sufficiency policy has restricted the supply, leading to lower consumption. IgG has been available in Japan since 1979, as in Europe and North America, and is prescribed for the same conditions as in Western countries: chronic inflammatory demyelinating polyneuropathy, primary immunodeficiency diseases, and chronic idiopathic thrombocytopenic purpura, as well as Kawasaki disease. In many emerging markets, IgG is mostly prescribed for acute conditions because the excessive cost of chronic treatment is beyond the means of patients and funding entities. In China, IgG is mainly used for serious bacterial infections, Kawasaki disease, and Guillain-Barré syndrome, all conditions that can be treated with only one or two infusions of IgG.

The consumption of plasma products on a per capita basis varies greatly around the world, for numerous reasons. Still, there are commonalities among many places, and a clear trend toward greater usage is seen in most countries.

With respect to factor VIII, Germany and the United States have the highest per capita consumption of plasma-derived and recombinant combined, at more than 9.0 international units (IU) per capita. Conversely, China has a very low average consumption of only 0.2 IU per capita (2016) because most domestic fractionators do not produce factor VIII and foreign plasma-derived factor cannot be imported. The Chinese government does allow the import of recombinant factor VIII products, but they cost more than plasma-derived products, limiting their usage to a minority of hemophilia A patients as there is no universal health insurance coverage in China. Consequently, prophylaxis is very low and many patients treating on demand do not have adequate access to coagulation factors. Given such low per capita usage, consumption in China has grown by an impressive rate of nearly 600 percent in the past 12 years, but much remains to be done to improve hemophilia care in the country. In other Asian countries, the consumption per capita of factor VIII has also grown significantly over the same time period, including Japan (+552 percent), South Korea (+254 percent), and Malaysia (+118 percent).

In almost all Asian countries, the consumption of the core plasma products (albumin, polyvalent Ig, and plasma-derived factor VIII) has consistently grown over the past 12 years. Exceptions are found in countries where strict self-sufficiency policies (Japan and South Korea) restricts patient access to the product. Still many differences exist between countries based on health care coverage, economic development, and government priorities, and much work remains to be done to close the gap. ●



China in the Spotlight

BY JULIA FABENS, MANAGER, INTERNATIONAL AFFAIRS

During the summer and fall of 2017, PPTA was extremely active on the China front, culminating in a weeklong visit to Beijing to co-host and host several important meetings and events.

CFDA GMP INSPECTOR TRAINING – SEPTEMBER 5

The China Food & Drug Administration (CFDA) conducted a daylong training session in Beijing for more than 120 new CFDA GMP inspectors from multiple provinces (31) and municipalities in China. PPTA Vice President, Global Regulatory Policy, Mary Gustafson, presented two modules covering regulations on plasma products in foreign countries and safety controls of plasma products. PPTA President & CEO Jan M. Bult presented a module on the global need for plasma.

The presentations were followed by a question-and-answer period. Senior officials in attendance asked questions, not the new inspectors. Topics of interest included lot/batch release, use of recovered plasma for fractionation, clinical trial requirements, use of nucleic acid testing, and justification of China's policy on quarantining (re-test the collection vs. hold in inventory).

The meeting was extraordinary in the sense that this was the first time that CFDA reached out to PPTA to share insights.

At the end of the meeting, the request was made to hold additional meetings with more in-depth discussions.

PLASMA PROTEIN INDUSTRY SUMMIT – SEPTEMBER 7-8

The Plasma Protein Industry Summit at the Parenteral Drug Industry Congress in Beijing gathered approximately 150 attendees. The Summit featured Chinese fractionators; PPTA members and staff; independent experts; and Chinese regulators. There was strong participation from domestic Chinese fractionation companies, with representatives from 15 local fractionators registered for the event. Representatives from two Chinese fractionation companies—Shanghai RAAS and Shangdong Taibang Biological—also gave presentations.

The first panel covered different aspects of manufacturing and collecting, offering valuable insights into best practices. The panel featured the following PPTA members: Roger Brinser, BioLife Plasma Services LP/Shire and Chair of the PPTA Source Board of Directors, discussed modern plasma collection; Charles Auger, Grifols Plasma Operations, reinforced the importance of quality systems; and Thomas R. Kreil, Shire, explored industry efforts in pathogen reduction and bovine spongiform encephalopathy/Variant Creutzfeldt-Jakob Disease. Additionally, Mr. Du

Xiangjun, a respected independent researcher, shared his suggestions for Chinese plasma collection centers, the majority of which focused on enhancing donor safety.

The second panel of the afternoon focused on standards. Joshua Penrod, PPTA Vice President Source & International Affairs, covered PPTA's voluntary standards program. Ms. Guo Zhongping from the Chinese Pharmacopoeia Commission discussed standards and the development plan for plasma protein products in the Chinese Pharmacopoeia. Her remarks were particularly timely in light of the ongoing revision of the China Pharmacopoeia, which will be released in 2020. She was pointedly critical of domestic industry in some areas and stressed that forthcoming GMPs will have a much stronger focus on safety. Dr. Hu Weibing of Shanghai RAAS discussed production management for blood products and shared his company's thinking on the future of high-tech and automated manufacturing.

The final panel of the afternoon addressed regulatory issues. PPTA's Mary Gustafson updated the audience on trends and new considerations in global regulatory policy. She was joined by Dr. Guo Xiuxia of the CFDA, who gave a regulatory update and discussed trends in plasma products in China, and Mr. Gao Xiuqiang, Director of the Division of Medical Safety and Blood of the National Health and Family Planning Commission, who spoke about regulatory policies for Chinese plasma collection centers. Additionally, Mr. Ma Shan of Shandong Taibang Biological gave an introduction of, and suggestions for, clinical trials of plasma products in China. The Chinese regulators were remarkably open in their remarks and noted there is room for improvement in some areas of the domestic industry, including donor health and safety.

The second day began with a panel on the profile of the plasma protein therapeutics industry. PPTA President & CEO Jan M. Bult covered the global footprint of the industry, and Matthew Hotchkko of the Marketing Research Bureau presented on global clinical usage, highlighting the clinical need for greater access to therapies in China. Professor Liu Zhong of the Institutes of Blood Transfusion of the Chinese Academy of Medical Sciences rounded out the panel with his thoughts on the current status of, and future prospects for, plasma protein therapies in China. Professor Liu made a point of mentioning that there is limited competition in the Chinese market and there are great gains to be made in better domestic plasma usage.

The last panel of the conference addressed clinical aspects of the industry. Dr. Fabrizio Fabbrizzi, a consultant for Kedrion, shared some exciting recent clinical data regarding albumin, which is the only plasma protein therapy currently allowed to be imported into China and is heavily utilized in the Chinese health care system. His remarks were followed by a discussion of the epidemiology, diagnosis, and treatment of primary immunodeficiency diseases by Professor Martin van Hagen of the Erasmus Medical Center in Rotterdam. For the final presentation, Sachi Satapathy of the World Federation of Hemophilia, gave a global snapshot of bleeding disorders.

The overall impression of the week was positive, both in terms of messages about the importance of donor and product safety, as well as the openness with which participants shared those messages. PPTA was pleased to give its members a platform to share their deep knowledge of domestic Chinese manufacturers, and we look forward to building on that cooperation going forward. ●

Speakers participating in the Clinical Aspects panel. (Left to right): Matthew Hotchkko (Marketing Research Bureau); Jan M. Bult (PPTA); Professor Martin van Hagen (Erasmus Medical Center in Rotterdam); Dr. Fabrizio Fabbrizzi (consultant for Kedrion); Sachi Satapathy (World Federation of Hemophilia)



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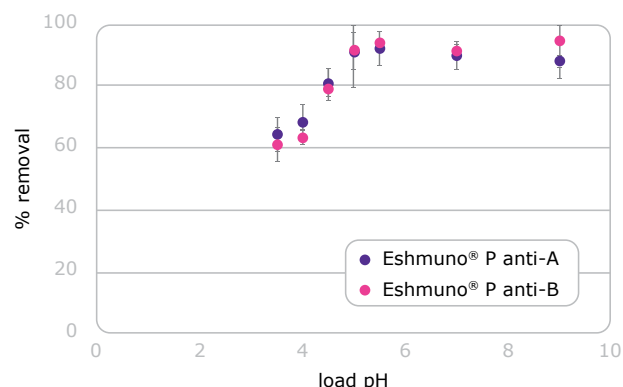


Figure 1. anti-A and anti-B % removal

References:

Kahwaji J et al. Acute Hemolysis After High-Dose Intravenous Immunoglobulin Therapy in Highly HLA Sensitized Patients. *Clin J Am Soc Nephrol* 2009; 4: 1993-1997.

Imboden M et al. Isoagglutinin reduction by a dedicated immunoaffinity chromatography step in the manufacturing process of human immunoglobulin products. *Transfusion* 2015; 55: 117-121.

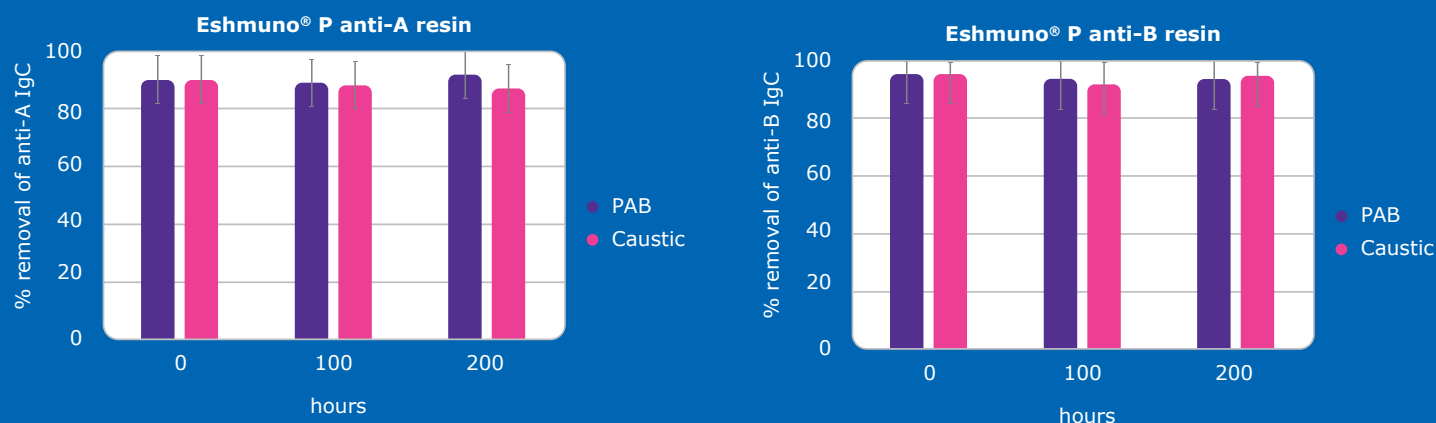


Figure 2a and 2b: Alkaline and acid resistance of Eshmuno® P anti-A and anti-B media.

New & robust performance assay for Eshmuno® P resins

The presence of antibodies to blood groups A and B, referred to as isoagglutinins, or anti-A and anti-B antibodies, can lead to hemolysis, which is a serious complication of intravenous immunoglobulin (IVIg) therapy.^(1,2) Typically, IVIg purification processes do not include a dedicated step to manage the levels of these isoagglutinins. To address this deficiency, the life science division of Merck KGaA, Darmstadt, Germany has developed products to effectively manage these isoagglutinins.

We offer two distinct affinity chromatography resins, Eshmuno® P anti-A and Eshmuno® P anti-B, designed to specifically remove the unwanted anti-A and anti-B antibodies, respectively. These resins allow customers to design the immunoglobulin purification processes with a primary goal of reducing patient risk through an additional chromatography operation. During this operation, anti-A and anti-B antibodies are bound to the Eshmuno® P resins, while the target immunoglobulins are collected in flow-through. This additional operation is intended to obtain a higher purity of immunoglobulins while minimizing the impact on process economics and providing operational flexibility.

One of the major challenges for consistently measuring the performance of affinity chromatography resins like Eshmuno® P is the availability of a

standard model molecule in its purest form. This is based on the fact that the anti-A or anti-B immunoglobulins are only present in trace levels in pooled plasma, and purification of these is typically not the focus of the process. Normally, the levels of anti-A and anti-B immunoglobulins are determined and characterized by agglutination assays. The same assays can be used to characterize the performance of Eshmuno® P resins in terms of reduction in titers. However, these assays are highly variable and rely on pools with varying titers. Consequently, performance of Eshmuno® P resins, measured in terms of reduction in isoagglutinin levels, could be impacted by the pool titers, and is therefore, subject to variabilities in the agglutination assay.

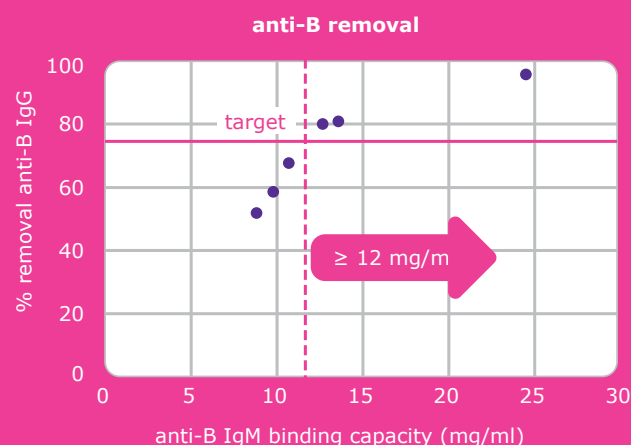
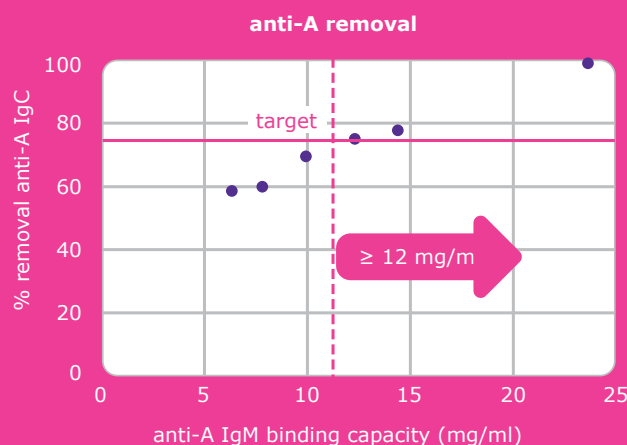
To reduce the variability in the measurement of the anti-A and anti-B titers, an assay was developed for the routine quality control testing of Eshmuno® P resins. The assay is highly simplified, and involves measuring the depletion of the anti-A or anti-B forms of IgM after incubation with respective Eshmuno® P resin using UV spectroscopy. The monoclonal anti-A or anti-B IgM are obtained in their purest form and at a known concentration by purification of cell culture.

The applicability of this method is confirmed by establishing a correlation between IgM binding capacity and

the ability to remove anti-A or anti-B immunoglobulin. A linear relationship is observed between the media's anti-A and anti-B IgM binding capacity and the ability to remove anti-A and anti-B IgG, respectively. Resins with IgM binding capacity of ≥ 12 mg/ml show higher than 75% removal in case of both anti-A and anti-B IgG. This is shown in figures 1 and 2 below. In essence, the anti-A and anti-B IgM molecules have been shown to be appropriate model molecules that are available in their purest form. Therefore, the test based on the binding of these to the respective resins offers a titer-independent method for consistently measuring performance of resins like Eshmuno® P.

References:

1. Kahwaji J et al. *Acute Hemolysis After High-Dose Intravenous Immunoglobulin Therapy in Highly HLA Sensitized Patients.* Clin J Am Soc Nephrol 2009; 4: 1993-1997.
2. Imboden M et al. *Isoagglutinin reduction by a dedicated immunoaffinity chromatography step in the manufacturing process of human immunoglobulin products.* Transfusion 2015; 55: 117-121.



Figures 1 and 2: anti-A and anti-B IgM Binding Capacity Correlation to % Removal



EU Commission Stakeholder Event: EVALUATION OF THE BLOOD, TISSUE, AND CELLS LEGISLATION

BY BRUNO SANTONI, EXECUTIVE DIRECTOR, EUROPE

The famous Italian adage « *chi va piano va sano* » (slowly but safely) might not be true when it comes to the modernization of the Blood Directive in Europe. Indeed, analyzing the blood and plasma sector takes a considerable amount of time for the EU Commission while patients are waiting for sustainable solutions for their future.

On Sept. 20, the EU Commission organized a stakeholder event gathering 206 participants, including 163 representatives from different organizations and 43 individual citizens. This meeting was an important step along the long road to evaluate the legislation in question as it allowed the different stakeholders to express positions and to participate in debates publicly.

After the opening of the event by Martin Seychell, Deputy Director General, DG-Santé, and the introduction to the evaluation by Anna-Eva Ampélas, Head of Unit, Medical Products, Quality, Safety and Innovation, Stefaan Van der Spiegel, Head of Sector, presented several key figures related to the different donations of Substances of Human Origin (SoHO). It was good news to see him mention specific EU collection figures for plasma for manufacturing (8 million liters). Indeed, this indicates an increased understanding of the importance of plasma protein therapies among EU Commission members

resulting from all the constructive exchanges that PPTA has had with them in recent years.

The meeting was divided into five sessions, each with four speakers who presented their views with only one slide and each session included a 40-minute debate with the audience.

The sessions addressed the following issues:

1. The key importance of donors—The gift of life
2. Regulatory oversight of the sectors—How to ensure safety and quality
3. Availability and sufficiency—Are patients getting the blood, tissues, and cells they need?
4. Legal consistency and coherence—Regulatory pathways for Substances of Human Origin
5. A changing world—Technological, societal, epidemiological, and international developments

PPTA was invited to present its views in Session Four, which again provided the opportunity to highlight that “ensuring

a high level of human health protection” (Art. 35 of the EU Charter of Fundamental Rights) involves the duty to protect patients. When developing recommendations on ethical aspects related to donation practices, several stakeholders (e.g., the Council of Europe in Strasbourg) too often forget to consider the specificities of the plasma donation process and the life-threatening conditions that affect the patients in need of plasma-derived medicinal products.

Johan Prevot, representing the Platform of Plasma Protein Users (PLUS), explained that the major current safety issue for patients is the risk of lack of supply of plasma-derived medicinal products. Indeed, in Europe more than 40 percent of plasma-derived medicinal products are made out of plasma collected in the United States and, at the same time, clinical needs are growing globally. Thus, it is time for the EU to encourage more efficient plasma collection practices (plasmapheresis) on a larger scale and to define “compensation” so such practice can be established more generally. Indeed, compensating donors for time and inconveniences, similar to the Tissue and Cell Directive (2004/23/EC), would allow the collection of much higher quantities of plasma. Alice Simonetti, from the International Federation of Blood Donor Organizations (IFBDO), made a remarkable new statement supporting the possibility to compensate certain donors. It is an important development to see more and more stakeholders understand a new system has to be put in place in the EU to ensure patients can get the treatments they need.

However, we have to see the reality, and there is still a long road before things can be changed in the EU. Several countries are not ready to vote for a change (e.g., France, Italy), and several stakeholders do not want to acknowledge the reality of a growing clinical need for plasma protein therapies, as expressed by some representatives during the meeting, to the point that

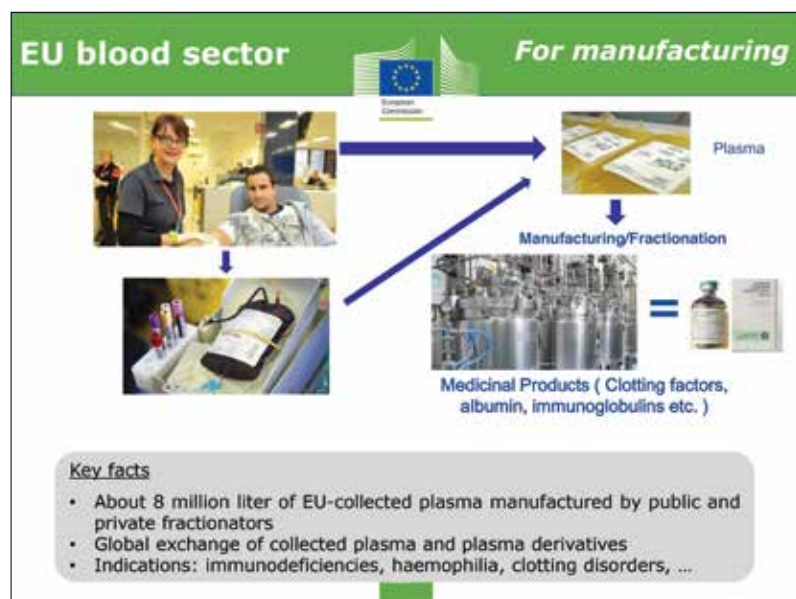
Laura Savini from the European Haemophilia Consortium (EHC) had to make an intervention referring to the scientific work done to evaluate the clinical usage of plasma proteins and to establish clinical guidance for their usage (e.g., Wildbad Kreuth recommendations). Ensuring that countries and the EU Parliament could approve some potential future changes to the legislation is quite a challenge. This will only be possible if countries have a clear understanding of the blood and plasma sectors and show an open-minded attitude. Public opinion will play a major role as well. Therefore, ongoing dialogue and education is essential; awareness about our sector is needed now more than ever.

The sectors related to the donations of SoHO are incredibly complex and contain political and technical elements that need to be reviewed or updated. At the same time, the public blood sector is redefining certain activities due to the decrease of blood usage (Patient Blood Management) while more plasma is needed in the world. For the EU Commission, understanding all these aspects in order to provide a modern legal framework is a huge amount of work for a limited staff. Andrzej Rys, Director, DG-Santé, confirmed at the end of the meeting that potential collaboration with external entities (e.g., World Health Organization, Council of Europe) is envisaged for some aspects but not yet decided. This is indeed risky if some of these stakeholders are not ready in their structure to have a robust and unbiased process to evaluate and propose recommendations.

PPTA company representatives actively participated in the debates during the meeting: Stephan Walsemann, M.D., Ph.D., (Chair, European Plasma Alliance; KEDPLASMA GmbH); Dr. Matthias Gessner (Shire AG); and Kristen Seidel, M.D. (CSL Plasma GmbH). They shared the sentiment that the industry

is available to engage in constructive dialogue for scientific questions or other issues where industry expertise would be valuable, as long as there is an official balanced process to include the input of the private industry.

As a final note, it is important to consider that the EU Commission is determining legislation that will be adapted on the basis of the added value the EU can bring. This is certainly the case for the blood and plasma sector, where standards and harmonization are key aspects, but the decision to review the Blood Directive (2002/98/EC) has not been taken yet. It was made apparent during the day that if there are improvements to be made, it will take quite a lot of time at the EU level. With all due respect for the evaluation process, patients and their families are hoping they will not reach a crisis situation in the coming years. We hope the same. ●



Source: EU Commission

The Ethical Perspective

AN INTERVIEW WITH
PETER JAWORSKI, Ph.D.

BY JOSHUA PENROD, VICE PRESIDENT,
SOURCE & INTERNATIONAL AFFAIRS



Professor Peter Jaworski of Georgetown University recently gave a Keynote Address to the audience at the 2017 PPTA Source Business Forum in Las Vegas. Professor Jaworski has a keen interest in compensated plasma donation, and we were able to sit down with him to explore some of his thoughts on the industry.

Q Tell me a little about yourself.

I'm Peter Jaworski, a member of the Ethics faculty in the Strategy, Ethics, Economics, and Public Policy area of the Georgetown University McDonough School of Business (Washington, D.C.). I received my Ph.D. in Applied Philosophy from Bowling Green State University (Ohio), hold an M.Sc. in Philosophy & Public Policy from the London School of Economics (United Kingdom), as well as an M.A. in Philosophy from the University of Waterloo (Canada). I've taught at Georgetown University, at the College of Wooster (Ohio), and was a Visiting Research Professor at Brown University's Political Theory Project (Rhode Island).

I spend most of my time researching and writing about the moral limits of markets, or "repugnant markets" as they are sometimes called. Recently, I've published a book with my colleague Jason Brennan titled "Markets without Limits: Moral Virtues and Commercial Interests." I'm also a Canadian, which explains my interest in compensating donors of blood plasma.

Q You've visited a plasma collection facility. What were your biggest takeaways?

There were a few big takeaways. First, I was impressed by how careful and respectful everyone was to the donors and the care the staff took when it came to the plasma. I didn't come in with any particular expectations about this, but it was striking.

And secondly, I appreciated the little things in that particular clinic that reminded everyone how they play a role in doing something truly remarkable and significant—saving lives and alleviating suffering.

There's a story about John F. Kennedy visiting NASA and meeting a janitor. Kennedy introduced himself and asked the janitor what his job was. The janitor is said to have responded, "Sir, I'm helping to put a man on the moon."

That's a really powerful story about how we understand not only what it is that we're doing at work, but also why we're busy doing it, and how meaningful it is to us. I spend a lot of time with my MBA students talking about how important it is for our jobs to not just be jobs, but to possess meaning beyond the money. The money matters, obviously, but you don't mop a floor with enthusiasm like the janitor did unless you feel part of something with real purpose and significance.

At this particular clinic, that message was often repeated and reinforced through the messaging on everything from the windows and mugs to a chart with little people that representing the number of lives donors at that clinic had saved so far. That will stick with me for a while, and I hope it makes people who work there and the donors who go there better understand that they are doing something just as, or maybe even more, important as putting a man on the moon.

Q You're from Ontario. What is your perspective on the ongoing debate in some provinces regarding compensated plasma donation?

My perspective is that I feel hopeful for the future, hopeful that good medical and empirical science and good arguments will win in the end. But simultaneously I feel a bit of shame and frustration as well. I'm hopeful because of the academic interactions that I've had with readers of my book, including critics and reviewers.

I'm also hopeful because of the work of economists and other social scientists, especially Mario Macis and Nico Lacetera but also Alvin Roth and economic sociologists like Kieran Healy and Viviana Zelizer, who consistently raise the standards for debates about commodification [treating something as a mere commodity] and the commercialization of blood and blood plasma, through the use of rigorous tools and methods.

So much of the discussion surrounding compensating donors is, in Canada anyway, stuck in the hunches and guesses of the 1980s, based on the science and technology of the 1980s, done in the shadow of the biggest medical disaster we've ever had—the tainted blood scandal of the 1980s. We have almost four decades of experience since then, with better studies, better tools, and better technology. We don't talk about highway safety by looking at the safety features of the Chevrolet Citation or the Nissan Leopard (both introduced in 1980), so why are we talking about plasma-derived therapeutics while thinking about the safety features and technologies in place in the 1980s?

As for why I feel shame: Ontario banned compensated plasma donation, but Ontario, like the rest of Canada, relies on plasma-derived therapeutics from the United States where, of course, you pay donors. It's amazing to me that this bit of hypocrisy doesn't inspire

shame in the members of Provincial Parliament who voted in favor of banning compensation while knowing full-well that we will continue to rely on a compensatory model for the security of our supply of plasma-derived therapeutics.

Q From your standpoint, why do people oppose donor compensation?

There are a number of reasons. The first one is some vague worry about “commodification.” Some things are sacred, some are profane. When you put a price tag on something sacred, you profane it with thoughts about material, impersonal, and fungible [mutually interchangeable] things. This is the weakest, but I think most often cited, objection to paying donors. It is weak because we pay teachers like me, and we don’t think that paying a teacher makes her no longer care about the intrinsic virtues of teaching. We also buy pets at pet stores, and yet care for them like members of our own family. There’s just no necessary connection between paying for something and profaning it.

Another worry has to do with selfish motivations. People think that you should give plasma with altruistic motives, not for selfish reasons like getting paid. But this one, too, is a weak argument. In response, I’d say that it’s much more important that lives be saved than that someone donates plasma with altruistic, rather than selfish, motivations. Morally speaking, it’s failing to see what matters more. And, separately, getting paid for something doesn’t mean you are incapable of acting from altruistic motives. Maybe money gets you in the door, but, as complicated as our psychology is, it is possible that saving lives plays a motivational role, too. Again, teachers get paid, but the teachers I know do it for the sake of future generations first, and the money second.

Some worry about empirical facts, like the safety of the donated plasma and the overall quantity of that plasma. The evidence appears to me to be pretty clear on the safety issue, and I think the standards, technologies, and procedures involved in modern-day plasma collection, modern-day donor screening, and modern-day techniques for virus deactivation and removal make plasma-derived therapeutics just as safe whether they come from paid or unpaid donors. Meanwhile, the economic studies I’ve seen on the matter decisively show that you get more plasma with economic incentives than without.

People think that you should give plasma with altruistic motives, not for selfish reasons like getting paid. But this one, too, is a weak argument. In response, I’d say that **it’s much more important that lives be saved than that someone donates plasma with altruistic, rather than selfish, motivations.**

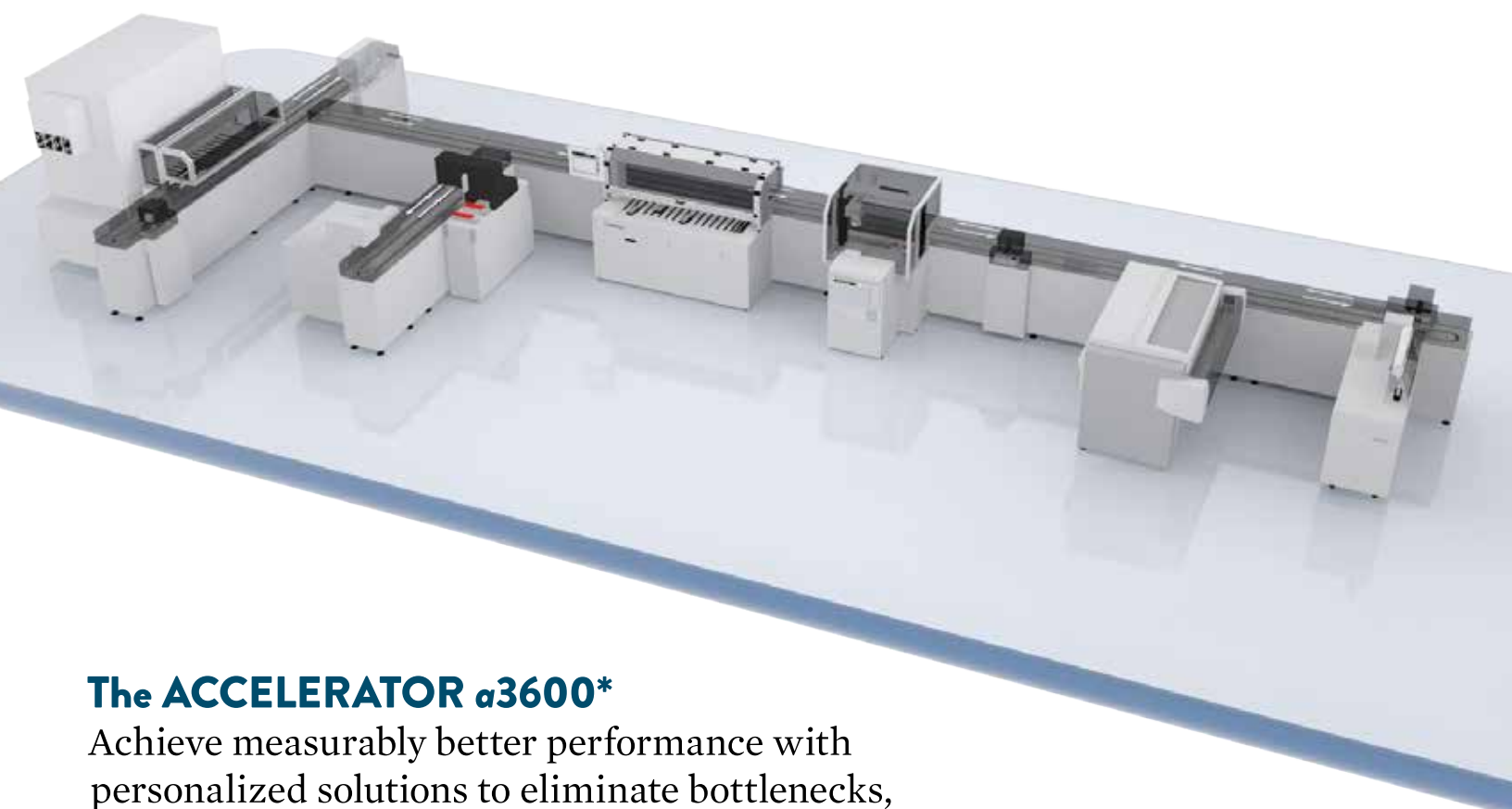
The last one is wrongful exploitation. The worry is that the poor and underprivileged donate plasma because of their poverty ... that they wouldn’t donate if they weren’t poor, and that we exploit their poverty to get our supply of therapeutics. I don’t find this argument compelling either. When Ontario banned compensated plasma donation, it didn’t replace that potential source of income with some alternative. All it did was remove an option for improving someone’s financial situation, someone who might now be stuck with even worse options. I just don’t see how that’s helpful. This worry would be more pressing if the pay [for donation] was low, the risks were high, and donors permanently lost something. But the pay is equal to or higher than \$15 per hour, the risks to the donor are negligible, and blood plasma regenerates. Rather than exploiting the poor, my view is that these clinics provide an additional option, and provide an opportunity for a hand up—all the while respecting the time and effort it takes to donate plasma, by compensating people for it.

Q If you could tell plasma donors one thing, what would it be?

This one’s easy: Thanks for your role in doing something as meaningful and important as putting a man on the moon: saving human lives. And if I were feeling cheeky, I’d add: On behalf of Canada, thank you for donating. Canadian lives depend on the therapeutics made from American blood plasma donors. •



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Inside PPTA

MEET THE PPTA STAFF

Mathew Gulick

DIRECTOR, GLOBAL COMMUNICATIONS



Q How long have you been with the Association?

I joined PPTA in October 2017 and was fortunate to meet many of our members at the Business Forum in Las Vegas.

Q What do you focus on in your role as Director of Global Communications?

I view communications as the primary route through which an organization tells its story and raises awareness of—and support for—its mission. As such, my role is to partner with all of our departments and offices to ensure PPTA develops and shares consistent messages across our various digital and print channels so our members, key partners, regulators, and the public all understand the unique and essential nature of plasma protein therapeutics.

Q Tell us about your background.

Immediately before joining PPTA, I led the communications, marketing, and public relations function for a regional nonprofit hospice provider in the Washington, D.C. area. Prior to that, I worked for several national and international trade associations, developing, implementing, and measuring the impact of communications plans that advanced their respective missions. In particular, while working with an international association within the food industry, my team and I developed a branded website and social media platform to build awareness of the safety of the ingredients the association's members use in foods and beverages, and we were able to counter some negative perceptions of our industry. By engaging with the public and providing factual content via our digital channels, we saw positive changes in the sentiment of news coverage about our work. I look forward to working with PPTA's

membership and staff to develop messages that support our mission to ensure the availability of plasma protein therapeutics worldwide.

Q What is most rewarding about working in this industry?

Ultimately, what I find most rewarding about working in this industry is the chance I have to help thousands of men, women, and children around the world lead normal lives by telling their stories and informing others of the unique nature of plasma protein therapies. These are relatively unknown medicines, yet their value to those who rely on them is immeasurable. In my short time with PPTA, I've seen many opportunities we have as an industry to build awareness of these lifesaving treatments and how our membership works every day to ensure patients have access to them.

Q What characteristic do you most admire in others?

I most admire authenticity and honesty in others.

Q Who's been an inspiration to you in your life?

My grandmother was one of the kindest and most gentle people I have been fortunate to know; she inspired me to find the positive in any situation and to seek the good in others. Despite being in poor health for the last few years of her life, she rarely complained about her various aches and pains and, instead, focused on ways to help herself and those around her to feel better. •

● Las Vegas Hosts PPTA Source Business Forum

PPTA Source members convened at the Business Forum on Oct. 19 in Las Vegas. Forum attendance reached a new high, surpassing last year's record. The program included notable talks and committee reports. The members received up-to-the-minute reports from Roger Brinser (Chair of the PPTA Source Board of Directors) and Jan M. Bult (PPTA President & CEO) on the industry's current environment, highlighting challenges and opportunities geographically, with regulatory bodies, and with communication efforts. Professor Peter Jaworski of the Georgetown University McDonough School of Business followed with a Keynote Address, which focused on the ethics of compensated plasma collection. Ensuing panels discussed public perception of the plasma collection industry, the uses of data in donor wellness, and the industry's environmental challenges and business continuity. The PPTA Source Board of Directors is considering the outcomes of this Business Forum and will shortly announce the date and place for the 2018 Business Forum.

NEW DIRECTORS OF THE PPTA SOURCE BOARD

The PPTA Source membership voted for the 2018-2020 Source Board of Directors while at the 2017 Business Forum. **PPTA would like to welcome two new members to the Source Board:**

- Jay Bae (GCAM)
- Bill Bees (Prometic Plasma Resources)

Other Board members re-elected are:

- Rudolf Meixner (Europlasma)
- Larry Moss (the Interstate Companies)
- David Morad (Southern Blood Services)
- Milan Maly (UNICA)

Source Board representatives of Global Members are: Chair, Roger Brinser (Shire), Ileana Carlisle (Biotest), Rob Jardeleza (BPL), Mike Deem (CSL), Shinji Wada (Grifols), and Paolo Melloni (Kedrion). ●

(From left to right): Bill Bees (Prometic Plasma Resources); Marilyn Rosa-Bray, M.D. (Grifols Plasma Operations); and Professor Peter Jaworski (Georgetown University)





● 2017 Robert W. Reilly Leadership Award Recipient: Marty Silver

PPTA congratulates the 2017 Robert W. Reilly Leadership Award winner: Marty Silver.

In 1973, Martin “Marty” Silver founded Life Resources as a broker of plasma and plasma products. Life Resources was the first independent plasma collection company to change from a manual collection system to an automated plasmapheresis process. The company was the first independent plasma producer to develop and implement its own comprehensive management information system.

During his tenure as President and Chief Executive Officer, Mr. Silver entered the source plasma market, opening his first plasma center in 1982 and building the company to 24 centers and more than 500 employees by 2002.

When Life Resources sold to the United Kingdom Department of Health in 2002, it changed its name to DCI Biologicals, Inc. This historical event was the first time the British government had purchased a private company outside of the UK. Mr. Silver was the President and CEO of DCI Biologicals and served in that capacity through 2006. He remained President through 2014, operating the 32 centers when DCI Biologicals was sold to Bio Products Laboratory; the centers are now operating as BPL Plasma.

Mr. Silver recently retired from the PPTA Source Board of Directors after more than 40 years in the plasma collection industry. We congratulate him for his industry success and his service to PPTA.

The Robert W. Reilly Leadership Award is named after the first Executive President of ABRA and a leader in the plasma collection industry. This award recognizes individuals for valuable contributions, achievements, and leadership on behalf of the source plasma collection industry. ●

PREVIOUS ROBERT W. REILLY LEADERSHIP AWARD RECIPIENTS

2016 — John Carlisle, Viropharma
2015 — Dr. Toby Simon, CSL Behring
2014 — Ileana Carlisle, Biotest Pharmaceuticals
2013 — Dr. Gerold Zerlauth, Baxter Healthcare SA
2011 — Dr. Donald Baker, Baxter/Retired
2010 — Ruedi Waeger, Talecris
2009 — Dr. Bernard Horowitz, Consultant
2008 — Peter Turner, CSL Behring
2007 — Jean-Marie Vlassembrouck, Baxter BioScience/BioLife

2006 — David J. Gury, NABI Biopharmaceuticals
2005 — Joseph Rosen, Baxter BioScience/BioLife
2004 — Dr. George Schreiber, Westat
2003 — S Tyrone Foster, Aventis Bio-Services
2002 — Richard Thomas, Bayer Corp
2001 — Victor Grifols Lucas, Grifols
2000 — Samuel Penninger Jr., Serologicals Corp
1999 — Jack Ryan, Bayer Corp
1998 — John Bacich, Baxter Healthcare Corp



● Fifth Annual IPAW Reaches New Heights on Social Media



INTERNATIONAL
PLASMA
AWARENESS WEEK
OCTOBER 8-14, 2017

Every year during International Plasma Awareness Week (IPAW), PPTA member companies, patients, and donors come

together to celebrate plasma donors, recognize the importance of Source plasma collection, and raise awareness for the rare disease patients treated by plasma protein therapies.

The starting material for plasma-derived therapies is a finite source; plasma-derived therapies are made from plasma donated by healthy, qualified donors who generously give their time to donate, which is necessary to manufacture lifesaving therapies that treat rare disease patients. Plasma donors are the foundation of the plasma protein therapeutics industry. Healthy and committed donors are paramount for preparing safe and effective therapies; plasma protein therapies would not exist without the generosity of donors, predominantly in the United States, Canada, Germany, Austria, the Czech Republic, and Hungary.

In recognition of IPAW, governors from 42 states and the District of Columbia issued proclamations recognizing the value of plasma protein therapies for treating rare, chronic conditions. Additionally, Rep. Doris Matsui (CA-6) submitted a statement into the Congressional Record. **In the statement, Rep. Matsui stated:**

"plasma-derived therapies save and improve lives of individuals throughout the world [and] have significantly improved the quality of life, markedly improved patient outcomes, and extended the life expectancy of individuals with rare, chronic diseases and conditions."

Rep. Matsui also highlighted that there are now more than 575 plasma collection centers in the United States that have earned the IQPP certification and asked her colleagues in the House of Representatives to stand to commemorate the start of IPAW. PPTA appreciates Rep. Matsui's support of the plasma protein therapeutics industry, and we look forward to continuing to work with her to protect patient access. PPTA is grateful for Rep. Matsui's continued and long-standing support of plasma donors who help to make orphan drugs that treat the rare disease community.

To continue building awareness about the importance of source plasma donation and the value of plasma protein therapies for rare disease patients, PPTA developed infographics and donor-focused graphics to be shared on social media. People across the world rallied on social media using #IPAW2017 to post information about plasma and plasma proteins, share their plasma donation experience, or to voice their appreciation for plasma donors. Even international footballer Cristiano Ronaldo joined the celebration and posted about IPAW on his various social media channels.

Each year, IPAW gains more recognition among policymakers, regulators, and the general public thanks to your support. Although IPAW lasts just seven days, PPTA would like to remind you to thank a plasma donor year-round! ●



● North America Social Media Platforms

Social media is pervasive in today's society. It is estimated that 81 percent of Americans have at least one social media account, while 67 percent of Americans report they get part of their news via social media. These platforms allow users to share thoughts and tell their stories, which can instantly reach around the world. Social media channels give businesses a novel way to interact with consumers and stakeholders. In fact, many people may not believe a company exists if it doesn't have a single social media account.

Earlier this year, stakeholders and member companies encouraged PPTA to develop its social media capabilities. These channels are a great way to enhance advocacy efforts and engage with patients, policymakers, and other stakeholders. For PPTA, social media can be an essential platform to tell the story of the unique nature and value of plasma protein therapies.

In October, the North America team launched three social media platforms: Facebook, Twitter, and LinkedIn. Each platform has distinct advantages and audiences: Facebook gives PPTA the ability to disseminate visual content, create a sense of community, and spark conversations among stakeholders; Twitter facilitates a steady stream of conversation and the ability to push out information quickly to followers; and LinkedIn allows PPTA to maintain a strong professional voice and become a trusted, branded partner.

PPTA'S SOCIAL MEDIA PLATFORMS' ROLE IN ADVOCACY

The role of social media in government relations has grown in recent years. Every member of Congress employs social media to communicate with constituents, and President Trump has tweeted more than 2,000 times since being sworn into office. It is imperative for PPTA to establish its social media footprint to




amplify our congressional advocacy efforts and to intensify our voice inside-the-beltway.

The initial messaging utilized current advocacy materials that demonstrate the value of plasma protein therapies and differentiate them from traditional pharmaceuticals. As the launch coincided with International Plasma Awareness Week (IPAW), PPTA used its new social media channels to tweet and thank Rep. Doris Matsui for her statement in the Congressional Record supporting IPAW and recognizing the benefits of plasma protein therapies. Rep. Matsui is a champion of rare diseases and access to care issues, with an important focus on primary immunodeficiency disease (PID) patients. Rep. Matsui co-authored and advocated for the passage of the Medicare IVIG Access Act, which allows PID patients to receive lifesaving therapies in their homes. People living with PID and other conditions now live longer, more productive lives thanks to Rep. Matsui's dedication and the efforts of plasma donors around the world.

Social media will be a vital tool we can use to interact with lawmakers, their staff, and stakeholders going forward. PPTA will target key policymakers to ensure information in support of our legislative agenda is received by the right audience.

PPTA's presence is growing on social media weekly as the campaigns continue and the channels gain more followers. Please find PPTA on social media at the handles posted below. We look forward to interacting with you on our new platforms! ●

FOLLOW US:

-  @PlasmaProteins
-  Facebook.com/PlasmaProteins
-  LinkedIn.com/company/2112158



Every member of Congress employs social media to communicate with constituents, and President Trump has tweeted more than 2,000 times since being sworn in.

● PPTA Congratulates John G. Boyle—IDF's New President & CEO



John G. Boyle is the incoming President & CEO of the Immune Deficiency Foundation (IDF), having most recently served as IDF's Vice President of External Relations. John has been instrumental in developing a number of new initiatives for the Foundation,

including the IDF Walk for Primary Immunodeficiency, launched in 2013. The walk has now grown to 12 cities across the United States and has raised in excess of \$3.5 million to support vital IDF programs and resources, including funding a new IDF research grant.

In his new role at IDF, John is focused on meeting the current needs of the primary immunodeficiency disease (PID) community and preparing for its future needs, as there are new advancements in treatment options on the horizon but growing uncertainty in terms of health care policy and insurance limitations. Overall, he works to reach more members of the PID community and to further advance the Foundation's advocacy, education, and research initiatives.

John was diagnosed with a PID, specifically X-linked Agammaglobulinemia, in 1978, when he was only 6 months old. He has received immunoglobulin replacement therapy ever since.

Prior to joining IDF, John worked for Children's National Medical Center and the Platelet Disorder Support Association. He received a B.S. from Boston University and an M.A. in Nonprofit Management from Notre Dame of Maryland University. ●



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Locations

HEADQUARTERS – SAN ANTONIO
6211 IH 10 West
San Antonio, TX 78201

ATLANTA
4258 Communications Drive
Norcross, GA 30093



Lisbon, Portugal

Upcoming Events

CONFERENCES & SYMPOSIUMS

February

- 15 – 16** ICI 2018: 20th International Conference on Immunology
London, United Kingdom
- 28** Rare Disease Day

March

- 13 – 14** PPTA International Plasma Protein Congress (IPPC)
Budapest, Hungary

April

- 17** World Hemophilia Day
- 25 – 27** World Orphan Drug Congress USA 2018
Oxon Hill, Md., United States

May

- 20 – 24** World Federation of Hemophilia (WFH) 2018 World Congress
Glasgow, Scotland

June

- 12 – 13** PPTA Plasma Protein Forum
Washington, D.C., United States

July

- 13 – 15** Platelet Disorder Support Association (PDSA) 18th National Patient Conference & 20th Anniversary Celebration
Cleveland, United States

October

- 13 – 16** AABB Annual Meeting
Boston, United States
- 24 – 27** 18th Biennial Meeting of the European Society for Immunodeficiencies (ESID)
Lisbon, Portugal

November

- 1 – 3** 15th Biennial GBS/CIDP (Guillain-Barré Syndrome/Chronic Inflammatory Demyelinating Polyneuropathy) Symposium
San Diego, United States

GLOSSARY OF TERMS

CFDA – CHINA FOOD & DRUG ADMINISTRATION

CIDP – CHRONIC INFLAMMATORY DEMYELINATING
POLYNEUROPATHY

EHC – EUROPEAN HAEMOPHILIA CONSORTIUM

ESID – EUROPEAN SOCIETY FOR IMMUNODEFICIENCIES

GBS – GUILLAIN-BARRÉ SYNDROME

ICI – INTERNATIONAL CONFERENCE ON IMMUNOLOGY

IDF – IMMUNE DEFICIENCY FOUNDATION

IFBDO – INTERNATIONAL FEDERATION OF BLOOD
DONOR ORGANIZATIONS

IgG – IMMUNOGLOBULIN

IPAW – INTERNATIONAL PLASMA AWARENESS WEEK

IPPC – INTERNATIONAL PLASMA PROTEIN CONGRESS

IU – INTERNATIONAL UNIT

PDSA – PLATELET DISORDER SUPPORT ASSOCIATION

PID – PRIMARY IMMUNODEFICIENCY DISEASE

PLUS – PLATFORM OF PLASMA PROTEIN USERS

PPT – PLASMA PROTEIN THERAPY

SOHO – SUBSTANCE OF HUMAN ORIGIN

WFH – WORLD FEDERATION OF HEMOPHILIA

One Company

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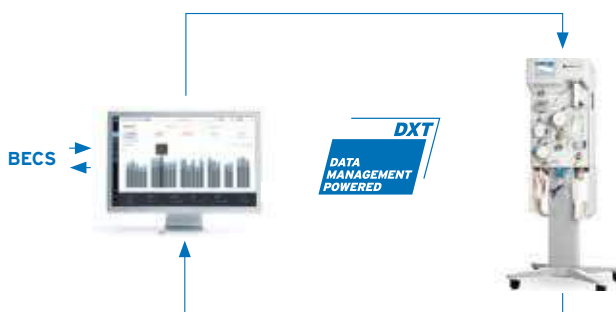
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