THE SOURCE

MAGAZINE OF THE PLASMA PROTEIN THERAPEUTICS INDUSTRY

WINTER 2014

Clinical Need:

What Can We Do in Other Parts of the World?

Sacramento Hosts Inaugural Blood and Plasma Symposium

Challenges in India to Meet Patient Needs

The Growing Attractivity of the Eastern World

PPTA
Plasma Protein Therapeutics Association

Roche Blood Safety Solutions

Count on us, because patients are counting on you.

Providing Total Workflow Solutions that Raise the Standards of Performance

Safety: State-of-the-art assay sensitivity and genotype coverage allow reliable detection at the earliest stage of infection.

Reliability: With the highest reliability on the market, our ingenious technologies maintain workflow, minimize user interactions, prevent cross contamination and provide full sample traceability.

Efficiency: High assay specificity coupled with innovative multi-dye technology reduce the need for retesting, while short turn-around times, automation and uninterrupted workflow generate time savings. and free staff for other tasks.

For more information, contact your local Roche Diagnostics representative.

*The serology product range is not available for blood screening settings in Angola, Argentina, Bahamas, Bangladesh, Canada, Guyana, Iraq, Korea D.R., Latvia, Lesotho, Lithuania, Malaysia, Philippines, South Korea, Uganda, and the United States. For all other countries, please contact your local Roche representative to check availability.

Roche

cobas®
Life needs answers

PPTA
Plasma Protein Therapeutics Association

Requests for permission to reprint should be directed to the editor at thesource@pptaglobal.org.

THE SOURCE is available as a PDF file at www.pptaglobal.org.

DESIGN AND PRODUCTION

B. Creative Group | www.agencybcg.com

THE SOURCE is published quarterly by **PPTA**.
147 Old Solomons Island Road, Suite 100
Annapolis, MD 21401

PHONE: +1.202.789.3100
EMAIL: thesource@pptaglobal.org

IQPP
INTERNATIONAL QUALITY PLASMA PROGRAM

QSEAL
QUALITY STANDARDS OF EXCELLENCE, ASSURANCE & LEADERSHIP

WINTER 2014

Contents

Collect with confidence and optimize operational efficiencies

At Haemonetics, we understand the pressures you face—from costs to increasing regulations to managing your supply chain. Our comprehensive portfolio of products and services is designed to support multiple facets of your operations, helping you achieve efficiencies and manage costs.




Solutions for the global plasma industry

An ongoing commitment
to donor safety and satisfaction

Dedicated customer support,
training, and process improvements

A reliable supply chain
helps ensure business continuity

Our supply chain management model
streamlines ordering and fulfillment

To learn more about our full range of products, programs and services, contact your Haemonetics Account Manager or visit www.haemonetics.com

HAEMONETICS®
THE Blood Management Company®

In My View

BY JAN M. BULT, PRESIDENT & CEO

Early October I attended and spoke at a conference in Manila, the Philippines. The day before the meeting started I met with a small delegation of persons with hemophilia. I was introduced to them by Laurie Kelley, someone who is very active in the hemophilia community as many of you know. In 2008, she visited The Philippines as part of her *Save One Life* program. My wife Rose (whose father came from the Philippines) joined her and told me after her return about the various experiences they had.

During the meeting, I met two parents of a son with hemophilia A, a mother of a 19 year old son with hemophilia B, a woman who lost her husband with hemophilia A, and with two persons with hemophilia. The story they told me was heartbreaking, but tragically, not uncommon in many countries.

The mother with the hemophilia B son told me that he currently had a brain bleed and that there was no Factor IX available. So no treatment at all!

One of the two persons with hemophilia had a bleed when we met. You could see in his eyes that something was not right. I was told that there was currently no Factor VIII available in the Philippines, there might be some treatment coming next month. The only treatments that were available were ice and a bandage. Sometimes it was possible to get cryoprecipitate, but if it came from a different hospital than the one that normally supplied the cryoprecipitate, so there were extra costs. The reason for that is that the test results from one hospital were not accepted by the other hospital. Here was an example what happens on a local level when there is no harmonization or recognition of test results.

President & CEO, Jan M. Bult, meets with hemophilia patients and family members in the Philippines.

The one patient with the bleeding showed me the medication he was using to deal with his pain. It was a capsule with ibuprofen and paracetamol. I asked the patients how many times they had a bleed. The answer was: every month. My next question how often they had hospitalization. The answer there was that this was the case at least 2–3 times a year. Each hospitalization was between 1 and 12 weeks. The persons I met were not angry, instead they were just sad. Once I saw this sadness, it made me realize how much more work needs to be done by all of us to help patients in different parts of the world.

I took a picture of my guests and put it in my presentation for the conference. There was silence in the room when I told the story to this international audience. •

Jan M. Bult, *President & CEO*

Donating Plasma—Saving Lives: A BERLIN EVENT

BY ALEXA WETZEL

"Donating Plasma—Saving Lives" was the motto of the International Plasma Awareness Week (IPAW) events that took place October 12-18.

PPTA, the German Arbeitsgemeinschaft Plasmapheresis e.V. (ARGE), and their members took the opportunity to raise awareness about plasma donation, the rare diseases that are treated with plasma protein therapies, and the patients that rely on these therapies. At the center of this initiative were plasma donors, with a focus on their important contributions to the treatment of patients.

For many collection centers, this celebratory week was the occasion to invite politicians to meet with donors and patients and to create awareness. The German Regional Ministers Anita Tack (Brandenburg), Heike Taubert (Thuringia) and Norbert Bischoff (Saxony-Anhalt) accepted the invitation and visited three plasma donation centers throughout Germany.

On October 16, the PPTA, together with the ARGE, organized a central event in Berlin where MP Martina Stamm-Fibich, Member of the Committee of Health of the German Parliament, referred to the increasing need for plasma protein therapies in her keynote message. Afterwards, she formally honored four long-term donors from the four different collection systems in Germany for their commitment.

As a result of demographic changes and a steadily aging population, clinical need for plasma protein therapies will increase. Therefore, it is important to create awareness, to motivate donors and to focus on to the importance of plasma donation.

(At Right) Horst Lüdtke, a patient with Guillain-Barré Syndrome.

Marion Hoffmann, a patient with primary immune deficiency.

Maik Martin has made more than 365 donations in order to help save and improve lives.

In the following panel discussion on donor motivation, the crucial role of the policy-makers was repeatedly pointed out. The participants of that discussion were representatives of the various donation organizations in Germany and they confirmed that first time donors are very often motivated by other donors. It was also stated that the relation between donor and center staff is an important criteria for the return of the donor.

This was confirmed by Maik Martin, who has already made more than 365 donations at the Haema Blutspendedienste in Berlin. He donates because he wants to help save and improve lives. As a teenager, he had an accident and needed a blood transfusion. After his recovery, he was so grateful that he wanted to give something back and so he decided to donate; first blood, then later also plasma.

Although in Germany the demand for plasma protein therapies is met, the diagnosis of a primary immune deficiency (PID) sometimes takes years. The ordeal, until the final diagnosis, can be very slow with frequently dramatic consequential damages. The very moving report of Marion Hoffmann, a PID patient who received her diagnosis only at the age of 34, made this particularly clear.

Horst Lüdtke also owes his life to a treatment with immunoglobulins. A few years ago, he suffered from Guillain-Barré Syndrome, a rare disorder that is manifested by muscle weakness and rapidly progressive paralysis and numbness. Thanks to a fast intervention of his physician and rapid treatment, he was able recover.

As a result of demographic changes and a steadily aging population, clinical need for plasma protein therapies will increase. Therefore, it is important to create awareness, to motivate donors and to focus on to the importance of plasma donation.

We would like to thank all donors! •

ALEXA WETZEL, *PPTA Manager, Source Europe*

Capitol Hill Briefing Raises PLASMA AWARENESS

BY CARRIE FIARMAN ZLATOS

During the second annual International Plasma Awarenesss Week (IPAW), the Plasma Protein Therapeutics Association continued its Congressional outreach and education in the United States about the plasma industry and the importance of plasma donation in treating rare diseases.

As part of PPTA's Congressional engagement, the Association hosted a briefing on Capitol Hill titled "Plasma Collection in Your District - A Global Model for Safety and Patient Access." The October briefing was widely attended with nearly 100 Congressional staff, patient advocates, and industry representatives present.

The briefing agenda focused on raising awareness about source plasma collection, recognizing the contributions of plasma donors, and the integral role that plasma protein therapies play in the treatment of rare and chronic diseases. Featured speakers at the briefing included: Joshua Penrod, PPTA Vice President, Source Division; John Boyle, Director of Development, Immune Deficiency Foundation and patient living with primary immune deficiency disorder; Christopher Healey, Vice President of Public Affairs, Grifols; Michael Deem, Vice President for Plasma Operations, CSL Plasma; and Janelle Jamison, Senior Plasma Center Manager, BioLife Plasma Services. The briefing also emphasized the important voluntary standards undertaken by collectors and manufacturers to ensure the safety of the therapies, the economic impact a local collection center can have on a community, industry innovation, as well as the day-to-day activities of a collection center manager. Key among the briefing highlights was the patient perspective of the importance of plasma donation, the contributions of plasma donors in helping to treat rare diseases and how these lifesaving therapies change patients' lives on a daily basis.

The briefing also provided an opportunity to highlight PPTA's newly developed infographics as well as proclamations issued by 38 states and the District of Columbia recognizing IPAW. In addition to the state proclamations, Rep. Grace Meng (D-NY) submitted a statement for the Congressional Record, on behalf of PPTA, commemorating International Plasma Awareness Week, recognizing the contributions of plasma donors, and raising awareness about plasma protein therapies and the rare diseases they treat. •

CARRIE FIARMAN ZLATOS, *PPTA Assistant Director, Federal Affairs*

John Boyle, Director of Development, Immune Deficiency Foundation and patient living with primary immune deficiency disorder speaks about the important role of plasma protein therapies in treating rare diseases.

INTERNATIONAL PLASMA AWARENESS WEEK

HON. GRACE MENG

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

Wednesday, September 10, 2014

Ms. MENG. Mr. Speaker, I rise to commemorate International Plasma Awareness Week, which will occur October 12 to 18, 2014. During this time, there will be observances throughout the United States and Europe designed to raise global awareness of the need for plasma to create lifesaving therapies, recognize the value that plasma donors contribute in saving and improving lives, and increase understanding of rare diseases and plasma protein therapies.

Raising awareness about plasma protein therapies is vitally important for the following reasons:

Plasma-derived therapies and recombinant blood clotting factors, collectively known as plasma protein therapies, are unique, biological products for which no substitutes or alternative treatments exist. They save and improve lives of individuals throughout the world;

Plasma protein therapies are used to treat bleeding disorders, primary immune deficiency diseases, alpha-1 antitrypsin deficiency, and certain rare, neurological disorders;

These therapies are also used in emergency and surgical medicine to save and improve lives;

Plasma protein therapies have significantly improved the quality of life of, markedly improved patient outcomes for, and extended the life expectancy of individuals with rare, chronic diseases and conditions;

Healthy, committed donors provide plasma essential to manufacture these lifesaving therapies; and

There are over 430 plasma collection centers in the U.S. that have demonstrated their commitment to plasma donor and patient safety and quality by earning International Quality Plasma Program (IQPP) certification.

I ask that my colleagues in the House of Representatives join me and rise in commemoration of International Plasma Awareness Week, a time dedicated to raising awareness about crucial, lifesaving therapies attained through using plasma proteins.

Rep. Grace Meng (D-NY) submitted a statement for the Congressional Record, on behalf of PPTA, commemorating International Plasma Awareness Week.

Thank you from PPTA

Thirty-eight states and the District of Columbia recognized and celebrated the second annual International Plasma Awareness Week, October 12 – 18, 2014. PPTA staff and member companies contacted gubernatorial offices to advocate and raise awareness about plasma donation and plasma protein therapies. PPTA received 39 proclamations honoring the contributions of plasma collection centers and healthy, committed donors across the country.

PPTA would like to thank the following Governors for declaring International Plasma Awareness Week in their states:

- Robert Bentley, *Alabama*
- Mike Beebe, *Arkansas*
- John Hickenlooper, *Colorado*
- Dannel Malloy, *Connecticut*
- Jack Markell, *Delaware*
- Vincent Gray, *District of Columbia*
- Rick Scott, *Florida*
- Nathan Deal, *Georgia*
- Pat Quinn, *Illinois*
- Mike Pence, *Indiana*
- Steve Beshear, *Kentucky*
- Paul LePage, *Maine*
- Martin O'Malley, *Maryland*
- Deval Patrick, *Massachusetts*
- Rick Snyder, *Michigan*
- Mark Dayton, *Minnesota*
- Phil Bryant, *Mississippi*
- Jay Nixon, *Missouri*
- Steve Bullock, *Montana*
- Dave Heineman, *Nebraska*
- Brian Sandoval, *Nevada*
- Maggie Hassan, *New Hampshire*
- Chris Christie, *New Jersey*
- Susana Martinez, *New Mexico*
- Pat McCrory, *North Carolina*
- Jack Dalrymple, *North Dakota*
- Mary Fallin, *Oklahoma*
- John Kitzhaber, *Oregon*
- Tom Corbett, *Pennsylvania*
- Lincoln Chafee, *Rhode* Island
- Nikki Haley, South Carolina
- Bill Haslam, *Tennessee*
- Rick Perry, *Texas*
- Gary Herbert, *Utah*
- Peter Shumlin, *Vermont*
- Terry McAuliffe, *Virginia*
- Earl Ray Tomblin, *West Virginia*
- Scott Walker, *Wisconsin*
- Matt Mead, *Wyoming*

Plasmapheresis in Austria

BY KARL PETROVSKY

A conference event celebrating 50 years of plasmapheresis in Austria took place on October 9, 2014, in Vienna at the Austrian Ministry of Health. It was organized by the Austrian source plasma collector association, IG PLASMA, and by the Austrian Pharmaceutical Industry Association, PHARMIG. The event celebrated the establishment of the first plasmapheresis center, 1964 in Austria and in Europe, run at that time by IMMUNO AG.

The conference was honored by the presence of the Austrian Minister of Health, Dr. Sabine Oberhauser, who addressed a warm welcome speech. Dr. Johann Eibl, founder of IMMUNO, and his spouse Prof. Martha Eibl, attended as special guests and were acknowledged with a round of applause.

The event gathered 130+ participants from Austria and abroad representing political decision makers, regulatory authorities, source plasma collectors, plasma donors, Austrian Red Cross, patient organizations, physicians, and industry.

The first part of the event was covered by presentations delivered by the Austrian Vice Minister for Health, Dr. Rendi Wagner, and the President of the Austrian Agency for Health and Food Safety, (AGES), Dr. Wirthumer Hoche, along with talks on the development of source plasma collection in Austria by Dr. Gessner (IG Plasma). Dr. Jacobson (PHARMIG) spoke on the challenges of plasma fractionation and Jan M. Bult, PPTA President & CEO, stressed the importance of plasma protein therapies in the international context. Amongst the highlights, emphasis was put on Austria's prominent role in having the longest tradition of modern plasmapheresis in Europe. As a result of this tradition, in 2013, according to the Austrian Ministry of Health, the Austrian source plasma collection industry generated plasma volumes of approx. 550,000 liters. This volume (approx. 20% of the

The need to collect more source plasma in Europe is the consequence of growing clinical demand of plasma products in Europe, with still important geographical disparities regarding patient access to care on the European continent.

whole European plasma collection) places the country with 65 liters collected by 1000 inhabitants, in relative numbers, as number two in the world after the U.S. Also very important, is the pioneering role of the country in establishing Europe's first modern blood plasma donation and safety legislation in the mid 1970's, which is constantly amended according to state of the art regulatory policies. Such legislation was put in place long before any specific European Union (EU) legislation was adopted. As another important milestone, it was highlighted that Austria initiated the introduction of the Plasma Master File (PMF) concept within the European Medicines Agency (EMA) process. In its contribution to the conference, PPTA paid tribute to: the development and progress of the Austrian source plasma collection system; pointed out that these achievements are a model in Europe; and put this in perspective when addressing the challenges which the whole blood sector faces with the declining need of transfusion intended blood components.

The second part of the conference focused on a talk given by Dr. Wolf (ITK Vienna) on medical progress regarding the treatment with immunoglobulins and a very moving presentation delivered by Karin Modl from the Austrian patient organization for primary immunodeficiency (OESPID) on patient quality of life as a consequence of plasma protein therapies being administered. Modl gave an excellent presentation on her own very long and painful journey toward the final diagnosis of her condition, primary immune deficiency (PID), and the crucial importance of today's well organized treatment with immunoglobulins. She very convincingly and emotionally spoke about how important source plasma collection is for the "transformation" into plasma protein therapies which very concretely helps her as a patient. This was followed by a high level discussion around "Plasma supply in Austria and the EU-an outlook in the context of present plasma policy developments" with participants from PPTA (Jan M. Bult), the Austrian MoH (Ministry of Health) (Dr. Kurz, as Ministry of Health consultant), a representative of the leading hospital pharmacy in Austria (Dr. Macher), as well as OESPID (Karin Modl) and ITK Vienna (Dr. Wolf). Amongst others, two main aspects were discussed: (1) the role of Austria in the international context of plasma collection and further manufacture into stable final plasma protein therapies, and (2) the consequences for plasma collection in the worldwide growing clinical demand of plasma therapies and product supply. Regarding the role of Austria, it was emphasized that the country is amongst the relatively few EU Member States hosting an effective and well regulated source plasma collection system. The need to collect more source plasma in Europe is the consequence of growing clinical need of plasma products in Europe, with still important geographical disparities regarding patient access to care on the European continent.
As a well regulated and developed geography, Europe furthermore has also the ethical responsibility to contribute more to the supply of quality and safe plasma products on a global level. Enhancing the collection volumes of source plasma in Europe would help to cope with this growing clinical need and Europe's resulting responsibility to act. It would also compensate the projected growing lack of recovered plasma, due to the declining need for whole blood collection, because of a declining need for whole blood for blood transfusion purposes.

Finally, approximately 20 long time plasma donors received IG PLASMA - honorary donor certificates for donating plasma on numerous occasions (from 200 up to 1000 donations). The certificates were awarded personally by OESPID's Karin Modl, who thanked each of the plasma donors personally for his or hers contribution.

Overall, the 50 years of plasmapheresis in Austria conference event was very successful.

KARL PETROVSKY, *PPTA Senior Manager, Health Policy, Europe*

(L to R) Robin Rumler, GM Pfizer Austria and President Pharmig; Dr. Christa Wirthumer-Hoche, CEO AGES (Austrian Medicines Regulatory Authority); Dr. Matthias Gessner, Head Baxter BioLife Plasma Operations Europe; Dr. Sabine Oberhauser, Austrian Minister of Health; Dr. Pamela Rendi-Wagner, Austrian Vice Minister of Health; Jan M. Bult, President & CEO, PPTA; Karin Modl, President OESPID and Vice-Chair "ProRare Austria"; Dr. Hermann Wolf, Immunologische Tagesklinik-Treatment Center , Vienna; Dr. Nicholas Jacobson, Pharmig; Helga Tieben, Director Regulatory, Compliance & Innovation, Pharmig.

Sacramento Hosts Inaugural BLOOD AND PLASMA SYMPOSIUM

BY MIKE FULLER

The International Plasma Fractionation Association (IPFA) and Blood Centers of America (BCA) recently cosponsored the first Global Symposium on *The Future for Blood and Plasma Donations*. Nearly 200 people from 22 different countries participated in the meeting held in Sacramento, California, on September 23–24.

The conference focused on the highly significant volume of plasma required for the production of plasma-based medicines. Transfusion medicine specialists from both blood banking and plasma fractionation organizations, along with healthcare professionals from around the globe, all participated with patients—the end users of these critical and life-changing medicines. The presentations highlighted the challenges and opportunities facing our industry. Attendees proposed a variety of considerations toward our commonality: to secure sufficient quantities of plasma for worldwide use.

There are several excellent reviews posted about this meeting, which can be located on the PPTA website, the IPFA website, and the IBPN newsletter by Patrick Robert of the Marketing Research Bureau. The meeting's agenda (programme) and individual presentations were compelling. I encourage those of you who are interested in learning more about this recent Global Symposium to access the information available through the cited publications.

BloodSource has been a PPTA associate member for several years. I have attended many PPTA conferences, dating back to the days when the predecessor of PPTA was known as ABRA (American Blood Resources Association). The most memorable PPTA meeting I attended was held many years ago in Washington, D.C. The PPTA Program Staff made a point to invite patients with hemophilia and achieved representation from countries around the world. A physician from Kuala Lumpur pleaded for improved access to cryoprecipitate so more of her patients could reach young adulthood. An attendee from India spoke of having lost one of his legs to the disease and then noted that with access to *just the products discarded by the USA*, they could significantly improve patient mortality rates and extend life into teen years. Several other patients shared personal stories that were every bit as powerful. The inability to adequately address the needs of patients throughout the world was the prevailing theme of this meeting. Unbeknownst to us at the time, this PPTA meeting was acutely intuitive and provided us with a glimpse into the future that was profoundly accurate. The unmet need of patients around the world continues to be the driving force behind most plasma association meetings.

The need for plasma becomes increasingly greater with each passing year. The resounding message of patient need, heard at a meeting that occurred so many years ago, continues to reside at the forefront of my thoughts. Although things have improved, we still have so much to do. It must always be about the patient! Fueled by this overarching reaffirmation, BloodSource took measures to enhance patient support and has since espoused the patient's perspective in all issues having an impact on the delivery of transfusion medicine.

Subsequent to joining PPTA, BloodSource was also able to join IPFA. One of the most interesting things we noticed during our IPFA introduction was their long-standing legacy of serving patients in need. Much like the patient-centric attitude that resonated with me at an early PPTA meeting, I noticed IPFA also recognized the unrelenting patient need and shares a determination—much like PPTA, a singular focus on achieving appropriate resolution.

IPFA has been sponsoring an excellent scientific program in collaboration with the Paul-Ehrlich-Institut (PEI). This international workshop, focused on Blood Borne Pathogens, recently celebrated its 20th anniversary. In light of that milestone success, the IPFA Executive Board agreed to a trial program with a broader focus. This endorsement resulted in the recent conference held in Sacramento. BloodSource was proud to host this inaugural Global Symposium. We are hopeful to create a substantial foundation capable of addressing demands for plasma and plasma-based medicines today and well into the future. Blood and plasma collections must keep pace with fractionation capacity. By working collaboratively together to advance **the promise of plasma**, we can increase plasma supplies, produce more plasma-derived products, and make life-changing medicines available to patients in need throughout the world.

Our call to action today is to promote the production of plasma-based medicines in plentiful quantities. Our cumulative effort to increase the global supply of plasma is truly one of the largest humanitarian efforts of our time. At the Global Symposium, a representative from Rotary International (RI) chronicled long-standing RI efforts to eradicate polio worldwide. The Rotary comparison to our current plasma objective illustrates that it is possible to prevail over large-scale challenges. Our common ground is to improve health and help patients in need around the world.

I find it interesting that both Jan Bult at PPTA and Paul Strengers at IPFA hail from the Netherlands. As the executive leaders for their respective organizations, they bring a rich Dutch heritage of working together. Specifically, people in Holland have made a collective effort, which dates back for centuries, to control water. More recently, both leaders responded to a Rome Declaration (carrying the WHO [World Health Organization] logo) on the topic of volunteer plasma donations. After both leaders went on record to identify serious consequences, WHO removed their logo and amended the disclaimer to state that "It does not necessarily represent the decisions or policies of the World Health Organization".

Historically, PPTA and IPFA have collaborated with only slight detours, which stem from particular operational issues. In addition to PPTA and IPFA, many of the member plasma and blood organizations have made significant contributions. One example is the Cell Saver, which was developed by BloodSource physicians in partnership with Haemonetics. We save lives when we work together.

The principal message at the PPTA meeting some years ago and the IPFA Global Symposium this past September, tells us that a significant patient population still needs our support. Both organizations have done their best over the years to highlight this critical need. Now we must engage to promote **the promise of plasma** and ensure patients win. •

MIKE FULLER, *CEO – BloodSource*

Challenges in India to Meet Patient Needs

BY RANJEET S. AJMANI, Ph.D.

India is the seventh largest country in terms of area and the second most populous country in the world. It has a plethora of natural resources and assets like the rich agricultural lands, deep gold and gemstone mines, some of the largest rivers, and, most importantly, its 1.2 billion people, which hold huge potential in more ways than one.

Plasma is one such resource, which India could have in abundance, but its potential is still unrealized. Being the youngest and second most populous country, India has a huge blood/plasma donor base which can greatly contribute to the local, as well as, global plasma product industry. Unfortunately for a variety of reasons, this potential is not explored and tapped to its fullest. The challenges in the Indian plasma industry are intense and prevalent at all the stages right from the start until the end point.

India collects about 10 million units of blood at more than 2600 blood banks across the country. These blood banks are in public, private, charitable, and hospital settings. As per the Drug and Cosmetic Act, each unit of blood is tested for HIV-I and HIV-II antibodies, Malaria, Syphilis, Hepatitis B surface antigen and Hepatitis C virus antibody and componentized within 6 hours of collection.

PLASMA

The current plasma fractionation program is purely based on recovered plasma, as the Indian regulatory system doesn't allow collection of source plasma for fractionation. Although India may be a huge reservoir for recovered plasma, one needs to consider the following facts:

- **Quantity:** Due to rampant use of whole blood, low componentization (only 30-40%) and high clinical use of plasma, only a limited amount of plasma is available for fractionation, which may not be sufficient to cater to the needs of 1.2 billion people.
- **Safety:** Dependence on one-time donors (70%) leads to issues of window period donations, donor deferral registry, etc., endangering plasma safety.
- **Quality:** Limited infrastructure for snap freezing and cold storage at blood banks may affect the yield of Factor VIII and other labile proteins.
- **Why not Source Plasma?:** Although paid blood donations were legal in India until 1996, lack of donor screening and blood testing parameters caused a major outbreak of transfusion transmitted infection (TTI) in the national blood supply, leading to mandatory voluntary non-remunerated donations. This catastrophe might inhibit regulators from permitting source plasma collection for fractionation in India.

Hence, consistent availability of safe and quality plasma is a major challenge and limiting factor in moving towards self-sufficiency for plasma protein therapies in India.

AVAILABILITY

India is largely import dependent for plasma protein therapies for the following important reasons:

- Lack of consistent availability of safe and quality plasma
- Limited domestic plasma processing capability
- Restriction on domestic hyperimmune plasma collection

Due to these abovementioned factors, India regularly faces issues of erratic supply and inconsistent availability of several plasma products. The situation gets further compounded during occurrences of global shortage of plasma / plasma products.

AFFORDABILITY

Being largely import dependent for plasma products, affordability is yet another major challenge in the Indian context. Any fluctuation in international currency has a huge impact on the domestic affordability factor. Furthermore, due to lack of a robust public healthcare system and low health insurance coverage, the majority of patients have to rely on out-of-pocket expenditure to access treatment. Considering the average Indian income, it is way beyond the reach of a common Indian family to provide long-term medical treatment, leading to reliance on on-demand therapy instead of globally preferred prophylactic care.

However, recently, the Central and State Governments have shown a positive commitment toward supplying various plasma proteins to ensure access to affordable care to its citizens. This is a key step toward developing a sustainable healthcare delivery model in India.

DIAGNOSIS

Based on theoretical prevalence, India would have one of the largest patient pools of PID's and hemophilia in the world. But due to a highly fragmented healthcare infrastructure (urban vs rural, public vs private), limited diagnostic centers and low awareness in medical fraternity and society, timely diagnosis is also a major challenge. While the majority of patients go undiagnosed, late diagnosis leads to increased burden of disease and diminishing quality of life. For example, currently the Hemophilia Federation of India (HFI) has < 20,000 patients in its registry, while going by global prevalence rate, India should have > 100,000 patients of Hemophilia-A itself. Similar scenarios resonate across other diseases as well, where timely diagnosis could make a significant difference in the patients' lives and help them become a productive member of society.

CURRENT STATUS

India is undergoing a very rapid transformation. There is a strong political will to change the landscape of India by focusing on education and healthcare. With this in perspective, the Government has taken several important steps toward providing safe blood and plasma products to its citizens like; changes in the Drug and Cosmetic Act, formulation of a National Plasma Policy, harmonization of plasma product testing protocols, launch of National Hemovigilance Program and increased focus on rare genetic disorders. Nonetheless, the most remarkable transformation has been the change in attitude toward issues prevailing in the plasma protein industry. In the last week of October 2014, the Department of AIDS Control (DAC), responsible for the National Blood Safety Program, invited all stakeholders involved in the plasma protein therapy – industry, bureaucrats, regulators, blood transfusion specialists and patient groups, to discuss various issues regarding enstrengthening of the national plasma fractionation program. Although the first of its kind, such initiatives would help India in developing a firm plasma supply from recovered as well as apheresis sources, build plasma fractionation capacity and undergo facilitative regulatory reforms. At the end, as a community, we need to work together toward ensuring regular access of safe plasma protein therapies to patients, who can see another beautiful day of their lives. •

RANJEET S. AJMANI, Ph.D., *PlasmaGen BioSciences, Bangalore, India*

Acknowledgment: Thanks to Apeksha Jaiswal, Awadhesh Tiwari and Falak Shah for their valuable inputs.

The Growing Attractivity OF THE EASTERN WORLD

BY PIERRE-FRANCOIS FALCOU

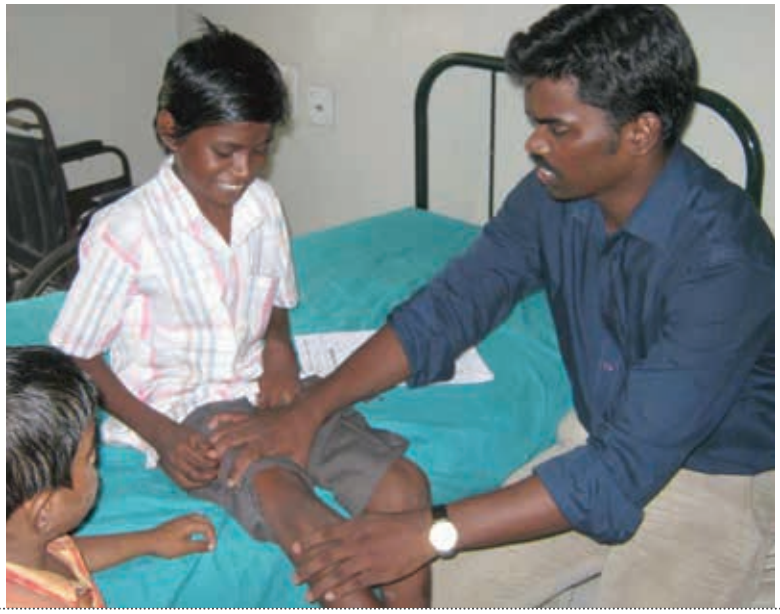
4th Annual BIOPLASMA World Asia 2015

BIOPLASMA ASIA SHANGHAI
September 1–3, 2015

Though the plasma protein industry has opportunities to gather in congresses and fora organized by e.g. IPFA, PPTA, patient groups or medical societies, it scarcely leads to significant contacts with the Asian part of the world. Only some could have noticed for example a Chinese manufacturer exhibiting in a couple of World Federation of Hemophilia (WFH) congresses. The role of the WFH congress in developing countries is significant for the awareness on bleeding disorders. During many years, most Asian countries were either showing a low consumption in plasma products per inhabitant and/or the needs of the country were essentially supplied by local players.

The situation is now changing at an accelerating rate. Several reasons support this shift. First, the world economic community is acknowledging that a bulk of the future growth will come from Asia. Starting from the Marketing Research Bureau (MRB) 2011 situation where half of the worldwide population represented only 14% of the plasma products market, anyone can see the economic potential of this zone, pulled by the known link between the gross domestic product (GDP) growth and the access to healthcare. With an average growth of 7 to 8% in the zone between 2009 and 2014 (source World Bank), the standard of care is becoming more and more prominent in the political priorities for many countries.

Beyond this local industrial nursery, Asia is also learning from the West about the importance of regulatory independence such as the requirement for local clinical trials for registration and on-site inspection of foreign facilities.



Second, several moves have recently shown that industrial players are emerging with the intention to break borders. From Korea we have seen that Green Cross is moving to North America with plasma collection activities and an industrial collaboration. In the meantime, the Red Crosses in Japan and Korea are thinking about their long term strategy and role in recovered plasma management, including a consolidation of the industry in Japan by the creation of JBPO (Japan Blood Products Organization). In China, an industry historically fragmented is progressively consolidating, including the creation of new capacities (forced by the increase in good manufacturing practice [GMP] compliance). Together with a growing mastery of chromatography process allowing them to diversify their portfolio beyond the usual immunoglobulins and albumin, some entrepreneurial tycoons are probably anticipating changes in the domestic regulation that will allow more flexibility between different sites and could lead one day to the emergence of several entities that will seek international recognition.

Projects of local new facilities are taking off in countries such as in Thailand and Malaysia. Finally in India, the government is willing to address the need for structure in the blood collection network in order to strengthen its quality and safety. If successful, it will lead to growing volume of plasma reaching fractionation grade with all the questions on its valuation domestically or through outside services that were already experienced in the past. This concern about the waste of plasma from improved local blood collection in countries as populated as Indonesia or Vietnam and which benefit from WHO or World Bank subsidies for their modernisation could further push more industrial development projects in these areas.

Beyond this local industrial nursery, Asia is also learning from the West about the importance of regulatory independence such as the requirement for local clinical trials for registration and on-site inspection of foreign facilities. This increasing complexity is requiring that peer exchanges are supported between agencies to either educate experts or push for regionally integrated structures (e.g. ASEAN [Association of Southeast Asian Nations]) that can help Asia to get efficient access to all lifesaving plasma therapies, even for rarer diseases.

Overall, there is a mutual interest for the plasma protein industry to have an increased knowledge of the boiling activity of the growing Asian players and for them to anticipate their future regulatory and technological environment. Once we know that the focus is shifting away from duplicating technologies, Asian entities can surprise by their agility in innovation and competitiveness. As I have had the chance to advise the Bioplasma Asia congress since its inception in Hong Kong in 2011, I strongly encourage all plasma protein industry stakeholders who are willing to assist in bridging between various parts of the world to bring their experience to the fifth venue in September 2015 in Shanghai. •

PIERRE-FRANCOIS FALCOU, MD, *ExMBA, LFB Biomedicaments France, member of AsiaBioplasma Advisory Board*

2014 ESID meeting participants

ESID Meets in the Country of Mendel

BY BRUNO SANTONI

It was in the beautiful city of Prague, Czech Republic, that the 16th edition of the European Society for Immunodeficiencies (ESID) meeting was organized from October 29 to November 1, 2014. For the first time in their history this triple congress (ESID/INGID/IPOPI) gathered more than 2,000 participants, creating a unique opportunity to bring together scientists, nurses and patients involved in Primary Immunodeficiencies.

It couldn't have been a better place than the country of Johann Gregor Mendel (1822-1884), who opened the way of genetic research by discovering the basic laws of genetics, to organize this edition of the ESID conference. The contribution of Johann Gregor Mendel was acknowledged throughout the congress and particularly in the opening session by Professor J. L. Casanova who presented an impressive and comprehensive historical review of the developments that led to the current knowledge in immunology. When the early steps of ESID were initiated in the 80's, only 10 genes, whose abnormalities account for diverse forms of primary immune deficiency (PID), were identified and today, more than 240 genes have been identified. The work of Professor Helen Chapel was recognized as she received a well-deserved lifetime achievement award during the opening session.

The program of the congress embraced a broad range of topics around immunodeficiencies under the motto: *Understanding Immunity. Treating Immunodeficiency.* There was particular attention this year to autoimmunity and inflammation and on the more innovative side, gene therapy. More attention was also dedicated to the quality of life of patients.

For the plasma protein therapies, the presentation of Dr. Esther De Vries, Jeroen Bosch Hospital, 's-Hertogenbosch, Netherlands, was notably captivating. She addressed the difficulty in diagnosis, highlighting as an example that only 10% of Dutch hospitals have a pediatrician specializing in immunology and infectious disease. In order to diagnose more patients, performing more tests is also needed. Regarding the ESID registry, a rapid poll in the audience, showed that, from the raised hands, only a limited proportion of the clinicians are participating in the registry. Regarding treatments, the lack of data for antibiotic prophylaxis was stressed and the increasing usage of immunoglobulins was mentioned. Dr. De Vries concluded her presentation by explaining the importance and priority to develop efforts in order to better understand immunodeficiencies, particularly mild immunodeficiencies and the consequences for the health of patients.

Both satellite symposia had such a considerable attendance that a live broadcast had to be organized in another conference room to allow the audience to follow the presentations.

The status of the ESID registry was presented during the congress. The registry contains more than 20,000 patient entries and can now show immunoglobulin use throughout Europe.

The new ESID Registry Steering Committee was elected during the ESID conference. The following ESID members were elected:

- Bodo Grimbacher, Germany
- Isabella Quinti, Italy
- Matthew Buckland, United Kingdom
- Markus Seidel, Austria
- Joris van Montfrans, The Netherlands

The Registry Working Party Chairperson is Nizar Mahlaoui (France).

The ESID conference was held in the Czech Republic, the country of Johann Gregor Mendel (1822-1884), who opened the way of genetic research by discovering the basic laws of genetics.

Regarding the severe combined immunodeficiency (SCID) newborn screening, the following update was released by ESID: 2.7 million babies are screened today in the U.S., representing 67% of all U.S. babies, and France has now launched the first SCID new born screening pilot project in Europe. This project will evaluate the medical and economical value of running such a program. 200,000 babies will be screened over a period of 2 years. The project is funded by the French Ministry of Health.

The International Patient Organisation for Primary Immunodeficiencies (IPOPI) gathered 90 participants representing 32 countries from all over the world. IPOPI leveraged the meeting to convene their National Member Organizations (NMOs) to exchange best practices and discuss achievements and work plans, including fund raising initiatives. IPOPI's executive Director insisted on the need and benefits to maximize collaboration with rare disease organizations as well as the importance to promote data collection (registries) in order to be able to better develop research programs. Moreover, medical updates on research and treatments were provided to the NMOs, with a session of particular interest on gene therapy, stem cell transplantation and bone marrow transplantation. Throughout the IPOPI sessions, the need for more knowledge and understanding of immunity and treatments was expressed by the patient groups, mentioning a specific interest in research on treatments with plasma protein therapies and long term use of immunoglobulins.

There were two sponsored satellite symposia (CSL Behring and Baxter) during the ESID conference.

Both symposia presented learnings from patient cases and highlighted that having different immunoglobulin treatment and administration options that fit the individual needs and lifestyles of people living with immunodeficiencies is enhancing progress towards

The ESID meeting was opened with a classical orchestra.

Professor Helen Chapel receives the lifetime achievement award.

individualized immuno-globulin therapy. These options can help the primary immunodeficiency patients who require lifelong, continual therapy to prevent frequent and recurring infections.

Both satellite symposia had such a considerable attendance that a live broadcast had to be organized in another conference room to allow the audience to follow the presentations.

Coming back to Mendel, the profound significance of his work was not recognized until the turn of the 20th century, more than three decades after the publication of his paper on Plant Hybridization. Similar for other several great discoveries, it took significant time before his findings could be accepted. I hope now that the scientific discoveries and recommendations presented in this congress will not need 30 years to have an impact on the diagnosis, the quality of life and the treatments of patients.

The next ESID Biennial meeting will be in Barcelona in 2016. •

BRUNO SANTONI, *PPTA Executive Director, Europe*

4th Annual
BIOPLASMA World Asia 2015

Facilitating the growth & innovation of quality plasma products in Asia

1 - 3 Sep 2015 | Shanghai, China

Bioplasma World Asia 2015 will be the pre-eminent platform for key decision leaders from the blood plasma industry in Asia and the rest of the world. Bioplasma World Asia will continue to bring together international and Asia's plasma fractionators, blood establishments, health authorities, regulators, academics and technology specialists to discuss pressing issues, share best practices, latest developments and explore opportunities and viable partnerships to meet the demand of the persistently rising Asian bioplasma market.

Scientific Organizing Committee/Advisory Board

Dr. Pierre Francois Falcou, Director of Alliances, LFB Biomedicaments, France
Dr. Ranjeet Ajmani, CEO, PlasmaGen BioScience, India
Jan M. Bult, President & CEO, PPTA, USA
Dr. BG Rhee, President, Green Cross, Korea
Dr. Lu Hui, Vice President, Shanghai RAAS, China

Bioplasma World Asia 2015 speakers include:

Dr. Glenn Pierce, Consultant, Former Biotechnology Executive with Biogen Idec, USA
Prof. R. Burger, President, German Robert Koch Institute, Germany
Prof. Shigeaki Nonoyama, National Defense Medical College, Japan
Dr. Karen Etchberger, Executive Vice-President Quality and Business Services, USA
Thomas R. Kreil, Ph.D., Assistant Professor of Virology, Senior Director Global Pathogen Safety, Baxter BioScience

It's your one stop solution to reach out to Asia's plasma industry! Act now to be part of 2015's most important and ONLY bioplasma event in Asia. For further questions, please contact tingting.wang@imapac.com or call her at +65 6493 1880.

4th Annual
BIOPLASMA World Asia 2015

Ontario Plasma Bill More to do with Ideology than Good Policy?

BY PATRICK NELSON

Decades of working in Canadian politics has taught me that it is very rare that ideology makes for good policy-making. That's not to say that policy-making isn't regularly made based on ideological pretenses – in fact, more often than not this is exactly the case.

The introduction of Bill 21 in the Ontario Legislature which seeks to ban the practice of paying donors for plasma in Canada's largest province, seems to be a classic case of this type of ideologically based policy-making. Given the level of debate around the bill, and the lack of a believable rationale for its introduction, it is the only reasonable explanation for the government taking the issue on with such fervor.

There is no doubt that the planned opening of several plasma collection centres, by Canadian Plasma Resources (CPR) in downtown Toronto and the surrounding area was a strong impetus. For certain, the public relations approach and difficulty navigating Canada's politics and culture provided an easy target for critics of the industry at large. The portrayal by major media and industry critics of the opening of plasma collection facilities in Ontario created a considerable disadvantage in advocacy in the Ontario provincial legislature. Despite the uphill battle, the PPTA accepted the challenge and has been working hard to educate legislators about plasma collection in North America and Europe, its safety and the hypocrisy of banning a practice that is almost solely responsible for the provision of plasma products to Canadian patients. Over the last several months, PPTA has met with dozens of Members of Provincial Parliament (MPP), with representatives of the Premier and Minister of Health, and with other stakeholders to advocate on behalf of its members and patients and to bring sanity to the discussion.

"Safety is the top priority of the industry," explained Mr. Penrod. "Donors undergo behavioural assessments, questionnaires and health screening; even then, plasma is collected and tested from a donor two times before it is considered to move onto any manufacturing steps."

Most recently, the PPTA hosted a briefing for MPPs at the Ontario Legislature. MPPs heard from three experts in the area of plasma protein therapies; individuals who know first-hand the potential risks that ill-conceived policy changes can bring. Attendees included the opposition Health Critics, House Leaders, political staff, and other concerned MPPs.

Joshua Penrod, Vice President of PPTA Source, gave an informational presentation of what plasma is, the collection and manufacturing processes, and uses of the finished therapeutic plasma products. Recognizing that the safety of the industry had been a part of the early debate in the media, Mr. Penrod focused significantly on the measures in place to ensure that donors and patients are protected. He explained that regardless if a donor is compensated for their plasma donation or not, that plasma goes through the same purification and manufacturing processes. "Safety is the top priority of the industry," explained Mr. Penrod. "Donors undergo behavioural assessments, questionnaires and health screening; even then, plasma is collected and tested from a donor two times before it is considered to move onto any manufacturing steps."

MPPs then heard from a medical professional, Dr. Stephen Betschel, Specialist in Allergy and Clinical Immunology at St. Michael's Hospital in Toronto. Dr. Betschel's practice is a combination of clinical, research and teaching. During his briefing, Dr. Betschel detailed the variety of conditions that rely on plasma derived therapeutics. "Although many of these diseases are rare, plasma is critical for their treatments. In some conditions, there is simply no other alternative."

"Although many of these diseases are rare, plasma is critical for their treatments. In some conditions, there is simply no other alternative."

Dr. Betschel went on to explain that in addition to the need for a consistent supply, that some patients may also benefit from a diverse supply of plasma.

As a recipient of plasma derived therapies, Whitney Goulstone, Communications Director, Canadian Immunodeficiencies Patient Organization (CIPO) shared her journey from illness, to diagnosis, to successful treatment. When Whitney was a little girl she was always sick and was in and out of the hospital nine times with pneumonia. As the years passed, her illness and hospital visits became more frequent. After many consultations, doctors' referrals and extended periods of time on antibiotics, Goulstone was placed under the care of Dr. Betschel. After 30 some years of being shifted through the health care system, Goulstone was diagnosed with Common Variable Immune Deficiency. Whitney's blood cells couldn't defend her body against illnesses as prevalent as the common cold. Since her diagnosis, Goulstone has been using plasma protein therapies and has now even started doing home treatments on her own. "As a mother of two young children, I am now able to participate in everyday activities. Before I would spend days on end in bed recovering from an infection," said Goulstone. "My quality of life has improved ten-fold due to plasma protein therapy."

The briefing of MPPs was successful in providing MPPs and their staff with a better understanding of the plasma industry, the safety measures in place to protect the public, and about how the therapies are used and by whom. But the tough challenge of convincing the government to withdraw the egregious portion of the Bill or amend it remains. As the Bill moves through the legislative process, the PPTA will continue to lobby government and call for change. When the Bill goes to Committee for further detailed consideration, this work will continue in earnest.

Convincing the government that their ideological stance is making for bad policy will be tough, but with the support of several patient groups, the ongoing advocacy work by PPTA will help ensure that the policymakers are as educated and informed as possible about their choices and the ramifications of policy.

POSTSCRIPT: As things turned out, Bill 21 went to the Social Policy Committee for a hearing in which PPTA and patient groups participated. As of this writing, the Committee has moved the Bill to the full Ontario Legislature without adopting the changes recommended by the industry and affected patient groups. •

PATRICK NELSON, *Principal at Santis Health*

State Patient Access COALITION EFFORTS

BY BILL SPEIR

State Medicaid pharmacy reimbursement is a simple formula that reimburses pharmacies based on the estimated acquisition cost of the pharmaceutical plus a reasonable dispensing fee.

In 2009, The American Medicaid Pharmacy Administrators Association (AMPAA) decided the estimated acquisition cost benchmark, Average Wholesale Price (AWP), was too high. The states and the federal government began an effort to determine pharmacies' actual acquisition costs and use this amount for the reimbursement equation.

They have done this without addressing the dispensing fee component of the equation. The dispensing fee has always been considered low but manageable since the estimated acquisition cost was inflated. However, if states reduce the estimated acquisition cost without addressing the low dispensing fee component, there is the potential that individuals with bleeding disorders will lose access to their medically appropriate blood clotting factor and specialty pharmacy provider.

As a result, PPTA organized the State Patient Access Coalition (SPAC) which represents manufacturers of clotting factor and distributors of clotting factor. The coalition members are:

Accredo Health Group
Express Scripts
Baxter Healthcare Corp
Grifols USA
Bayer HealthCare
Kedrion Biopharma
Biogen Idec
National Cornerstone Healthcare Services
BioRx
Novo Nordisk
CSL Behring
Plasma Protein Therapeutics Association
CVS Health
Walgreens

The SPAC's goal is to inform decision-makers in the Centers for Medicare & Medicaid Service (CMS), state Medicaid agencies, and state legislatures about the need for sound policies related to the purchase, dispensing and administration of blood clotting factor therapies. In furtherance of that goal, SPAC was very active in Wisconsin Medicaid's Hemophilia Outpatient Workgroup. The goal of the workgroup was to improve care coordination for Medicaid recipients who receive blood clotting factor.

This participation allowed SPAC to provide comments on draft standards before they became public. SPAC members attended a meeting on the standards in July. At this meeting, SPAC members were able to have an open discussion with Wisconsin Medicaid staff and all stakeholders concerned with quality care for individuals who rely on blood clotting factor. The other stakeholders included individuals from specialty pharmacies, hemophilia treatment centers, and the local bleeding disorders chapter.

The efforts of all involved led to an improved draft document that was presented to the public in September. SPAC specifically advocated for changes in standards governing assay management and home visits.

The original draft requirements prohibited non-clinician specialty pharmacy representatives from entering a patient's home. SPAC advocated that this requirement could be detrimental to patient care coordination. Wisconsin Medicaid listened and this requirement was removed.

Wisconsin is an example of the role of the SPAC in discussions concerning Medicaid recipients' access to blood clotting factors. As states continue to debate health care delivery in 2015, SPAC will have new challenges and opportunities to improve patient access to care. •

BILL SPEIR, *PPTA Director, State Affairs*

The SPAC's goal is to inform decision-makers in the Centers for Medicare & Medicaid Service (CMS), state Medicaid agencies, and state legislatures about the need for sound policies related to the purchase, dispensing and administration of blood clotting factor therapies.

Senator Greg Reed

Alabama Senate Majority Leader Reed CHAMPIONS PLASMA DONATION LEGISLATION

BY BILL SPEIR

There are over 430 International Quality Plasma Program (IQPP) certified centers in the United States, including 14 in Alabama. The minimum age to donate plasma at the vast majority of these centers is 18 years old.

In Alabama, and Nebraska, the minimum age to donate is 19 years old. Alabama law does not specifically prohibit compensated plasma donation at 19 years of age. It does so indirectly since Section 26-1-1 of the Alabama Code establishes the age of majority at age 19.

Section 26-1-3.1 of the Alabama Code provides two exceptions to the law by allowing individuals to donate blood at age 16 with parental consent. 17-year-olds are able to donate blood without parental consent, as long as they are not compensated for the donation. Therefore, individuals can donate plasma at age 17 in Alabama, as long as they are not compensated for their donation.

Senator Greg Reed has been working with the Plasma Protein Therapeutics Association (PPTA) to lower the donation age to 18 in Alabama. During the 2014 Legislative Session, Senator Reed sponsored Senate Bill 204 that would amend Section 26-1-3.1 to allow a person 18 years of age or older to donate blood or plasma in a blood or plasma donation program without the permission of a parent or guardian.

Senator Reed shared his motivation for sponsoring this bill when he stated, "The law in Alabama doesn't make sense when you consider an individual can enlist in the military and fight for their country at 18, but they can't donate plasma. We should do everything we can to allow people to donate plasma. Plasma is necessary for the manufacturing of life-saving plasma-derived therapies that treat patients with rare and chronic conditions. Allowing 18-year-old Alabamians to donate their plasma represents an important step in helping ensure patients continue to have access to these important plasma protein therapies."

The bill rocketed through the Senate with his leadership. The Legislative Session began on January 14, 2014. A week later, The Alabama Senate Committee on Health, chaired by Senator Reed, passed Senate Bill 204 by a vote of 8-0. The bill passed the Senate on February 6, 2014.

Unfortunately, the bill did not do as well in the House of Representatives. The bill made it through the committee process and was listed on the special order calendar the last week of session. There it died when the Alabama Legislature concluded the 2014 Legislative Session on April 3, 2014.

The 2015 Alabama Legislative Session convenes on March 3, 2015. Senator Reed will be the Majority Leader. Lucky for PPTA, he has committed to sponsor the legislation again in 2015. PPTA could not have a better sponsor. We look forward to working with him to successfully pass this necessary law in 2015. •

BILL SPEIR, *PPTA Director, State Affairs*

Inside PPTA

NEWS FROM AROUND THE GLOBE

MEET THE PPTA STAFF

Rachel Liebe

ASSOCIATE, NORTH AMERICA

Q How long have you served at PPTA?

I joined PPTA in August 2013.

Q What is your role in the Association?

I work on many of the Communications efforts at PPTA. I maintain and update PPTA's websites: PPTA Global; PPTA Deutschland; and PPTA's Donating Plasma sites in three languages (English, German, and Czech). In addition to website maintenance, I also send out e-blasts to Member companies and press releases that are sometimes distributed internationally. Throughout my time at PPTA, I have also been able to contribute to many of the Association's meetings by utilizing my graphic design skills and developing materials, in addition to capturing moments from behind the camera. Additionally, I have had the opportunity to step into the role of Managing Editor for the Association's internationally distributed *Source* magazine, which is distributed quarterly. Coupled with my responsibilities in the Communications department, I also support the North America division at both the federal and state levels. This year I enjoyed participating in the preparation of the Congressional Fly-in. This is a major endeavor that requires a lot of focus and attention to detail. PPTA scheduled 80 Congressional visits and included teams of industry representatives and patients.

Q Tell us about your background.

I have always gravitated more toward the fields of art and design. While acquiring an Associate's degree in media production, I had the advantage of gaining experience in graphic design and media editing as a media assistant at the Sheet Metal Workers' International Association (SMWIA). During my time with SMWIA, I assisted in creating graphics which were used on various Sheet Metal Workers' local union webpages. Additionally, I was tasked with editing and enhancing footage gathered from SMWIA events and conferences which was used for educational, as well as promotional purposes.

While finishing my degree, I transitioned to an internship with Paul Reed Smith Guitars (PRS). With this opportunity, I was able to hone my skills in media editing, as well as in video and photography. I have utilized these refined skills on various projects undertaken at the Association. During the summer months, I enjoy carpentry and was able to help my father and younger brother build my parents' new house. Working in many disciplines has been beneficial by allowing me to approach projects in various ways in order to find a solution.

Q What is most rewarding about working in this industry?

I find interacting with patients and patient groups to be the most rewarding experience I've had working at the Association. I had the benefit of advocating for access to care with my colleagues on Capitol Hill at PPTA's annual Fly-In. During this time, I had the privilege of being teamed up with a patient advocate from the Alpha-1 Foundation and heard first-hand not only of the daily struggles that come with living with a rare, chronic disease such as Alpha-1 antitrypsin deficiency, but also of the challenges associated with accessing proper care. I consider myself very fortunate to have had the opportunity to hear such humbling stories from the patients that the Association advocates diligently for. •

PPTA Source Industry Profile Committee

BY SONIA BALBONI

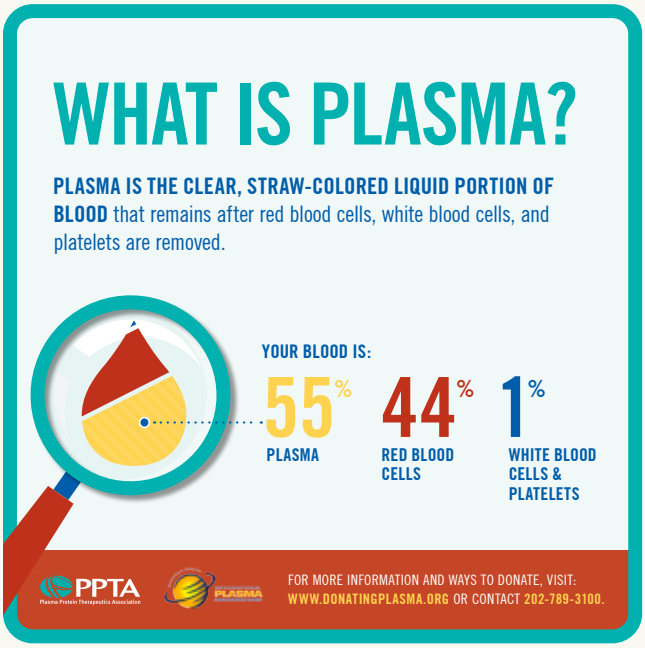
The Source Industry Profile Committee (SIPC) works to help the industry raise global awareness about source plasma collection and plasma protein therapies, the diseases and conditions plasma protein therapies treat, and the patients who rely on them. The SIPC, led by chair Beth Eacret, is comprised of communications experts from Source member companies. Membership on the Committee is balanced with company representatives from Europe and the United States. The cross-continental makeup of the Committee has allowed for a truly international effort to strengthen the Source industry profile, paving the way for the development of a global communications footprint for industry.

This year, the Committee facilitated the development of materials for companies and stakeholders to execute successful events celebrating industry's second annual International Awareness Week (IPAW). A major accomplishment was the development of print media "infographics." These are simple, visual representations designed to educate the general public about plasma donation, and the lifesaving manner of plasma protein therapies. The visuals present the information to readers in a quick and easy-to-digest read. They were made available in English, German, Spanish, Czech, and Hungarian.

The Committee also worked with staff to produce a media kit for members and stakeholders to use in conjunction with IPAW. This allowed press to access comprehensive information about the industry and the events. The media kit contained IPAW logos, press releases, infographic posters, banners, and a social media kit. The social media kit included seven individual graphics taken from one of the infographic posters, along with suggested text to accompany the images when posted on social media sites such as Facebook, Twitter, Instagram, etc. Member companies were encouraged to use '#IPAW_2014' when posting about IPAW on social media sites to assist PPTA in tracking, as well as including the website 'www.donatingplasma.org' to aid readers in finding a source plasma collection facility in their area. •

SONIA BALBONI, *PPTA Senior Manager, Source & Standards*

To view the infographics, please visit: www.pptaglobal.org/meetings-events-international-plasma-awareness-week/media-center.



You may have heard of donating blood, but what about donating plasma? Your plasma can be used to treat patients with rare, chronic disease. Celebrate International Plasma Awareness Week and learn more about donating plasma at www.donatingplasma.org #IPAW_2014

Safety and quality are top priorities of the plasma protein therapeutics industry. Celebrate International Plasma Awareness Week and learn more about donating plasma at www.donatingplasma.org #IPAW_2014

PPTA Business Forum

BY RACHEL LIEBE

The annual PPTA Source Business Forum was held on October 26, 2014, in Philadelphia. Shinji Wada, Chair, Source Board of Directors, addressed members and staff, highlighting the work of the Source division this year. Activities include the ethics of compensated plasma donation, Regulatory projects, European Plasma Collectors Committee Leadership, enhancement of the IQPP Standards, and International Plasma Awareness Week (IPAW).

Ileana Carlisle, IQPP Standards Committee chair, outlined developments with the IQPP certification program. She highlighted the final stages of the revised the IQPP standards for global relevancy and the development of an automated solution for compliance with the IQPP Cross Donation Management Standard, the Cross Donation Check System. Dr. Stephan Walsemann, Chair, European Plasma Collectors Committee, discussed key developments in plasma collection for the region. Projects include a potential review of the Blood Directive, VAT on plasma sales (national and export), physician project and outreach activities. Beth Eacret, Chair, Source Industry Profile Committee provided an overview of the IPAW activities. Roger Brinser, Chair, Regulatory Policy and Compliance Steering Committee, gave an overview of the Committee's projects. These included the completion of the study of ferritin levels in plasma donors, plasmavigilance, CLIA Waiver, PPTA Regulatory Workshop, and ongoing discussions with FDA on a number of issues of interest. David Morad, Teasurer, Source Board provided the 2014 Treasurers' report.

The second session drew attention to donor compensation issues. Ian Mumford, Canadian Blood Services, provided an overview of the challenging legislative climate in Canada. PPTA President and CEO, Jan M. Bult, provided an overview of the global coexistence for the whole blood and source plasma industries. Nicola Lacetera, PhD, University of Toronto, described his published research which shows that compensated source plasma donations do not result in non-remunerated whole blood donations. James Stacey Taylor, PhD, The College of New Jersey, completed the panel with a discussion on the validity of the sources that contributed to conclusions in the WHO report, and addressed other ethical considerations.

The program ended with a reception celebrating the success of 2014's International Plasma Awareness Week.

Ian Mumford, Canadian Blood Services provides an overview of the challenging legislative climate in Canada.

Dr. Stephan Walsemann, Managing Director, KEDPlasma GmbH and Chair of European Plasma Collectors Committee (EPCC), with Joshua Penrod, PPTA Vice President, Source, addresses the members at the Business Forum.

RACHEL LIEBE, *PPTA Associate, North America*

Ileana Carlisle and Shinji Wada, Chair, Source Board of Directors

Ileana Carlisle Honored withRobert W. Reilly Leadership Award

BY RACHEL LIEBE

PPTA recognizes outstanding contributions to the provision of plasma protein therapies with its prestigious Robert W. Reilly Leadership Award. The award recognizes an individual for their valuable contributions, achievements, and leadership on behalf of the source plasma collection industry.

Ms. Ileana Carlisle (Biotest Pharmaceuticals) received a standing ovation when she received the 2014 Robert W. Reilly Leadership Award at the Business Forum. Ileana was recognized by her peers as demonstrated unquestionable leadership, professional character, ethics and commitment to the advancement of the plasma protein therapeutics industry and to the goal of improving access for patients to these lifesaving therapies. Ileana exemplifies what the Robert Reilly Award represents.

Ileana's career in the plasma industry spans more than 30 years having displayed extraordinary leadership and significant contributions over that time. Her illustrious career began when she first started working with Dade Reagents in a marketing position for their diagnostic test kits and then moved on to North American Biologicals (NABI) in 1982 as a product manager for their Hepatitis B test kit. Over the years with NABI she assumed various responsibilities including supervision of their warehouse, operation of their testing lab, and finally into plasma operations where today she is Vice President, Plasma Operations for Biotest Pharmaceuticals.

Ileana has been involved with PPTA Source since its inception and has served and continues to serve as a Source Board member. She has contributed to this industry as Chair of the Standards Committee for many years as well as Chair of the Source Board. In her role as Chair of the Standards Committee she has been responsible for providing leadership that contributed to significant changes to the IQPP program and. She has served on various PPTA task forces for special projects and has also made numerous presentations at the Plasma Protein Forum and the International Plasma Protein Congress (IPPC) meetings. •

PREVIOUS HONOREES

2013 Donald Baker, *Baxter, Retired*
2011 Donald Baker, *Baxter, Retired*
2010 Ruedi Waeger, *Talecris*
2009 Bernard Horowitz, *Consultant*
2008 Peter Turner, *CSL Behring*
2007 Jean-Marie Vlassembrouck, *Baxter BioScience/ BioLife Plasma Services*
2006 David J. Gury, *NABI Biopharmaceuticals*
2005 Joseph Rosen, *Baxter Bio-Science/ BioLife Plasma Services*
2004 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*

RACHEL LIEBE, *PPTA Associate, North America*

Patient Notification System (PNS): Make Sure You Are Registered!

BY JULIE A. BIRKOFER

Sixteen years ago, the Plasma Protein Therapeutics Association (PPTA) and its members, working in collaboration with consumer organizations, developed a first-of-its-kind Patient Notification System (PNS). This model notification system is a rapid web-based tool that empowers patients with information about their medicines and is also available to physicians, nurses, and pharmacists. All you need to do is: Sign Up! Register at www.patientnotificationsystem.org. The PNS is a great source of trustworthy information; it provides confidential notification of therapy withdrawals and recalls. There is no charge to register.

We would like to make you aware of the many great features about the PNS. It's easily accessible and it is the one place on the web that you can visit and log-in to receive comprehensive information about immune globulins, blood clotting factors, alpha-1 proteinase

inhibitors and other lifesaving plasma protein therapies. Another important feature is that the PNS is confidential. Registrants, whether they be patients, physicians, family members, nurses, or pharmacists, are guaranteed that their information is never shared nor is it accessible by anyone other than the third-party company that houses the computers to run the system. The PNS was created to provide consumers, health care providers and others with a single, convenient source for up-to-date information about the plasma protein therapies they use and depend on.

ENSURING CONFIDENTIALITY

Maintaining patient confidentiality was a major consideration when developing the system. A working group comprising of representatives from from the FDA,consumer organizations, including: Alpha-1 Association, Alpha-1 Foundation, Committee of Ten Thousand, Hemophilia Federation of America, Immune Deficiency Foundation and National Hemophilia Foundation, helped to design the system to safeguard sensitive registrant information. To ensure confidentiality, the PNS is operated by Stericycle, Inc., an independent organization that specializes in informing the public of pharmaceutical withdrawals and recalls (notifications). All registrant information is kept strictly confidential.

REGISTER ONLINE OR TOLL-FREE

Anyone interested in registering with the PNS can go online at www.patientnotificationsystem.org or call the toll-free number, 1-888-UPDATE-U (1-888-873-2838). When you sign up, some basic contact information will be required, such as your name, address, email and phone number. You'll set up your own log-in and receive a password.

NOTIFICATION METHODS

During the registration process, you will be asked to select your "primary" method of notification. Registrants currently have the option of being notified by email, telephone or fax. We think you'll agree that email is a great choice for your "primary" method of notification because it is instantaneous and it is accessible anywhere, even if a registrant is traveling. It is very important for patients to receive this information about recalls or withdrawals; don't delay in registering and consider email as your "primary" choice for how to be notified.

PNS IN ACTION

Here's how the PNS works. If a therapy is withdrawn or recalled after consultation with the FDA, the company involved immediately contacts Stericycle, Inc., which then notifies the registrant. Every effort is made to notify registrants within 24 hours. Registrants are notified twice. First, you will receive an email, phone call or fax from Stericycle depending on your designated "primary" notification. Second, you will receive a a letter via U.S. mail containing the same information. The reason you will receive two notifications is because this is important information – you need to know before you infuse or inject your therapy that there has not been an event. "Event" is the term that is used for a recall or a withdrawal. The redundancy of two types of notification is intended to ensure that you have received your notification and helps to ensure your contact information is correct.

Consumers also can go online to www.patientnotification-system.org or call a 24-hour, toll-free number 1-888-UPDATE-U (1-888-873-2838) for current information on product recalls or withdrawals. To maximize the usefulness of the system, it is important for consumers to keep accurate infusion logs and record the lot number, therapy and manufacturer for all therapies they use. Infusion logs are available by calling the toll-free number.

PPTA'S ROLE

The system is administered by the Plasma Protein Therapeutics Association (PPTA). You may have seen PPTA exhibits at your annual meetings. At our exhibit booth we have information about the PNS and always have brochures with registration forms and Log Books to give away. The PNS is a comprehensive web-based system that is funded by manufacturers including: Baxter BioScience, Bayer Healthcare LLC, Biogen Idec Inc., Biotest Pharmaceuticals Corporation, Cangene Corporation, CSL Behring, Grifols USA, Kedrion Biopharmaceuticals, NovoNordisk Pharmaceutics, Octapharma, and Pfizer. •

To make accessing the PNS site easier for users, the Association has developed a QR code which is a machine-readable code and will allow users to scan a barcode with a smart phone and immediately be taken to the PNS website.

JULIE A. BIRKOFER, *PPTA Senior Vice President, North America*

Procleix

Procleix Solutions | SETTING NEW STANDARDS IN SAFETY & OPERATIONAL EFFICIENCY

Procleix NAT Solutions

By Hologic and Grifols

Innovative solutions to increase lab efficiency

In today's evolving NAT landscape, labs need versatile and efficient screening solutions to deliver safe blood for patients. Procleix NAT Solutions offer comprehensive blood and plasma screening products to help you achieve the highest levels of safety and operational efficiency.

Grifols (formerly Novartis Diagnostics) is proud to support you with advanced automation and a range of new products in development. Learn more about the Procleix NAT solution that's right for your laboratory by contacting your representative or visit us at www.novartisdiagnostics.com.

GRIFOLS

GLOSSARY OF TERMS

AABB	AMERICAN ASSOCIATION OF BLOOD BANKS
ABRA	AMERICAN BLOOD RESOURCES ASSOCIATION
AGES	AUSTRIAN AGENCY FOR HEALTH AND FOOD SAFETY
AMPAA	AMERICAN MEDICAID PHARMACY ADMINISTRATORS ASSOCIATION
ARGE	ARBEITSGEMEINSCHAFT PLASMAPHERESIS E.V.
ASEAN	ASSOCIATION OF SOUTHEAST ASIAN NATIONS
AWP	AVERAGE WHOLESALE PRICE
BCA	BLOOD CENTERS OF AMERICA
CIPO	CANADIAN IMMUNODEFICIENCIES PATIENT ORGANIZATION
CMS	CENTERS FOR MEDICARE & MEDICAID SERVICES
CPR	CANADIAN PLASMA RESOURCES
DAC	DEPARTMENT OF AIDS CONTROL
EAHAD	EUROPEAN ASSOCIATION FOR HAEMOPHILIA AND ALLIED DISORDERS
EBMT	EUROPEAN SOCIETY FOR BLOOD AND MARROW TRANSPLANTATION
EHA	EUROPEAN HEMATOLOGY ASSOCIATION
EMA	EUROPEAN MEDICINES AGENCY
ESID	EUROPEAN SOCIETY FOR IMMUNODEFICIENCIES
EU	EUROPEAN UNION
GDP	GROSS DOMESTIC PRODUCT
GMP	GOOD MANUFACTURING PRACTICE
HFI	HEMOPHILIA FEDERATION OF INDIA
IDF	IMMUNE DEFICIENCY FOUNDATION
IPAW	INTERNATIONAL PLASMA AWARENESS WEEK
IPFA	INTERNATIONAL PLASMA FRACTIONATION ASSOCIATION
IPOPI	INTERNATIONAL PATIENT ORGANISATION FOR PRIMARY IMMUNODEFICIENCIES
IPPC	INTERNATIONAL PLASMA PROTEIN CONGRESS
IQPP	INTERNATIONAL QUALITY PLASMA PROGRAM
ISBT	INTERNATIONAL SOCIETY OF BLOOD TRANSFUSION
JBPO	JAPAN BLOOD PRODUCTS ORGANIZATION
MOH	MINISTRY OF HEALTH
MPP	MEMBERS OF PROVINCIAL PARLIAMENT
MRB	MARKETING RESEARCH BUREAU
NABI	NORTH AMERICAN BIOLOGICALS
NMO	NATIONAL MEMBER ORGANIZATION
PEI	PAUL-EHRLICH-INSTITUT
PID	PRIMARY IMMUNE DEFICIENCY
PMF	PLASMA MASTER FILE
PNS	PATIENT NOTIFICATION SYSTEM
PPTA	PLASMA PROTEIN THERAPEUTICS ASSOCIATION
RI	ROTARY INTERNATIONAL
SCID	SEVERE COMBINED IMMUNODEFICIENCY
SIPC	SOURCE INDUSTRY PROFILE COMMITTEE
SMWIA	SHEET METAL WORKERS' INTERNATIONAL ASSOCIATION
SPAC	STATE PATIENT ACCESS COALITION
TAP	TECHNICAL ADVISORY PANEL
TTI	TRANSFUSION TRANSMITTED INFECTION
WHO	WORLD HEALTH ORGANIZATION
WFH	WORLD FEDERATION OF HEMOPHILIA


Rome, Italy

Upcoming Events

CONFERENCES & SYMPOSIUMS

January

27–28 European Forum for Good Clinical Practice Annual Conference
Brussels, Belgium

February

11–13 8th Annual Congress of European Association for Haemophilia and Allied Disorders (EAHAD)
Helsinki, Finland

23–27 Rare Disease Week on Capitol Hill 2015
Washington, DC

24–27 59th Annual Meeting of the Society of Thrombosis and Hemostasis Research
Düsseldorf, Germany

27–28 6th International Meeting on Pulmonary Rare Diseases and Orphan Drugs
Milan, Italy

March

10–11 PPTA International Plasma Protein Congress (IPPC)
Rome, Italy

22–25 41st Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT)
Istanbul, Turkey

26–28 HFA Symposium
St. Louis, Missouri

June

11–14 20th Congress of European Hematology Association (EHA)
Vienna, Austria

16–17 PPTA Plasma Protein Forum
Washington, DC

25–27 Immune Deficiency Foundation (IDF) 2015 National Conference
New Orleans, Louisiana

27–July 1 25th Regional Congress of the International Society of Blood Transfusion (ISBT)
London, England, UK

September

1–3 Bioplasma World Asia 2015
Shanghai, China

October

11–17 International Plasma Awareness Week (IPAW)

24–27 Annual Meeting of the American Association of Blood Banks (AABB)
Anaheim, California

25 PPTA Business Forum
Anaheim, California

QUALTEX[SM] LABORATORIES

Your Testing Service Solution[sm]

Our Mission

QualTex Laboratories is dedicated to supporting global public safety with the timely delivery of high quality testing services for patients, donors, and regulated biological products.

Services Provided

- Infectious Disease Testing
- Nucleic Acid Testing
- Immunohematology Reference Lab
- Microbiology Testing
- Specialty Testing

About QualTex

- Customer-centric culture
- Independent not-for-profit laboratory
- Innovative testing solutions
- Multiple laboratory sites
- State-of-the-art technologies
- Supports multiple industries
- 24/7/365 testing schedule
- FDA registered
- EU GMP certificate of compliance
- German Health Ministry certification
- ISO9001:2008 certified
- Active research & development

qualtexlabs.org 6211 IH 10 West ▪ San Antonio, Texas 78201 ▪ (210) 736-8952 ▪ Toll Free (888) QTX-LABS

THE AURORA™
PLASMAPHERESIS SYSTEM

FRESENIUS KABI

Power and Productivity

Aurora is the automated system that streamlines plasma collection procedures, produces virtually cell-free plasma and provides an improved experience for both operators and donors.

- Intuitive touch screen display
- Data Management with Aurora provides easy, accurate data collection, remote procedure setup and paperless documentation
- Designed to improve plasma center efficiency

Find out more today at **1-800-333-6925**
or visit **www.fresenius-kabi.us**