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INSIDE

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In the interest of encouraging broad and open discussion of issues relating to plasma protein therapies, collection and fractionation, the Source newsmagazine may contain statements of opinion on such issues. 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

One of the biggest contributions of the industry we represent is the fact that the manufactured therapies save so many lives and improve the quality of life of so many others.

Recently I spent some time with family and spoke a lot with one member who is in the terminal phase of renal cancer. Though he has survived far longer than what was predicted, he is going to leave us at an age that is still too young. Seeing this man inspiring his family and being an example for so many others, makes you realize how important life is and what good an individual can do.

As I write this, he is very engaged in a project that will result in a youth center and a baseball field next to the local church so that children can play ball in their small town in North Carolina. His inspiration and leadership are the drivers behind this great initiative, his legacy.

People should be able to live a normal life and not die prematurely. Unfortunately, many persons suffering from Primary Immune Deficiency (PID) have died at a young age because it was not recognized that their infections were caused by a deficient immune system. The Jeffrey Modell Foundation is named after Jeffrey who died at the age of 15. His diagnosis came too late and he could not battle his last fatal infection. At the recent Plasma Protein Forum we heard heartbreaking stories of two persons explaining what it was like to live with an undiagnosed PID. More about that can be read in this edition.

Immune globulins have become a very important tool for many physicians to treat their patients. Many clinical indications have been treated, some of them recognized by the regulatory agencies and licensed, some others require more work. But the one thing in common is that patients live a better life after using this outstanding therapy.

The manufacture of the therapies can not be done without plasma. Both speakers discussing PID (and other) participants at the Forum verbalized their gratitude to all those who are involved in the collection of plasma. This starts with the donors who spend so much of their valuable time donating their plasma, but it also includes all the personnel working at the various collection sites. The patients at the Forum said "THANK YOU" to all involved in the collection and manufacturing of plasma protein therapies.

It feels good to work within an industry like ours when individuals express their gratitude. It motivates, stimulates, encourages, helps; it is just wonderful.

Thank you for the trust and confidence in the ability of this industry to continue its work and save other lives!

Jan M. Bult / President, PPTA

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Plasma Protein Forum 2007

By Kara Flynn

Over 300 attendees and speakers participated in the 2007 Plasma Protein Forum, held June 5-6 at the Hyatt Regency Reston in Reston, Virginia. The theme of this year's Forum, which included a number of patient representatives participating in panel sessions, was "Committed to the Community," as PPTA highlighted industry's commitment to the community of plasma protein therapeutics users. The 2007 Forum addressed many of the policies and regulations that impact consumers' access to life-saving therapies. Attendees came away with the knowledge that for everyone in the plasma protein therapeutics community, there is a shared understanding of the need to partner together to assure patient access to life sustaining therapies.

Julie Birkofer, PPTA's Vice President North America, opened the 28th Plasma Protein Forum, thanked attendees and welcomed everyone to join her in celebrating 15 years of PPTA by wearing a special pin proudly to mark the occasion. She recognized that the industry is constantly evolving and changing in response to patients' needs and to meet the challenges of providing life saving therapies and assuring access to them.

Peter Turner

Terry Halper

Peter Turner, PPTA Chairman and President of CSL Behring L.L.C., warmly welcomed participants to the 2007 Forum and declared the industry to be in "good shape" after a few bumps in the road in years past. Mr. Turner discussed supply and access issues for plasma protein therapies and said that there are many parties responsible for maintaining both - including, manufacturers, physicians and regulators. Mr. Turner indicated that clinical research is ongoing and delivery of therapies to patients is at record levels in the U.S. A major concern right now, however, according to Mr. Turner, is the lack of support for treatment and inadequate reimbursement. He said payors have a major responsibility to assure access and regulators continue to be a critical partner in the equation as their actions often have a tremendous impact on patients' health. Mr. Turner concluded his remarks by noting that all stakeholders have responsibility in furthering supply and access given the stakes for patient well being.

Alpha-1 Panel

Kathy Antilla, the Immune Deficiency Foundation's (IDF) director of education and volunteer development and Terry Halper, a patient representative, who uses intravenous immune globulin (IVIG) therapies, gave the Keynote Addresses and provided attendees with their inspirational, true-life stories to help members of the audience understand why plasma protein therapies are so vitally important. In her remarks, Ms. Antilla discussed how she experienced first hand the difference that IVIG therapies can make. Her son Isaac was diagnosed with a primary immune deficiency at five and is now living a healthy, energetic life at 15. Finally, Ms. Antilla focused on the importance of plasma donation and the need for more awareness of plasma therapies and the role they play in saving lives. Terry Halper talked about the two lives he has lived - the first without IVIG and the second life with IVIG. According to Mr. Halper, in his first life, he was very sick with a number of serious infections that were treated with antibiotics. He said he had no energy and felt that he wasn't going to survive for much longer. At age 33, he finally was diagnosed by a doctor with a primary immune deficiency. In his remarks, he described how his doctor prescribed IVIG therapy, and from the moment he started taking it, his life turned around quickly. For more on Ms. Antilla and Mr. Halper, see page 14.

In the first presentation, Patrick Robert of the Marketing Research Bureau Inc., provided a comprehensive overview of the global plasma protein therapeutics industry and furnished global historical data on the core plasma-derived and recombinant analog therapies used to treat individuals with chronic diseases and disorders. In his presentation, Mr. Robert said the trends for products including Factor VIII, Factor IX, Polyvalent IVIG, Alpha-1 Antitrypsin and Albumin continue on an upward spiral. IVIG's continued market expansion being attributed to a long track record of safety and efficacy as well as the influence of patients' advocacy groups who rely exclusively on the therapies. He added that the re-insertion of IVIG into the World Health Organization's (WHO) list of essential medicines will make it accessible to patients in less developed countries, although it's high cost may hamper its wide application. In conclusion, Mr. Robert noted that therapeutic plasma proteins remain essential life-saving drugs for which there is still no competitive drug.

Kathy Antilla

The full gamut of issues impacting the bleeding disorders community was explored in the second panel, "Bleeding Disorders: Fundamentals of Access," featuring caregiver and consumer perspectives. Anna DeSimone of the National Hemophilia Foundation (NHF) discussed Project Red Flag (PRF), which is NHF's education and outreach program to women and their healthcare providers about the symptoms of bleeding disorders and the importance of proper diagnosis and treatment. With PRF, the NHF is looking to increase the diagnosis of the number of women with bleeding disorders, especially those with von Willebrand disease who are diagnosed and properly treated. In addition, according to Ms. DeSimone, the group wants to reduce inappropriate treatment of women with bleeding disorders. Kerry Fatula of the Western Pennsylvania Chapter of the National Hemophilia Foundation described her personal experiences in serving as a caregiver for three children with severe Hemophilia A. She said all three of her four boys have developed inhibitors with varying degrees of severity and it has taken a toll on the life of her family. Ms. Fatula urged members of industry in attendance at the Forum to keep supplies of treatments coming, as without

Mark Ballow, Dorothy Scott and Don Baker

these life saving therapies, her sons would suffer tremendously. The final speaker on the panel, Dana Kuhn of Patient Services Incorporated (PSI), said his organization helps people locate health insurance and afford the premiums in all 50 U.S. states. He said PSI has programs for Alpha-1, Hemophilia and Primary Immune Defiencies, recognizing that treatments for these rare diseases are expensive and treatments are difficult for some patients to access. Mr. Kuhn said PSI works with federal government, and has helped to introduce legislation in Congress, H.R. 5613: the Health Insurance Tax Credit Assistance Act of 2006. Finally, Mr. Kuhn noted that patients using PSI's services have improved financially, met out-of-pocket costs and ultimately went back to work because of improved health.

"Balancing the Perfect with the Practical: IVIG Analytes" panelists looked at the composition of IVIG from the perspective of the patient, industry and the regulator. This unique approach to examining IVIG, focused on some of the key issues of importance to consumers, namely, the desired composition of IVIG for treatment, in addition to taking into consideration manufacturing and regulatory issues. Guest speakers for this informative event included Dr. Don Baker of Baxter Bioscience, who offered an industry perspective on the complexities of manufacturing human plasma-derived therapeutics. The second speaker, Dr. Mark Ballow, a renowned health care researcher who currently serves as the Chief of Division, Director of Allergy/Clinical Immunology and Pediatric Rheumatology at the Women and Children's Hospital of Buffalo, represented the patient perspective on the panel by discussing the importance of having an adequate supply of IVIG to treat patients; and Dr. Dorothy Scott, who currently serves as Chief, Hematologic Products Branch, Division of Hematology (DH), Office of Blood Research and Review (OBRR), FDA, talked about regulatory issues related to safety and efficacy of immune globulins and shared some of the outcomes from a workshop sponsored by IDF, FDA and PPTA on immunoglobulin products on April 25-26.

The "Day in the Life of a Center Manager" panel highlighted the unique and challenging occupation of a center manager, who is often expected to have a broad knowledge of virtually all facets of plasma collection, including marketing, regulatory, management, accounting and

Randy Richards, Julia Bean and Johana Rummings

operations. As Baxter Biolife's Julia Bean stated, a center manager faces a number of challenges and opportunities. She said that the key character traits of a center manager are ethics, commitment, passion, support and the person must be a visionary. Randy Richards of ZLB Plasma said as a manager of a center, he wears many hats to round up 450 donors each day. He is often a bridge to his customers, employees upper management and the community. He says

the heaviest hat to wear, is what he described as "the crown of authority, responsibility and dedication." The third and final speaker for the panel, Johana Rummings of Nabi Biopharmaceuticals, said her job is more than just running a center, as it often requires her to be a bridge to the community where she often attends local events, runs food drives, participates in job fairs and holiday fund-raising activities. She said the biggest key to her success is asking her staff for ideas, soliciting feedback and understanding their needs and providing recognition. According to Ms. Rummings, every center manager is only as good as the team that works with them.

"Alpha-1 Proteinase Inhibitors: Treating Rare Disorders," explored some of the issues surrounding Alpha-1 Antitrypsin deficiencies and other rare genetic diseases. Miriam O'Day and John Walsh of the Alpha-1 Foundation, provided an update on patient registries, disease management programs and other important activities of

Diane Dorman, Ryan Faden, John Walsh, Elsa Anders and Miriam O'Day

the Foundation. Elsa Anders, a patient representative, provided her unique perspectives on this rare disease and described some of the challenges she has faced over the years due to complications of Alpha-1. Diane Dorman of the National Organization for Rare Disorders discussed challenges inherent in the treatment and diagnosis of Alpha-1 and Dr. David Wanner of the Alpha-1 Foundation discussed Alpha-1 Antitrypsin deficiencies and related it to the broader national initiative focusing on the treatment and diagnosis of Chronic Obstructive Pulmonary Disease.

After an educational first day of events, Forum attendees were invited to attend a cocktail reception and were treated to a musical performance by the band, "Izzi Does it." PPTA's Director of Member Services, Cathy Izzi, serves as the lead singer for the band.

On day two of the 2007 Plasma Protein Forum, PPTA Source Board Chairman discussed trends in source plasma collections. Kathleen Nolan, Health Division Director of the National Governors' Association (NGA) gave the Keynote Address on the second day of the Forum. In her role, Ms. Nolan works collaboratively with Governors' offices around the country to develop health policy initiatives and best practices. Her presentation focused on developments in universal health care in the states and the implications for the future of the U.S. health care system. In her remarks, Ms. Nolan said that right now is a time of innovation and there are a lot of plans at the state level with regard to health care initiatives. She noted that states are using a variety of innovative tools because they believe there is not going to be a federal remedy. Among those tools, are the expansion of public programs, covering individuals under private sector coverage and offering premium assistance to employers and tax incentives for individuals and employers. Ms. Nolan said economics are the driver since the uninsured cannot be ignored. In addition, drug costs are high and there is a desire now to encourage healthy lifestyles. Further, she suggested that if the plasma protein therapeutics industry is looking for exemptions for plasma protein therapies, they might be facing an uphill battle as there are many challenges right now following the exclusion of certain pharmaceuticals treating mental illness that were later seen to be of no assistance to patients.

The "Immuneglobulin: Life Saving Plasma Therapy" panel explored many facets of treating individuals who suffer from chronic diseases with immunoglobulins. Marcia Boyle of the IDF shared new data and provided an overview of the primary immune deficiency community. In her remarks, Ms. Boyle said that right now 35,000 to 50,000 people in the U.S. are being treated for a primary immune deficiency, but that is far lower a number than it should be. She said many people have trouble accessing therapies or others are prevented from obtaining IVIG due to product availability or price. Ms. Boyle said IVIG is the only known therapy for those who suffer from primary immune deficiencies and a lot of time is spent advocating for changes in reimbursement. She said there is a fight right now in all 50 states regarding coverage for healthcare. According to Ms. Boyle, if everyone wants to assure patients are getting access to care and the quality of care they deserve, there is no choice but to engage in these discussions. Lyle Dennis who spoke at the Forum on behalf of the Jeffrey Modell Foundation, a U.S.-based consumer organization, described some of the results of the public service advertising campaign undertaken by the Foundation, which thus far has reached approximately 90 million households via television. Mr. Dennis said the advertising campaign is supported by the U.S. Congress, National Institutes of Health and Centers for Disease Control and has generated $75 million in donated media thus far. Dr. Richard Hong of the University of Vermont, provided a history lesson for attendees, tracing the background of gamma globulin

therapies and offering his perspective as a provider about the importance of access to immunoglobulin for individuals with life threatening conditions. The final speaker on the panel, David Watters of the International Patient Organization for Primary Immunodeficiencies (IPOPI), provided a global perspective on the rare disease and discussed three areas for priority action worldwide, including awareness and education, screening and diagnosis and treatment and management. He said there is great value in working together, however, people in the community need to be patient, because there are no instant miracles. In addition, Mr. Watters talked about the need for resources, and said although IPOPI is encouraged that immunoglobulin was added by the WHO to the essential medicines list, many people continue to have problems accessing therapies when needed.

"Source Plasma Collection: A Snapshot of the Future," featured panelists working in that sector discussing the impact of emerging technologies and opportunities for innovation. The first panelist, Roger Brinser of BioLife Plasma Services provided a pictoral presentation of technological advances and innovations in the plasma collection industry. Dan Gamache of Nabi Biopharmaceuticals said most plasma donors are now coming from rural and urban

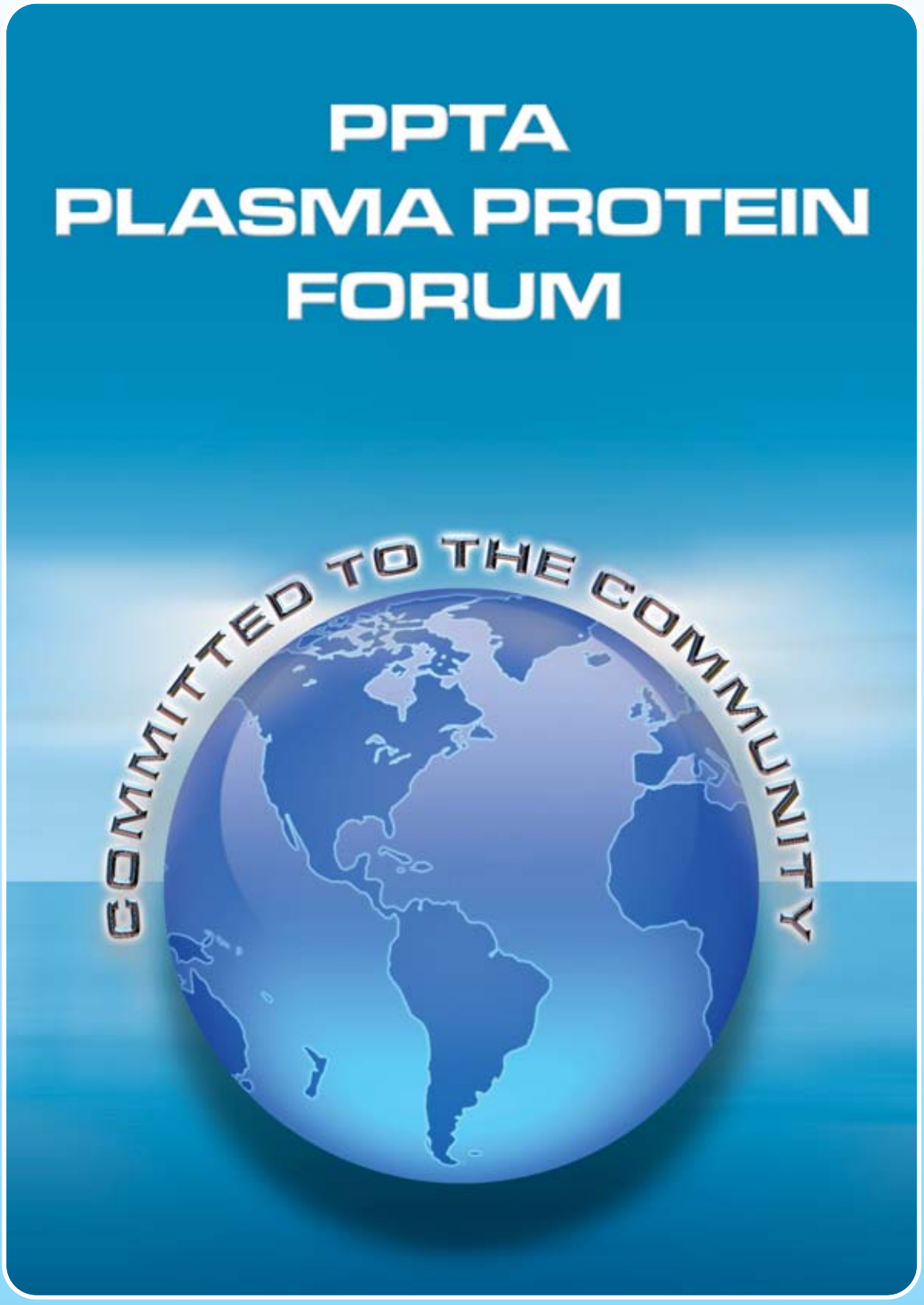
Lyle Dennis, Richard Hong, Marcia Boyle and David Watters

metropolitan areas. They tend to be students or those serving in the military or they are groups of people including firefighters, nurses or from a church. He said they donate, because of a family member's experience or altruistic motivations. The second speaker, Robert Kratzel of Talecris Plasma Resources, focused on the history of testing in the plasma collection industry. New standards require centers to ask probing questions regarding sexual practices, travel outside the U.S. and whether enough time has elapsed since a piercing or tattoo. Dr. Kratzel said that when he peers into his "crystal ball," he believes there will be an interactive interview process for potential donors with audio components. Finally, Gordon Naylor of ZLB Plasma Services discussed the future trends for the source plasma industry.

The last panel, "Audit/Inspection Q&A," featured Ruth Biehl of BioMed Management Solutions, Dr. Gerd Werner of the Paul Ehrlich Institut and Linda Alms of FDA's CBER. In this informative session, panelists discussed how plasma collectors and therapy manufacturers are complying with standards under strict regulatory controls. In her presentation, Ms. Alms focused on field inspections of plasma collection centers as well as inspections for licensing and approvals of new centers. In the second presentation, Dr. Werner, provided an international perspective on the inspection process taking place currently in Europe and in the final presentation of the day, Ms. Biehl discussed PPTA's certification programs, Q-SEAL and the Source IQPP Viral Marker Standard.

Bill Zabel, PPTA North America Chairman, closed the 2007 Forum, thanking attendees and performing a team building exercise that involved separating the audience into the following catagories: PPTA employees, attendees with a Source affiliation, manufacturers, patient groups, regulators/policymakers and physicians. After acknowledging the amount of work that went into planning the meeting, Mr. Zabel said all of the people in those groups have the same goal at the end of the day – to contribute in a meaningful way. "Always start and end your day with the patient in mind," he said. "And treat others as you would want to be treated. It's a simple mantra, but it's one that works."

The 2007 Plasma Protein Forum was a resounding success with more attendees than any Forum previously held. PPTA would like to thank the many consumer and industry representatives, regulators and other experts who presented at the meeting and allowed for an informative discussion. In addition, a special thanks goes to all of the attendees who took time out of their busy schedules to attend the conference. PPTA looks forward to seeing everyone at next year's Forum which will take place at the Washington Marriott in Washington, D.C. on June 17-18, 2008.



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Interview with Jean-Marc Spieser

Jean-Marc Spieser

The Source spoke with Dr. Jean-Marc Spieser, Head of Department of Biological Standardisation, OMCL Network & HealthCare at the European Directorate for the Quality of Medicines & HealthCare, about the role of EDQM in the world of plasma protein therapies.

Can you briefly summarize the history of the European Directorate for the Quality of Medicines & HealthCare (EDQM) and the European Pharmacopoeia?

The European Pharmacopoeia was created in 1964 by eight countries, six of which were founding Member States of the European Union, namely Belgium, France, Germany, Italy, Luxembourg and the Netherlands plus Switzerland and the United Kingdom (UK). Switzerland and the UK were at that time extremely interested in being involved in a standard-setting institution for pharmaceuticals because they had – and still have – a strong interest in pharmaceuticals (industry and authorities). Since they did not belong to the European Union, it was decided by the European Commission and the Council of Europe to host the European Pharmacopoeia under the auspices of the Council of Europe. Interest has grown over the years and one by one the European Pharmacopoeia has involved more and more Member States. It began with the Scandinavian countries joining in the 1970s, and then Spain, Greece, Austria and Portugal followed by Central European and Eastern European countries.

In addition, the need to strengthen the collaboration between the European Pharmacopoeia and EU Commission was acknowledged. The EU Commission has developed legislation for the pharmaceutical sector, such as the Directives 65/65 and 75/318 and 319 as well as many other Directives and guidelines, including for example the Directives and guidelines for vaccines and blood products in 1989 implementing the possibility for Official Control Authority Batch Release (OCABR). There was increasing interest in involving the European Pharmacopoeia Secretariat in more activities and contractual links between the EU Commission and the European Pharmacopoeia Secretariat were developed which led, as a consequence, to the establishment of the European Directorate for the Quality of Medicines (EDQM) in 1995.

The establishment of the European Pharmacopoeia is done by one department of the EDQM. Other departments include one which is responsible for the Biological Standardisation Programme and for control activities, including batch release of vaccines (human and veterinary) and medicinal products derived from human plasma through the Official Medicines Control Laboratories (OMCL) network. Another which is responsible for the Certification Procedure related to the suitability of the Ph. Eur. monographs.

Recently, the activities pertaining to blood transfusion and organ transplantation have been transferred from another section within the Council of Europe to EDQM (hence our change in name to the European Directorate for the Quality of Medicines & HealthCare). We are setting the standards used by industry, coordinating the control labs for testing materials, coagulation factors, immunoglobulins and other substances. In addition, we have developed the necessary methods and have a large experience in the field of medicines control and other therapeutic means. Consequently, it is logical to have everything under the same roof, although these are clearly separate activities running under separate bodies and structures.

What is the most important role of EDQM in the supervision of plasma protein therapies?

EDQM has at least three important roles:

1) We are the standard-setting body for plasma protein therapies (ppt) by developing and updating monographs in the European Pharmacopoeia. The monograph for Plasma for Fractionation which sets the requirements for all the source material of the ppts is one of the most frequently revised standards. It is steadily under scrutiny to be state of the art and fulfill the needs in terms of safety and quality as it represents the basis of the requirements with which the companies manufacturing plasma protein therapies have to comply.

2) We have another important role in ensuring that the

reference standards, i.e. the standard preparations, are available to both industry and control laboratories to fulfill the requirements of the monographs and to perform the batch release by the manufacturer and the OMCL. And that is a huge business because we need to provide all the different proteins such as coagulation factors, the different immunoglobulins, albumin and others. Whenever the stocks of a standard preparation are exhausted it has to be replaced ensuring continuity from one batch to another. We work together with the World Health Organization (WHO) and our U.S. Food and Drug Administration (FDA) colleagues to improve standardization on a global level.

3) The third activity is the coordination of the Official Control Authority Batch Release (OCABR) procedure, because in addition to the manufacturer's batch release, plasma protein therapies are submitted to an official batch release by an OMCL. We have developed, together with the involved OMCLs, a procedure based on mutual recognition and work to ensure that the Official Control Authority Batch Release (OCABR) procedure is only performed once on each batch. All EU Member States and European Economic Area (EEA) countries as well as Switzerland are participating in this work-sharing programme, a unique situation.

What will be your next priorities with respect to these products?

Our priorities depend on the scientific and technical developments. We need to make sure that we fulfill the needs of both industry and control authorities. With particular respect to blood and plasma-derived products, there is always the possibility of contamination with blood-borne pathogens, such as viruses. Therefore, EDQM's priority is to guarantee the safety of patients by state-of-the-art measures.

There are some new plasma-derived components and we have to ensure that we provide the scientific and technical support for these new products.

The European Pharmacopoeia (Ph. Eur.) and the U.S. Pharmacopoeia (USP) are two different organizations with a different legal basis. Is there a defined strategy for a harmonized approach of the two agencies?

There is a difference in the legal approach of the Ph. Eur. which is a part of the regulatory process, clearly mentioned in a certain number of EU framework directives, such as the Code for human medicines and the Code for veterinary medicines and its annexes. Therefore, the monographs of the Ph. Eur. are mandatory and have to be applied within the EU and EEA territories. If a manufacturer chooses an alternative approach, this has to be validated against the respective Ph. Eur. monograph. The USP is of a different nature. It is an industrial standardization body, governed by a private approach linked to the needs of industry, to provide standardization. Nevertheless, the USP is mentioned in the Code of Federal Regulations (CFR) with respect to the active substance and ingredients.

The strategy for harmonization between the different regions is linked to the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) process. The Pharmacopoeial Discussion Group (PDG) meets regularly with the aim of developing a harmonized approach for pharmaceuticals and general methods within the Q4 programme. This is a lengthy procedure because of the many different approaches and regulatory environments but the framework exists. On the PDG website regular reporting on the programme and progress is provided.

The European Union now has 27 Member States, what is your experience with the level of acceptance of the OCABR procedure by the new Members?

Is there an ongoing OCABR training programme for the new Member States?

The EU legislation and regulations agreed to by the 15 original EU Member States apply automatically to all countries joining the EU. We need to make sure that the rationale and the reasoning behind the "acquis communautaire" is understood, implemented and applied correctly.

Specific training involving representatives from Member States such as Germany, France, Belgium, the Netherlands, Italy and the UK was provided to train their new colleagues in methods and their implementation into different systems (a very important session took place in Vienna, Austria in December 2006).

It is obvious that the entire 27 Member States, EEA and Switzerland apply the same rules and standards, which has been quite a challenge.

We will continue this training on a periodical basis and we would like to invite PPTA member companies to participate in future sessions. We believe that not only authorities should be trained but also staff members from the manufacturers to provide them with an overview of the system and how to apply it. We are currently planning some training activities in 2008 and 2009 and will inform interested parties in due time; this will provide the opportunity for junior officers to cope more easily with the system and its procedures and guidelines.

One important part of this discussion is the Proficiency Testing Scheme (PTS), which is a very important technical training component, which should be ongoing. We have had experience with HCV and the B19 virus for a number of years, but also in the area of product characterization and

potency assay, in particular for coagulation factors or immunoglobulins. The programme involves both manufacturers and OMCLs. On a global level, the U.S., Australia, Canada and Turkey are also part of this initiative. In the future we might invite other countries including Russia, India or even China if they so wish.

You have recently inaugurated your new building including a significantly expanded laboratory. What will be the main activities pursued in these facilities and how will it affect other OMCLs, which are also WHO reference laboratories, such as the National Institute for Biological Standards and Control (NIBSC)? What will be the impact on your collaboration with industry?

Demand for our reference standards has increased by 3 to 5 times and we urgently needed additional capacity.

In addition to the need for more space, we also needed more modern facilities to ensure the highest quality of our services and standards.

At the end of 2006, our portfolio consisted of 1898 different reference standards.

In 2006, we honoured about 25,000 orders representing a distribution of a total of about 185,000 vials in over 100 different countries worldwide. In addition, we organized collaborative studies in different areas of activities, inter alia the plasma protein therapies, which in total required the preparation of about 6,000 study samples and their dispatch. This is obviously a tremendous activity, which is increasing constantly. As the standard-setting body, we need to apply the highest quality standards and there was clearly a need to enhance our system. In addition, we also have to prepare and to control the samples which are used in the PTS programme, which is also steadily increasing in activity.

Our aim is to work together in a network to ensure that unnecessary duplication is avoided and that the system is cost effective. There is no competition between us and other relevant organizations such as WHO, but an ongoing trend towards more and more cooperation; we have many common projects.

New pathogens are a constant challenge for industry and regulators. We believe that a real-life practical approach to pathogen safety has to be employed as opposed to a more academic approach. What is your opinion?

This is an ongoing challenge because with globalization and the continuous movement of people all over the planet there are a certain number of risks which are different today than they were some time ago. The most important issue and I cannot imagine that it is not a shared opinion, is the safety of the patients, for which we are all collectively responsible. This needs, of course, a very thorough approach and thinking. What happens when there is a new disease? There are several possibilities of a new contamination or possible contamination being under control. There are a number of precautionary measures which can go as far as excluding a certain territory or area from

The new EDQM building

donation. But this could lead to a shortage of the source material. There are of course other possibilities, such as testing. But as a test is not currently available, the first approach is to exclude donors who are exposed, to clearly avoid unnecessary transmission.

The second possibility is screening of donors. Using a risk-based approach, unnecessary loss of valuable source material, which might not contribute to any possible transmission has to be avoided. I cannot imagine that authorities are insensitive to the demonstration of validated methods which show that a given process eliminates the infectivity or brings it to a very low level risk. In addition, it is important to note that we are one part of the system and need to develop the appropriate rules, which are requested by the licensing authority and then implemented by the manufacturer of these products. As mentioned, with the globalization and the movement of people we are presented with continued challenges in terms of new diseases and as soon as there is a potential threat we apply precautionary methods or screening as soon as a suitable method is available. Then we have to eventually decide what the danger of the infectivity in the end product versus the starting material is. A very pragmatic and always scientifically safe approach will prevail and will continue to prevail which is a big challenge regarding potential shortage of the product and the economical impact.

The certification scheme for specific risk material of bovine origin is in place for a number of years. What is the practical experience with the programme?

For the time being I do not see any reason why we should move away from the certification procedure. There are still cases of bovine spongiform encephalopathy (BSE) so we have to continue to be vigilant. We have also to be vigilant with cases of potential transmission to humans. Regarding variant Creutzfeldt Jakob Disease (vCJD), the hope is that sooner or later researchers will be able to develop biological markers which can then be tested and screened for. This will be an additional challenge again if we do not have the appropriate methods providing validation. Until we have the possibility to detect the potential indicator, the certification is, for the time being, something which contributes to minimizing the risk and we should not abandon that possibility, especially as it also provides the opportunity for the relevant inspections to be carried out.

In an ideal world, what role would EDQM play on a global level?

We are continuously challenged by our customers and stakeholders. We try to make sure that we are continuously responsive to their needs as well as being conscious of the need to stay relevant and timely. Our relationship has evolved over time, but we continue to learn from each other and to learn how the system could contribute to avoiding an additional layer of unnecessary burden. Our major principle is safety and efficacious products for the patient and being as cost-efficient as possible.

We have been able to develop a leading role through our activities and are not prepared to give that up. In an ideal situation we would continue to provide leadership, which we have built together with all stakeholders. This is becoming more important with ongoing globalization. In addition, we are working together with our colleagues from North America, although with slightly different approaches and interpretations. We also collaborate closely with the WHO. One of our challenges is probably to enlarge the collaboration as much as possible to other territories including the Eastern European countries, which we hope to include more in the future. Also our colleagues from two of the most populous countries, China and India, will be very welcome, because their products can potentially soon begin to appear on our market, similarly to the situation which already exists for the chemical/pharmaceutical products. We have to ensure that these products are of the same good quality as those which are licensed under the highest possible standards in Europe.

IDF Honored at Biomat Plasma Center

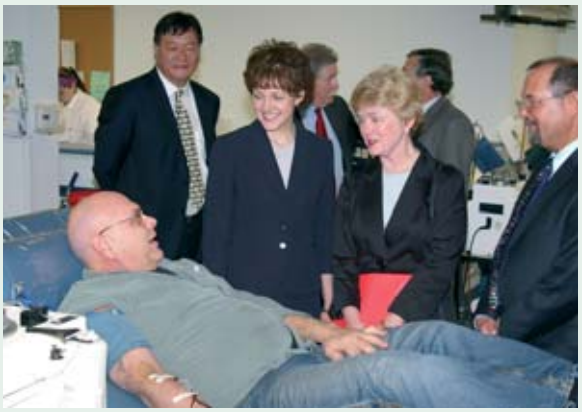
By Kara Flynn

PPTA Source member Biomat USA invited PPTA to join them in a special event on April 20 as it honored the Immune Deficiency Foundation (IDF) and the city's plasma donors at its Biomat Plasma Center in Reading, Pa.

On hand for the festivities, which drew local government officials and media under sunny skies, were Marcia Boyle, IDF's President and Co-Founder along with Kathy Antilla, IDF's director of education and volunteer development and Terry Halper, a volunteer for IDF and intravenous immune globulin (IVIG) user. Representing Grifols and Biomat were Victor Grifols Roura, the President and CEO of Grifols, S.A., Greg Rich, president and CEO of Grifols' U.S.-based operations and Shinji Wada, the president of Biomat USA.
"It is very personal to visit a plasma donation center," said Terry Halper, an IVIG user and IDF volunteer. "I feel connected to everyone who is a donor. It goes beyond plasma, in terms of the way I feel about people in general now. I see people on the street and I feel I have to be kind to them – these are the people donating plasma and saving lives, it could be anyone from your neighbor to the guy on the street."

Victor Grifols Roura presents a check for $25,000 to IDF's Marcia Boyle as attendees at the event look on

"They gave me my second life, because really I had two lives until I started using IVIG"



Shinji Wada of Biomat USA, Kathy Antilla of IDF, Marcia Boyle of IDF and Terry Halper, a patient representative of IDF, visit a plasma donor at the Reading Biomat Plasma Center. On the back: Victor Grifols Roura and Greg Rich of Grifols.

According to Halper, his goal in coming to the Reading event, was to help the donors understand that their efforts to donate plasma really are about saving lives – including his. "I'm only here today because of what plasma donors and companies like Grifols and Biomat do," he said. "They gave me my second life, because really I had two lives until I started using IVIG."

Halper said in his first life, he was very sick with a number of serious infections including pneumonia, bronchitis and various other infections that were treated by antibiotics. He said he had no energy and felt that he wasn't going to survive for much longer, after his five year old started to attend nursery school and he came down with a whole new set of serious infections from bacteria that his daughter brought home. "I was sicker than I had ever been in my entire adult life, but when I was 33, I finally was diagnosed by a doctor with a primary immune deficiency," he said.

Marcia Boyle of IDF poses with employees at the Reading Biomat Center after receiving a check for US $25,000 from Biomat USA

"The doctor prescribed IVIG therapy, and from the moment I started taking it, my life turned around pretty quickly. I was suddenly able to pick up both my kids and I had never had so much energy before. This was the beginning of my second life."

Halper says that he learned to cope with sickness for 33 years of his life and now he feels like Superman. "I appreciate my life in a way that I didn't before," he said.

According to IDF, thousands of people in the U.S. are diagnosed each year with primary immune deficiency diseases like Halper's and for many the only treatment available is IVIG, a plasma therapy that begins with the donation of human plasma at centers just like the facility in Reading.

During the event in Reading, which is known for a famous railroad and is one of the largest mushroom producing regions in the U.S., Corey Stein, the Reading Biomat Plasma Center Facility Manager, presented a check for $25,000, raised by employees and donors from more than 70 centers across the country, to IDF's Marcia Boyle, that the company plans to match through IDF's Blue Jeans for Healthy Genes Program. This national project brings companies, schools and other organizations together on a designated day, where adults are asked to pay money for the chance to wear jeans and join the fight against primary immune defiency diseases. All funds raised are used to support IDF's research, education and advocacy.

"Reading's donors play an important role in maintaining an adequate supply of plasma needed to produce IVIG and other life saving plasma therapies," said Shinji Wada, president of Biomat USA. "Without these donations, countless people who depend on IVIG and other plasma therapies would suffer unnecessarely."

Another representative of IDF attending the event, Kathy Antilla, said she has experienced first hand the difference that IVIG therapies can make. Her son Isaac was diagnosed with a primary immune deficiency at five and is now living a healthy, energetic life at 15. "My son was sick from the day he was born," she said. "From the moment he had his first infusion, however, there was a sparkle in his eye that wasn't there before and his life changed – our whole family's life changed for the better."

Antilla said her son is now six feet tall and in the ninth grade and recently was awarded a varsity letter for excellence in swimming at his high school. In fact, Isaac Antilla was elected the best ninth grade swimmer in his school this year. "My son is getting this life saving therapy and it all comes down to the people making the donations here in centers like the one we are standing in now," she said. "I want donors to realize that for people like my son, it's more than just the money – you are doing a great service. I think every donor of plasma needs to have a sticker just like those given for donating blood that says "I donated plasma today" – to me it's no different and just as critical." For more on Mr. Halper and Ms. Antilla, see pages 4 and 5.

Victor Grifols Roura echoed the comments of many by focusing on the importance of centers such as the Reading facility, but also made the important point that U.S. donors in Biomat's 58 centers located throughout the nation, provide plasma used in life-saving therapies in the U.S., Europe and elsewhere. "These donors are not just saving lives in the U.S., but they are also saving lives throughout the world," he said.

If you have a special event that you would like to highlight in The Source, please contact Kara Flynn, PPTA via e-mail at kflynn@pptaglobal.org.

Patient Profile: Gabriele Fehr

Hello, my name is Gabriele Fehr, I live in Berlin, Germany and I am 45 years old. Right now, I am still working almost full time (80%) at the German trade union "ver.di".

I would like to tell you about my illness and my everyday life with common variable immunodeficiency (CVID) syndrome.

In early 2004 I was diagnosed at the internationally recognized Charité hospital in Berlin as having this disease. Before that time my medical insurance company and my health were under a great burden due to misdiagnosed symptoms.

But I will start at the beginning of my story. As a child, I was already considerably more susceptible to infection than my sister. I was always quite delicate and small.

I remember, for example, that I missed most of my sixth year of school because of illness and spending time on medical treatment.

My first serious illness came when I was 17 years old: pleurisy and a respiratory infection with pleural contusion which led to eight weeks of hospitalization.

My son was born in 1983. I was 21 years old. From then on I was very ill almost once every year, often with long periods of hospitalization for such reasons as pneumonia, bladder infections, uterine and ovarian infections, pyelonephritis, as well as two miscarriages. I took antibiotics at least three to four times a year.

Most of the time, physicians, friends and family advised me to take better care of myself. Most of them were simply at a loss and kept asking me 'what is going on with you?'

In my mid-30s rheumatic complaints were added to my problems. At that time I was living and working near Koblenz, Germany, where I visited a rheumatologist.

He made the diagnosis of lupus erythematodes. I received high doses of cortisone and Quensyl, a medication, which eases symptoms of malaria.

At this time, my complaints were less vocal. But the typical side effects started as well: weight gain, water retention, osteoporosis, limitation of my range of vision, and depression, to mention but a few.

After three years, I visited a Lupus self-help group and it soon became clear to me that my symptoms were different than those of the others. My physician considered them typical of this disease and there were no further studies, and I continued to battle with all kinds of infections.

After another two years I moved to Berlin for professional reasons. Immediately, many of the same rheumatic symptoms started up again and after a visit to the department of rheumatology at Charité hospital it became clear relatively quickly that I was not suffering from lupus. With the aid of a 14-day admission and many studies and treatments in the outpatient clinic of rheumatology, the diagnosis of CVID had been confirmed, along with other diseases such as Sicca syndrome, chronic exhaustion syndrome, spondylosis deformans of the thoracic spine, arthritis and primary hypercholesterolemia.

Having learned from all the errors I previously experienced, I then immediately contacted the German Self-Help Organisation for Congenital Immunodeficiency (DSAI) and obtained a great deal of information about my disease from them.

My therapy at first was as an in-patient at Charité hospital. Here I received the therapy intravenously every four weeks. This intravenous administration of medication was then continued by an oncologist. I really had a hard time even obtaining my treatments at the beginning. For reasons of cost, as the doctor himself admitted, I was being given only very minimal doses at intervals that were much too far apart.

Via the DSAI, I then became aware of subcutaneous therapy. After long discussions and interviews, my physician at that time had become convinced to use subcutaneous therapy, to begin with only at his practice.

But here, too, extremely small doses at far too great intervals were prescribed. I did not receive the medication to take home with me and after weeks without therapy, I was battling serious infections once again.

But with the help of the DSAI, I then found a physician who had been prescribing an IVIG therapy for me regularly and in the rigth doses up to today.

I now carry out subcutaneous therapy at home three times a week. Of course there are problems with my abdomen, and it also sometimes irritates me considerably to always have this obligation in the evening after work. On the basis of the many infections I had in the past, these days I suffer from many chronic conditions. For example, chronic enteritis, rachitis, sinusitis, and abdominal and bladder infections. These may have been avoidable had the disease been diagnosed earlier.

I also have to take antibiotics frequently, and these treatments are also accompanied with a certain amount of side effects. But nonetheless I am very thankful, because my immunoglobulin G value is currently usually a bit over 700 and I feel considerably better, and even the infections remain within certain limits.

My rheumatic complaints have been increasing again somewhat recently and I do not tolerate the antirheumatic medications well at all. Bowel problems and hypertension are some of the consequences.

But here I obtained a tip from another patient to try enzyme treatment to control the pain and swelling. And a slight improvement has already commenced.

The infections, bowel problems, joint pain, therapy and doctors' visits put a burden on my everyday life and my professional life and it is not always easy to be able to deal with everything and complete my daily tasks. When a person is also faced with suspicions of abdominal carcinoma it is indeed rather difficult to remain cool and collected. Thank God it was only a small tumor, but it did wipe the smile off my face for a while.

Gabriele Fehr

At the moment I am worrying because it is suspected that my son might also have CVID.

And so a person is happy about every positive thing and all help that one encounters.

Since the end of last year I have been given a certificate of disability and therefore receive a few benefits at work. Of course I am sick more often than my colleagues, but fortunately I have a job where consideration is taken and understanding is demonstrated. Otherwise I would certainly have been terminated long ago on the basis of an illness without a positive prognosis.

Unlike the experiences of some of my fellow patients, my health insurer has never caused any trouble when it came to the prescription of pumps and medications. This is another thing for which I am very thankful.

I met my husband two years ago and moved in with him at the beginning of this year, and that is another reason why things are going very well for me these days.

I would like to thank everyone who has always been there for me. There have been some difficulties along the way, but things are improving.

CMS Assures Patient Access to IVIG

By Julie Birkofer

On April 18th, the Centers for Medicare & Medicaid Services (CMS) of the United States Department of Health and Human Services issued a decision that should over time have a positive impact on Medicare beneficiary's ability to access intravenous immuneglobulin (IVIG) in the appropriate site of care. Effective July 1, 2007, CMS, the federal payor of health care services to the elderly and disabled will reimburse IVIG according to individual brands that were on the market after October 1, 2003. The October 2003 date is significant because it was mandated in statute and was previously not acknowledged by CMS.

Prior to July 1, 2007 IVIG Medicare reimbursement under Part B (the physician office site of service) and the Medicare Hospital Outpatient Prospective Payment System (HOPPS) were reimbursed based upon a volume-weighted average of the entire class under the reimbursement model of Average Sales Price (ASP) plus 6%. IVIG was one of a very few designated single-source therapies in which Medicare uses a volume-weighted average to determine the ASP for the Healthcare Common Procedure Code (HCPCS). Regardless of the ASP for an individual brand, the reimbursement rate was previously based on the volume-weighted average of the entire class.

Product specific reimbursement for IVIG is an important decision made by CMS that takes an important step towards addressing reported difficulties encountered by patients seeking access to IVIG. Dividing IVIG into two groups for reimbursement purposes in April 2005 just did not go far enough to address patient access needs. Calculating reimbursement for liquid and lyophilized IVIG therapies without regard to specific brands led to a situation where access to IVIG brands was made more difficult because certain individual brands were at a higher sales price than the volume-weighted ASP for the class of IVIG, thus making those brands less appealing in terms of purchase. It is important that CMS recognized this distinction because 1.) Individual brands of IVIG differ in their makeup and characteristics and individual patients have better responses with one brand versus another (one brand can perform very well on one patient but not another in terms of, for instance, tolerance and reactions) 2). This is a critical care product in high demand. Access to all volume of production (all brands), appropriately matched to individual patients, is important. When reimbursement is deterring access to certain brands, then overall IVIG access issues develop.

PPTA proposed several remedies to CMS to improve the IVIG patient access situation. The Agency listened and responded by putting in place individual HCPCS codes for each brand of IVIG so that reimbursement will be ASP plus 6% (an additional payment adjustment for IVIG is also sought) for the individual brand instead of the class. Brand- based reimbursement will eliminate the disincentive to purchase only certain brands within the IVIG class, thus increasing access to all brands of therapy. Such a measure should assist in improving patient access to this life-saving product. Brand-specific reimbursement will improve patient access because:

The incentive to purchase only brands of IVIG whose costs are below the volume-weighted average will be eliminated. This measure would free up a portion of the IVIG market where there is economic disadvantage (thus reduced access) from purchasing under the existing bundled IVIG codes.

All brands will be reimbursed based on the same reimbursement formula, thus removing the lack of appeal for certain brands with a cost higher than the volume-weighted average in the current bundled IVIG class reimbursement.

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Immune Globulins in the 21st Century

By Mary Gustafson

Immune globulins became available in the United States in the 1940's with the first immune globulin licensed under the Public Health Service Act in 1943. In 1953, the government published the first standards (i.e., minimum requirements). These minimum requirements were codified into regulations in 1966. The first requirements in the Code of Federal Regulations (CFR) included potency requirements for measles, diphtheria and polio. The testing was to include neutralization assays to demonstrate functionality of the antibodies, not simply presence of antibodies. These requirements are in effect today, but are they as relevant in 2007 as they were in 1966?

There have been changes in products over time. The intended use and route of administration are different than when the regulations were put in place. Immune globulins in the middle of the last century were intended for prophylaxis in the general population, often given when people were traveling. The route of administration was intramuscular. The intramuscular product was given to replace antibodies in patients with immune deficiencies, but the route of administration limited the dosages and value in restoring complete antibody protection. Although intramuscular immune globulins are available today, an important use of immune globulins is treating patients with primary immune deficiency diseases (PIDD). The immune globulins are administered in larger doses by the intravenous or subcutaneous route of administration. The PIDD community relies on the therapies to sustain life and live nearly free of symptoms associated with the underlying immune deficiency conditions. The success of the therapies in this community is demonstrated by the increased activities, including travel, by people with PIDD. The active lifestyle of people with PIDD makes it important to understand the current most important needs for infection prophylaxis in people with PIDD.

There have been other changes over time. The immune globulins are prepared from plasma from human donors. For this reason, it is important to review changes in the donor population. It is known that the epidemiology of antibody specificities in donors is changing. This is due to many reasons. One is the basic quality of life and community hygiene measures. People in developed countries today are rarely exposed to food-borne and water-borne pathogens. Also, people are vaccinated against diseases that were once common in the population. Examples of these include measles, diphtheria and polio (the required potency specificities), as well as, chicken pox, rubella, mumps, and hepatitis A and B. As donors age, the number of donors that had common childhood diseases decreases. They are replaced by younger donors who were vaccinated. Often the profile and potency of antibodies differ in the vaccinated population. There is evidence of this in looking at measles antibodies. Measles antibody levels, as demonstrated by the required potency test, have decreased in immune globulins over time. This is thought to be because the donor population is younger and has been vaccinated against measles. The antibody levels in vaccinated individuals, while protective, are not as high as in people who have had the infection. This change in antibody levels is becoming an issue with the current measles potency requirement.

To address the changing demographics of donors and people with PIDD and the changing epidemiology of diseases, the U.S. Food and Drug Administration (FDA), Immune Deficiency Foundation (IDF) and PPTA co-sponsored a workshop in Washington D.C. on April 25 - 26, 2007. The workshop was entitled: Immune Globulins for Primary Immune Deficiency Diseases - Antibody Specificity, Potency and Testing. The goals of the workshop were four-fold:

- Assess current potency testing of immune globulins
- List antibodies needed to protect PIDD patients from infections
- Identify candidate antibody specificities for potency testing of immune globulins for treatment of PIDD
- Address approaches to provide measles protection with immune globulins despite diminishing measles antibody levels in the plasma donor population

The workshop was divided into three sections. In the first, presentations focused on identifying the most relevant antibody specificities needed by people with PIDD. The

second focused on the antibody levels in currently licensed immune globulin products. From these sections, it was hoped that information would be provided that would lead to identifying clinically relevant antibodies that could be measured by practical tests to assure lot-to-lot manufacturing consistency. The third section was devoted to measles antibodies. It reviewed the epidemiology of measles, the level of antibodies needed for protection, the levels of antibodies in products and donors and explored possible approaches to address the decline of antibodies in immune globulins.

As a result of the first sections, two bacterial infectious agents, Streptococcus pneumoniae and Hemophilus influenzae were noted to be the most clinically relevant by clinicians. Studies would need to be developed and performed to evaluate whether these specificities are amenable to replacing one or two of the currently required potency testing specificities. With regard to the measles potency requirement, information revealed at the workshop and further developed by industry and FDA will be presented to FDA's Blood Products Advisory Committee at its meeting on August 16, 2007. Workshop presentations are posted (for one year) on the FDA website at http://www.fda.gov/cber/summaries/htm. A transcript of the workshop is at http://www.fda.gov/cber/minutes/workshop-min.htm.

"The success of the therapies in this community is demonstrated by the increased activities"

2007 PPTA Robert W. Reilly Leadership Award

The Robert W. Reilly Award was presented to Mr. Jean Marie Vlassembrouck at a reception at the Plasma Protein Forum at the Hyatt Regency Reston. The award is given to an individual who "has had a positive influence on the industry and who has demonstrated unquestionable professional character, ethics and commitment to the advancement of the plasma industry."

Mr. Jean Marie Vlassembrouck is the Vice President of Global Industry Affairs for Baxter. He has served on the European Board of PPTA since its inception in 1994 and has also served as its Chairman. Currently he is Chairman of PPTA's Global Management Committee (GMC) and has helped develop the long range strategy of the association and led the GMC in implementing the plans of the Global Board.

Mr. Vlassembrouck has regularly attended the Board meetings of PPTA Europe, PPTA North America and PPTA Source as well as participating in their annual planning meetings. In fact, he is one of the most knowledgeable persons in the plasma protein industry.

He has represented the industry all over the world in helping to promote open access to markets. In addition, he has informed politicians, stakeholders, physicians, and industry leaders to better understand the complexity of the plasma protein industry and the safety of our therapies.

Mr. Vlassembrouck's dedication and commitment has paid off in the form of meaningful results for industry.

PPTA Chairman Peter Turner presents the 2007 PPTA Robert W. Reilly Leadership Award to Jean Marie Vlassembrouck, Vice President of Global Industry Affairs for Baxter Bioscience

PPTA would like to congratulate Jean Marie Vlassembrouck and thank him for his integrity and ethics that have represented our industry so well over the past decade. His dedicated and thoughtful leadership has greatly contributed to the success of this industry and his efforts are indeed worthy of the plasma protein therapeutics industry's prestigious award.

"He is one of the most knowledgeable persons in the plasma protein industry"

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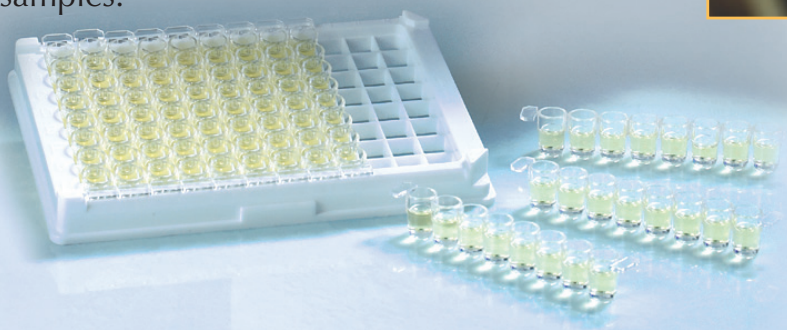

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PPTA Hosts 2007 Congressional "Fly-in"

By Kara Flynn

Dozens of PPTA staff, member company representatives and plasma protein therapy consumer advocates descended on Capitol Hill on May 8, to educate policymakers on the unique and complex characteristics of plasma protein therapies. Approximately 55 meetings took place over the course of a day as consumers and PPTA members wore out their shoes visiting Congressional delegations for PPTA's 2007 Congressional Legislative Day or "Fly-In."

In the meetings, lawmakers were urged to support H.R. 1282, the Medigap Access Improvement Act of 2007, which would allow all Medicare beneficiaries, regardless of age, to be eligible for Medigap coverage and would extend coverage in all states to those who are disabled or who have end stage renal disease. As many of the consumers who use plasma protein therapies are disabled due to injuries and other complications due to their rare diseases, support by policymakers is critical. In addition, during the meetings in House and Senate offices, the united group of consumer and industry representatives, discussed the ongoing intravenous immune globulin (IVIG) Medicare beneficiary access dilemma

"Fly-In" attendees also expressed concerns that follow on biologics legislation, (S. 623 and H.R. 1038) authorizing the U.S. Food and Drug Administration (FDA) to approve abbreviated applications for licenses of biological products are not appropriate for unique plasma-derived therapies. In discussions with Congressional members and their staff, consumer representatives, PPTA members and staff explained that an abbreviated application process for follow-on plasma protein therapies could raise concerns and that it was important for policymakers to understand that the development of these therapies is complex, time consuming and very expensive.

The "Fly-In" kicked off with an overview of upcoming issues that will be considered by Congress in coming months, provided by Mr. John Myers, Legislative Assistant to U.S. Sen. Arlen Spector (R-PA), Chairman of the Labor, Health and Human Services, and Education Appropriations Subcommittee. Mr. Myers updated attendees over breakfast on such health care issues as the State Children's Health Insurance Program (S-CHIP) which is being enhanced to allow for more flexibility so that dollars can be used in the most effective manner possible to cover as many individuals in need as possible. Additionally, he noted that Sen. Spector is very supportive of funding for the National Institutes of Health, which has lagged behind in terms of keeping up with medical inflation over the years.

> ***"Approximately 55 meetings took place over the course of a day as consumers and PPTA members wore out their shoes"***

Rep. Phil English with Jan Hamilton and Kelly Lavin, congressional staffer

In a special presentation during the breakfast briefing, PPTA was honored to recognize Rep. Lois Capps (D-CA), a trained Registered Nurse (RN) who has worked on numerous patient access issues while serving on the influential House Energy and Commerce Committee. The award was given to Rep. Capps for her continued leadership in Congress for championing health care issues benefiting millions of Americans. Upon accepting the award, Rep. Capps said that in Congress, policymakers often have a full plate of health care issues that require attention, but it is difficult to tackle everything at once. “We need to hear how the work we do here in Washington impacts you – the patients,” she said. “For some people, it is so hard to get to Washington, but it is so much more effective in terms of reaching out to legislators if you can educate them in person.”

Julie Birkofer gives award to Rep. Joe Pitts

Following morning visits in both House and Senate offices, PPTA proudly presented Rep. Joseph R. Pitts (R-PA) the 2007 Legislator of the Year award during a special luncheon in his honor, for his outstanding leadership in helping to ensure access to lifesaving plasma protein therapies. Rep. Pitts is a champion for plasma protein users and for leading a May 31st, 2006 letter to Health and Human Services (HHS) Secretary Michael Leavitt urging the agency for an immediate and comprehensive solution to the IVIG Medicare beneficiary access dilemma. Rep. Pitts was joined by 34 additional members from the House of Representatives in this effort. In addition, Rep. Pitts has let his fellow representatives know about the IVIG access problems by inserting messages of the dire access situation in the Congressional Record on a number of occasions. Lastly, Rep. Pitts was willing to sponsor potential legislation that would address the IVIG patient access situation late last fall.

Following this year's slate of Congressional briefings and the incredible effort that it took to travel to the many offices over the period of just a day, the consumer community and PPTA members, reaffirmed the importance of plasma protein therapies and worked to illuminate some of the challenges that lie ahead in terms of ensuring access to these life saving therapies. Thanks to all of the attendees who traveled far and locally to attend these meetings and to make this year's "Fly-In" a successful event!

Workshop Plasma Donor Suitability

By Joshua Penrod

The Plasma Protein Therapeutics Association (PPTA) hosted a workshop examining Source Plasma donor suitability. Held in conjunction with PPTA's annual Plasma Protein Forum on June 4, 2007, the Workshop attracted more than fifty attendees, including members of the regulatory community from the U.S. and E.U., the plasma collection and fractionation industry, and other industries with similar concerns regarding infectious disease and donor suitability criteria.

The one-day workshop's agenda featured introductory and keynote remarks, a panel discussion on risk reduction on the plasma collection and fractionation processes, a panel discussion comparing regulatory regimes and practical implications, followed by closing remarks.

After brief introductory remarks, Jan M. Bult, PPTA President, gave a provocative presentation to begin the discussion. Mr. Bult focused on the meaning of plasma donation in a global sense, pointing out that the same individual could be eligible or ineligible for donation, depending on the type of donation and national policy. He stated that plasma is a precious starting material, and that the need for donations should be balanced with quality and safety requirements that add value and are science-based. As the industry grows more globalized, a harmonized regulatory structure grows in importance, to ensure quality, safety, and the best use of this precious starting material.

Following Mr. Bult's opening remarks, the first panel took the stage. This panel was designed to examine issues of risk and risk reduction in plasma collection, epidemiology of behavioral risks, and a case-study of local regulation of a body art establishment.

Dr. Christine Arcari, University of Texas Medical Branch, Galveston, Texas, opened the panel with an examination of hepatitis-C (HCV) risk from tattoos and other routes. Dr. Arcari's framework for discussion showed a balance between understanding the theoretical nature of a risk and donor screening with the goal of eliminating high-risk donors. Dr. Arcari reviewed many of the leading epidemiological studies in the area, and noted that transmission of HCV via tattoos is biologically plausible, but that "presence of a risk factor does not necessarily equate with 'increased risk.'"

Dr. George Schreiber, Westat, gave a different perspective on tattoos and piercings for plasma donors. Dr. Schreiber gave a detailed overview of risk reduction by each of the safety steps present in the collection of Source Plasma. After demonstrating the marked increase in prevalence of body art in the U.S. population, Dr. Schreiber noted that commercial tattooing establishments still remain as a point of concern, along with the size and number of tattoos that an individual may have.

Dr. Thomas Kreil, Chairman of the PPTA Pathogen Safety Steering Committee, offered a perspective from the standpoint of a scientist ensuring safety of the final product. Dr. Kreil drew special attention to the use of Source Plasma as a part of an industrial, manufacturing process, differentiating it from transfusible products. Dr. Kreil acknowledged the utility of donor selection and testing, and enhanced the well-known "safety tripod" by demonstrating the 100 million-fold risk reduction that occurs in modern manufacturing processes. Dr. Kreil concluded by demonstrating several recent, successful case studies and re-affirmed that selection and testing limit the amount of pathogens, but reduction confirms effectiveness and final product safety.

> **"commercial tattooing establishments still remain as a point of concern"**

Ms. Susan Spring, City of Albuquerque Consumer Health Protection Division, illustrated her organization's usage of a regulatory paradigm for body art facilities. Ms. Spring described the program as an inspection regime for licensure of establishments, focusing on maintenance and upkeep of the physical facilities, cleanliness, recordkeeping, waste disposal, lighting, and sterilization. Ms. Spring noted that the Albuquerque ordinance is currently being expanded to the State of New Mexico's legislature, and it is expected to become a state-wide law in the near future.

The second panel discussion highlighted U.S. and E.U. regulatory policies and their respective impacts on Source Plasma collection facilities and fractionators. This panel represented some of the policy outcomes that had been determined some time ago, based on the risks described in early publications. The second panel, noting that the theory and science has changed, as described by the participants in the first panel, showed the integration of regulatory policy and the scientific theory.

Dr. Alan Williams, U.S. Food and Drug Administration (FDA), gave the talk "Regulatory Perspective on the Eligibility of Source Plasma Donors." In it, he named the FDA priorities: maximizing blood safety, minimizing donor loss, minimize operational burden, and ensuring staff safety. After summarizing the stages of donor qualification, Dr. Williams examined U.S. regulatory policy for a variety of behavioral issues, including tattoos and piercings. Dr. Williams noted that the FDA is always willing to reconsider current policies, so long as a proposal is accompanied by scientifically valid studies and data.

Dr. Gerd Werner, Paul Ehrlich Institut, summarized current E.U. requirements in "European Lookback and Deferral Policy (Implications and Practical Limitations.)" Dr. Werner's presentation examined E.U. regulatory policies and legislation relevant to donor suitability and health, behavioral deferrals, and the scientific derivation of the policies, including the four-month deferral and lookback period for tattoos, with the donation being Nucleic Acid tested (NAT). Dr. Werner also expressed interest in continuing dialogue regarding scientific re-evaluation of lookback and deferral policies, along with harmonization of those same lookback and deferral criteria.

Mr. Roger Brinser, Baxter Biolife, gave a presentation entitled "Lookback and Deferral Policies, Implications and Practical Limitations – A Collector's Experience." Mr. Brinser recapped some of the high points of the policies described by Drs. Williams and Werner, and turned to the practical implications of those policies within a plasma collection center. He noted the geographic diversity of the modern donor base, the overview of unit retrieval, the impact of donor deferrals, and the utility of the policies given the modern donor screening process. Mr. Brinser called for a standardized approach among regulatory authorities, along with an understanding that the ever-increasing popularity of tattoos and piercings demonstrate it as a new cultural norm that should be accounted for in regulatory policy.

Dr. Yvan Giroud, CSL Behring, delivered the address "U.S. and E.U. Lookback and Deferral Policies, Implications, and Practical Limitations: The Fractionator's Perspective." Dr. Giroud discussed the relevance of continued reporting of post-donation information and lookbacks given modern practices, time for pooling, and the layers of safety throughout the collection and manufacturing processes. Dr. Giroud suggested that notifications should be restricted to unpooled units and that policies for critical and potentially critical situations could be maintained.

Dr. Toby Simon, ZLB Plasma, gave closing remarks that spanned much of the discussion from the morning to the close of the second panel. In capturing much of the proceedings, his presentation distilled several areas for consideration:

- Does risk assessment allow changes to donor suitability policies, given changes in demographics, testing algorithms, and manufacturing processes?
- The next steps for discussion and review: workshops, FDA Advisory Committees, follow-up meetings, such as the FDA-PPTA liaison venue.
- Reasons for investigating potential policy changes:

testing improvements, demographics changes, tattoo techniques, continuance of a strong safety record, and improvement of the donor experience.

The question and answer sessions revealed a number of areas for future discussion and inquiry:

- The presence and content of local regulatory authorities observing licensure of body-art establishments.
- A data-driven effort to better understand the risk factors associated with HCV.
- The areas of critical need that can demonstrate safety and improve efficiencies.
- Methods of collecting information from donors that can be used to improve the donation experience and lead to a more satisfied donor base.
- Ways of reconciling divergent policy views derived from the same base of scientific information.
- A better understanding of any changes and trends in the donor population that can impact the industry and policymaking.

In all, the Workshop was very well-received by both the audience and the participants. It is expected that the Source membership will begin working toward collecting information relevant to the inquiries above. The Source Board expressed its appreciation to all of the participants and the industry working group that planned and executed the Workshop.

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Minnesota: Focused on Quality of Care

By Ryan Faden

On May 10, the Minnesota Senate introduced SF 2290 focusing on ensuring quality of care for all patients utilizing plasma protein therapies. The bill was co-sponsored by Minnesota State Senators Kathy Sheran and Sharon Erickson Ropes. Sen. Sheran has a background in education for children with special needs and Sen. Ropes has a nursing background. Both are committed to ensuring that Minnesotans receive the highest quality health care possible. To that end, they have also been very involved this year in the legislative efforts surrounding universal health care access legislation in Minnesota. While those bills did not pass this year, they are receiving considerable attention during the interim period between legislative sessions and will likely be a high priority in 2008.

SF 2290 was referred to the Senate Health, Housing and Family Security Committee. With this bill introduction, there are now two states (Pennsylvania is the other) actively considering quality of care legislation based upon the existing New Jersey law. The Minnesota legislation would, if enacted, require that:

1) Consumers have access to qualified home care providers with the requisite expertise. Under the legislation, home care providers would be required to meet the following requirements:

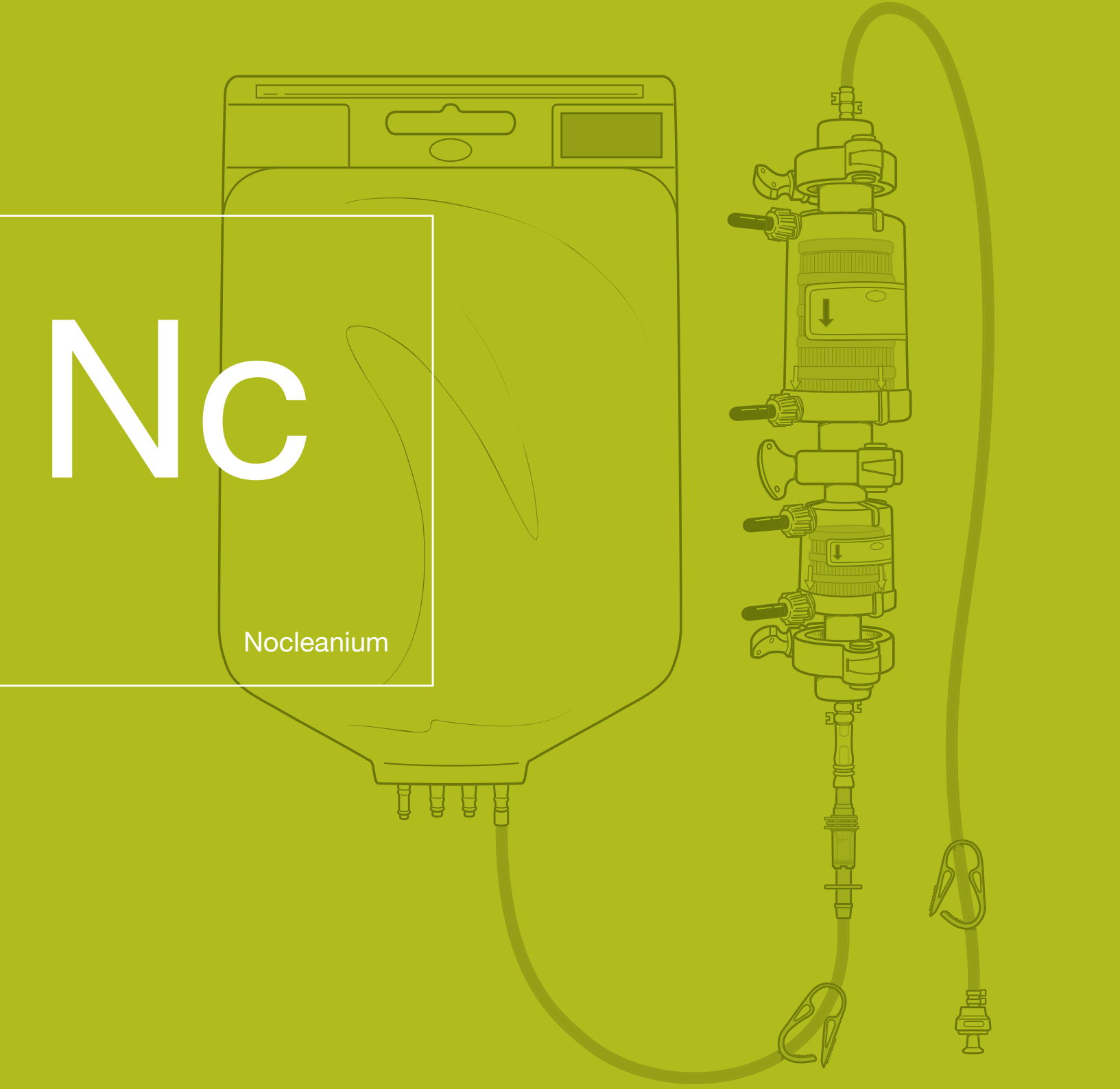
- Supply products and services under a prescription from the covered person's treating physician and not make any substitutions of plasma protein therapies without prior approval of the treating physician;
- Supply all needed drugs and ancillary supplies for the administration of plasma protein therapies, including, but not limited to, needles, syringes, and cold compression packs;
- Provide directly, or through a third party agency, supportive home nursing services to assist in the reconstitution and administration of plasma protein therapies when such services are prescribed by the treating physician;
- Provide record keeping and documentation and assist covered persons in obtaining third party reimbursement;
- Provide expedited notification to patients of plasma protein therapy recalls or withdrawals;
- Provide for proper removal and disposal of hazardous medical waste in compliance with applicable state and federal law and;
- Provide covered persons, upon request, information about the expected costs for medication and services that are not otherwise reimbursed by the covered person's health plan company;
- Require the Commissioner of Health to compile a list of home care providers who meet the minimum standards set out above and make the list available to health plans and to covered persons upon request.

2) Consumers have access to specialized laboratories with expertise in the complex testing associated with conditions treated with plasma protein therapies; and

3) Screening for von Willebrand's disease prior to undergoing a hysterectomy for unexplained menstrual bleeding. Estimates from the National Hemophilia Foundation indicate that as many as 30,000 women in the U.S. each year have unnecessary hysterectomies.

Earlier in May, Minnesota Governor Tim Pawlenty signed a proclamation recognizing the importance of access to plasma protein therapies.

These exciting developments in Minnesota represent an important victory in the efforts of the community to ensure that consumers receive high quality care. It is the result of members of the patient community and industry working together to achieve an important goal. PPTA is committed to continuing its work on this important issue in Minnesota through the remainder of 2007 and 2008 as the state continues to work on reforming its health care system.



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Key Studies on IVIG Marketplace Released

By Jon McKnight

The U.S. Department of Health and Human Services (HHS) Releases Key Studies on the Intravenous Immune Globulin (IVIG) Marketplace while Congress Introduces Legislation to Provide Viable Solutions to the IVIG Patient Access Dilemma

The genesis of the Medicare beneficiary access problem to lifesaving IVIG therapies began when the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 changed Medicare's reimbursement methodology from the average wholesale price (AWP) to the average sales price plus six percent (ASP +6%). The new reimbursement policies became effective January 1, 2005 for physicians, and January 1, 2006, for hospital outpatient departments. The new reimbursement methodology implemented by the Centers for Medicare & Medicaid Services (CMS) had the unfortunate effect of reducing payment rates paid to providers of IVIG on behalf of Medicare beneficiaries. Since the implementation of the new reimbursement rates in the physicians office in 2005, the entire IVIG community informed policymakers that Medicare beneficiaries around the nation were experiencing difficulty accessing their IVIG because physicians' expenditures were drastically outpacing Medicare's reimbursement. This trend led to many physicians either reducing their IVIG infusion services to Medicare beneficiaries or discontinuing the practice altogether.

In the summer of 2005, as a result of persistent advocacy efforts by consumer organizations to the ongoing IVIG patient access dilemma, the Committees on Energy and Commerce and Ways and Means of the United States House of Representatives jointly requested that the HHS Office of Inspector General (OIG) examine the current IVIG marketplace. In addition to assessing manufacturer actions, this study was initiated to examine the role of distributors, group purchasing organizations (GPOs), and physicians in the IVIG distribution channel. At a July 13 Committee on Ways and Means, Subcommittee on Health hearing, CMS' Director of Medicare Reimbursement, Herb Kuhn, announced the commission of a second study for the purpose of better understanding the IVIG marketplace and elevating access and reimbursement concerns from patients and physicians. Thus, the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) contracted with Eastern Research Group to examine supply, distribution, demand, and access issues associated with IVIG.

While policymakers and the IVIG community eagerly awaited the completion of the government led studies, regulatory successes in addressing the IVIG patient access issue were achieved by the IVIG community's persistent communication and advocacy with CMS. For example, the agency recognized that an additional payment for the pre-administrative related services was warranted. Thus in 2006 and 2007 a temporary add-on payment was implemented to help address the reimbursement shortfall. Although a temporary pre-administration add-on payment for IVIG was helpful, the additional reimbursement was not enough for providers to cover the purchase price of IVIG, thus medicare beneficiaries were still having difficulty accessing IVIG at their preferred site of service (as of press time, it appears likely that the pre-administration payment may continue through 2008).

Another regulatory success was achieved this April when CMS, after intense PPTA involvement, made the decision to reimburse liquid IVIG therapies at their own average sales price rather than a volume weighted average (See in depth article on this topic on page 18). This reimbursement decision will help patients receive the IVIG treatment that is best suited to their own individual needs because providers will be reimbursed for the product of their choice based on medical efficacy and not the price of a specific product. Although, the aforementioned regulatory successes help providers in treating patients, the IVIG community has consistently advocated for a permanent viable legislative solution to the complex reimbursement methodologies that affect patient access to IVIG. While working with many congressional legislators over the past two years, it became evident that until the OIG and ASPE report was released, a legislative solution to the access issues surrounding IVIG would have to wait until the important information was obtained from the studies that

were published. During this time however, many members of Congress urged HHS Secretary Michael Leavitt to expedite the two studies' release in order to address the problem.

On April 26th, 2007, nearly two years after the commission of the OIG report, the Department released the long anticipated OIG Report, Intravenous Immune Globulin: Medicare Payment and Availability. Just a week later, on May 3, 2007, HHS released the Assistant Secretary for Planning and Evaluation (ASPE) study entitled, Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immune Globulin Intravenous (IGIV). Both reports revealed what the IVIG community has been advocating for the past two years: that inadequate Medicare reimbursement is a leading factor as to why patients are experiencing difficulty accessing IVIG. For example, the ASPE report cited the recent patient survey commissioned by the Immune Deficiency Foundation (IDF), which found that 54 percent of Medicare beneficiaries using IVIG attribute poor reimbursement as the leading reason for their difficulties in accessing IVIG in the appropriate site of service. Again, the ASPE report cited the IDF patient survey that found substantial numbers of Medicare patients have had their treatments postponed and/or reduced in frequency because of reimbursement problems. As a result of these access problems, patients began to suffer increased infections and more hospitalizations. In addition, the OIG Report revealed that 61 percent of the physicians surveyed indicated that they had sent patients to hospitals for IVIG treatment because of their inability to acquire adequate amounts of IVIG or problems with Medicare payments. The OIG report also validated the difficulty physicians have in obtaining IVIG at a price below Medicare reimbursement rates. The report highlighted that the current Medicare payment rate fails to recognize all of the costs incurred by a physician in administering IVIG to patients.

Through a close collaboration with the tireless advocates at the IDF and armed with the recent OIG and ASPE reports on the IVIG marketplace regarding the inadequate reimbursement model surrounding this lifesaving therapy, some influential policymakers in the House of Representatives have taken decisive action in helping to restore patient access to IVIG by introducing legislation that will assist providers in obtaining adequate levels of Medicare reimbursement payments. On June 28, 2007 H.R. 2914, the "Medicare IVIG Access Act" was introduced by Representatives Kevin Brady (R-TX) and Steve Israel (D-NY) along with original co-sponsors Marcia Blackburn (R-TN), Michael Burgess (R-TX), Barbara Cubin (R-WY), Phil English (R-PA), Wally Herger (R-CA), Maurice Hinchey (D-NY), Gregory Meeks (D-NY), Michael McNulty (D-NY), Devin Nunes (R-CA), Ron Paul (R-TX), Jim Ramstad (R-MN), Lucille Roybal-Allard (D-CA), Pete Sessions (R-TX), Chris Smith (R-NJ), Ellen Tauscher (D-CA), and Bill Young (R-FL).

H.R. 2914 seeks legislative authority directing the Secretary of Health and Human Services to review the OIG and ASPE reports and other surveys to update the Medicare payment to provide appropriate reimbursement related to the furnishing of IVIG. The bill does not dictate to the Secretary what rate should be implemented but rather, it directs the Secretary to collect, within 6 months, the necessary data related to the unique characteristics of IVIG and asks the Secretary, if appropriate to adjust the current reimbursement rate. Moreover, there is such a precedent for this current approach as reflected in the Medicare Modernization Act (MMA) treatment of hemophilia blood clotting factor. Blood clotting factor, like IVIG, is a lifesaving plasma protein therapy. In addition, H.R. 2914 also provides for an IVIG home infusion benefit that will help Medicare beneficiaries with primary immune deficiency diseases access their IVIG in their homes. The current Medicare Part B home infusion benefit is 'hollow' because it only covers the cost of the product and does not cover the costs of professional services such as nursing, supplies or equipment. Thus, the current home infusion benefit makes it difficult for beneficiaries to receive IVIG treatment in the home. Lastly, the bill requires CMS to conduct two beneficiary surveys over three years to measure changes in patient access to IVIG and providers, as well as changes in health outcomes.

Currently, legislative opportunities for H.R. 2914 are extremely fluid so PPTA and others in the IVIG community will be actively working with Members of Congress in addressing this current patient access priority. Readers are encouraged to log on to the IDF website at www.primaryimmune.org and click on the 'Action Alert' banner on the right hand side to find your local U.S. Representative and urge them to support this important piece of legislation.

If you need additional information or have any questions please contact Jon McKnight at jmcknight@pptaglobal.org or Jay Greissing at jgreissing@pptaglobal.org.

Meet PPTA Staff: Ryan Faden

Ryan Faden

Background

My name is Ryan Faden and my title is Assistant Director of State Affairs. I have been with PPTA for 18 months. I'm a native of Philadelphia, but I've also lived in such varied locales as Dallas and Houston, Texas; Gig Harbor, Washington and Mission Viejo, California where I lived beginning from the sixth grade. All of the traveling growing up has proven to be good training for my current work at the Association, which takes me to state capitals across the country. My wife Lena and I live in Washington, D.C. and we have a two-year old daughter-Emily and a chocolate lab-Philly.

Tell us about your background.

My dad worked for Humana when it was primarily a hospital company, which was a major spark for my interest in health care issues. After graduating from high school, I attended the University of California at Los Angeles (UCLA) where I majored in history and pre-medical science and from there I went on to receive a Masters in Public Health in Health Policy and Management-also from UCLA. After working in the health care industry for a couple of years, I decided to continue my education at Seton Hall University's School of Law in New Jersey, where I earned a Juris Doctor with a concentration in Health Law & Policy. Following graduation from law school, I moved to Washington, D.C. in 2000 where I began a position with a major law firm in their health care practice group. My career has included professional experience in all aspects of the health care system, which provides me with the perspective to understand how changes in policy might impact consumer group interests and PPTA member companies.

What is your proudest professional achievement?

It would have to be achieving success in getting quality of care legislation introduced in the Minnesota legislature this year. It was a cooperative effort from member companies and the patient community that led to this success. It was so exciting for everyone involved to see an actual bill in the system that was the culmination of our work. Hopefully, if asked this question next year, I could say my proudest moment was holding this legislation with the governor's signature emblazoned on it indicating it has been signed into law.

What is most rewarding about working in this industry?

Since joining PPTA, I have had the opportunity to speak at and participate in numerous patient group events. At last year's National Hemophilia Foundation meeting in Philadelphia during the policy panel, I had a chance to comment on a question from the audience about what we can do as a community to be proactive in ensuring access to therapies. I was able to raise the point that legislation requiring high quality care is the best example of a proactive approach. In other words, laws that hold providers to certain standards for delivering care in the community reduces the likelihood that access crises will occur. Following the session, a consumer attending the meeting came up to me and told me how much he appreciated what I had to say.

In fact, it is the contact with the consumer community that I enjoy most about working at PPTA. When you attend a consumer meeting, you really can see what the work we do is all about. As an Association representing manufacturers, we have a responsibility to provide safe and effective therapies for consumers so that they can lead healthy and productive lives. Along with that, interacting with the consumers has inspired me to learn more about the conditions that our therapies are utilized to treat. I believe that having a detailed understanding of the science of these conditions is essential to being an effective advocate when dealing with sophisticated policymakers.

PPTA's United Kingdom (UK)-based group is cooperating with the Deloittes's (UK Department of Health advisers) proposed immunoglobulin "Demand Management Plan." Based on a very detailed database intended ". . . to record the infusion of every gram of immunoglobulin" used in the UK, this approach demonstrates a relatively sophisticated government response to the tight supply of immunoglobulin that they are experiencing. An associated new tendering procedure was commenced June 1, 2007. It is too early for a meaningful assessment of its impact.

The European Commission has published the meeting report of the 62nd meeting of the Pharmaceutical Committee. The Commission presented results of the consultation of its strategy paper on "Better Regulations of Pharmaceuticals: revision of the Variations Regulation" which expressed an overall support for all five key proposed items. The outcome of the consultation will be taken forward in the preparation of draft legal texts, which will be subject to public consultation in the course of 2007.

On June 27, 2007, the U.S. Senate Committee on Health, Education, Labor, and Pensions reported out the "Biologics Price Competition and Innovation Act of 2007." This bill provides an abbreviated application and approval process for follow-on biologics if the applicant demonstrates its product is either biosimilar to or interchangeable with the reference product. Because two competing follow-on biologics bills exist in the House, it is unclear when or if the House Committee on Energy and Commerce will consider such legislation. This Senate bill will bypass floor action and be added to the FDA Revitalization Act once a conference committee meets to reconcile the differences between the Senate and House versions of the FDA bill. Among other things, the FDA bills include reauthorization of the Prescription Drug User Fee Act. The House has yet to pass its FDA package but is expected to after the July recess.

The U.S. Food and Drug Administration (FDA), the European Commission (EC), and the European Medicines Agency (EMEA) have agreed to expand their current cooperative activities in several important areas. At a meeting June 14-15, 2007, the U.S. and the EU reviewed the past year's activities under the existing Implementation Plan for the confidentiality arrangement. The ultimate goal of the initiative is to promote and protect public health, reducing regulatory burden and costs, and bringing innovative products to patients in a timely manner. Furthermore, important safety information about medicinal products is shared among the parties.

On May 29th, the Texas House of Representatives approved a resolution aimed at raising awareness as to the importance of access to IVIG. The resolution was the result of the cooperative efforts of the consumer community and industry. This accomplishment represents a further incremental step in the community's efforts to ensure access to therapies and quality of care. In Texas, it is hoped that the resolution will be an important first step in outreach efforts to policymakers and the media.

PPTA staff has been working with member companies to address the inappropriate reimbursement policies for Alpha-1 proteinase inhibitor therapies in Washington and West Virginia. PPTA was alerted by member companies that these two states' Medicaid programs are reimbursing pharmacies at the multi-source rates rather than single source rates. This situation has a real potential to impact patient access if providers are unable to obtain adequate reimbursement. PPTA has had discussions with officials in each state and a letter is being drafted to the states and First Data Bank, Inc. which currently has the A1PI therapies listed as multi-source drugs in their reports.

As the European Union's official body for the evaluation and supervision of medicines, the European Medicines Agency (EMEA) has a wealth of information to share with patients and consumers about the latest developments in this field. The Agency makes this information freely accessible to support and encourage widespread public understanding of medicines and their use.

Calendar of Events

2007

September 24-25
5th World Federation of Hemophilia's Global Forum on the Safety and Supply of Treatments for Bleeding Disorders
Montreal, Canada

September 28–30
The 3rd World Congress of Alpha1 Patients
Rome, Italy

October 14-17
Biannual Meeting of the Australian and New Zealand Society of Blood Transfusion (ANZBST)
Queensland, Australia

October 21
Source Business Forum
Anaheim, California, USA

October 20–23
American Association of Blood Banks (AABB) Annual Meeting
Anaheim, California, USA

November 10-13
XVIII Regional Congress of the International Society of Blood Transfusion (ISBT), Asia
Hanoi, Vietnam

November 26-27
First Latin American Symposium on Hematology, Transplantation, Regenerative Medicine & Cellular Therapy
Buenos Aires, Argentina

December 8-11
American Society of Hematology (ASH) 2007 Annual Meeting
Atlanta, Georgia, USA

2008

March 4–5
International Plasma Protein Congress
Warsaw, Poland

June 1-5
Hemophilia World Congress
Istanbul, Turkey

June 7-12
XXXst International Congress of the International Society of Blood Transfusion (ISBT)
Macao, China

June 12-15
13th Congress of the European Hematology Association (EHA)
Copenhagen, Denmark

June 17-18
NOTE NEW DATES:
PPTA Plasma Protein Forum 2008
Washington, D.C., USA

July 2-5
54th Annual Scientific and Standardization Committee (SSC) Meeting
Vienna, Austria

September 16-19
41st Annual Meeting of the German Society for Transfusion Medicine and Immunehaematology (DGTI)
Düsseldorf, Germany

October 16-19
XIIIth Meeting of the European Society for Immunodeficiencies (ESID)
's-Hertogenbosch, The Netherlands

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IPPC 08
International Plasma Protein Congress

International Plasma Protein Congress

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