the risk of hemolysis. Roger Berg, M.D., Baxter Innovations GmbH, presented preliminary PPTA analyses of data from 263 hemolysis case reports at the workshop. A paper with additional PPTA analyses has been published in the supplement.

The following PPTA member companies also contributed individually with presentations at the workshop and papers in the supplement:

- Baxter: Anti-A and anti-B titers in donor plasma, plasma pools, and immunoglobulin final products (John McVey, Don Baker, Rajesh Parti, Roger Berg, Maria Gudino, and Wolfgang Teschner)
- CSL Behring: Donor screening reduces the isoagglutinin titer in immunoglobulin products (Brigitte Siani, Katharina Willimann, Sandra Wymann, Adriano Marques Antunes, and Eleonora Widmer); Effects of the manufacturing process on the anti-A isoagglutinin titers in intravenous immunoglobulin products (Val Romberg, Liane Hoefferer, and Ibrahim El Menyawi); Isoagglutinin reduction by a dedicated immunoaffinity chromatography step in the manufacturing process of human immunoglobulin products (Liane Hoefferer, Isabelle Glauser, Annette Gaida, Katharina Willimann, Adriano Marques Antunes, Brigitte Siani, Sandra Wymann, Eleonora Widmer, Ibrahim El Menyawi, Reinhard Bolli, Martin Spycher, and Martin Imboden)
- Kedrion: Anti-A and anti-B hemagglutinin depletion during Cohn purification process of 5% immunoglobulin (Alfonso Salvatore, Semih Esin, Giovanna Batoni, Ester Ascione, Claudio Farina, and Claudia Nardini)

PPTA’s contributions were only one part of the FDA workshop and Transfusion supplement exploring strategies to address hemolytic complications of IG infusions. PPTA also is collaborating with FDA to develop consensus labeling pertaining to hemolysis for all normal IG products. Along with clinicians, regulators, and hematology researchers, PPTA member companies are a key part of the on-going effort to address this important issue for IG patients.

Transfusion is free to AABB members. Nonmembers may subscribe through Wiley-Blackwell or by calling +1.800.835.6770.

PPTA Hosts 2015 Plasma Protein Forum

BY JULIE BIRKOFER

The 2015 Plasma Protein Forum kicked off June 16 with a keynote address from Rep. Doris Matsui (D-CA), a longtime champion of rare diseases and access to care issues.

Rep. Matsui, who received the 2015 PPTA Leadership Award, shared her enthusiasm for the 21st Century Cures Act, which she thinks will be “a great turning point” in leading to more innovation and advances in medical technology. The bill, which passed unanimously out of the Energy and Commerce Committee, will next head to the House of Representatives. It is expected to provide funding to telehealth services to expand practices into underserved communities and help ensure that federal policies are consistent with needs for rare disease patients.

More than 300 people attended the June 16-17 event in Washington, D.C., which covered diverse issues such as industry challenges, patient voices, plasma donation benefits, self-sufficiency, and regulatory. The conference was well attended by patient group representatives, industry, regulators and academics and provided substantive and thoughtful discussions while highlighting key challenges facing patient access to plasma protein therapies.

Alabama Senate Majority Leader Greg Reed (R-5) received a special recognition for his commitment to getting his state to lower the minimum plasma donation age. Earlier this year, Alabama Gov. Robert Bentley signed Senate Bill 13, which lowers the minimum age to donate plasma in that state from 19 to 18. “It was a privilege and an honor for me to help you in our state,” Sen. Reed told Forum attendees in thanking PPTA for the honor. He also promised to talk to other politicians in other states on the importance of allowing individuals 18 and older to donate. Nebraska is now the only state that doesn’t allow plasma donation at 18.

PPTA President and CEO, Jan M. Bult, moderated the Access to Care Panel: Vision for the Future in which the CEOs of the National Hemophilia Foundation (NHF), Immune Deficiency Foundation (IDF), Hemophilia Federation of America (HFA), and Alpha-1 Foundation all took part. The importance of access to treatments globally was discussed.

*Now known as Baxalta Inc.*

*BY MARY CLARE KIMBER, PPTA Senior Manager, Regulatory Policy*
Herbert Dichtelmüller Honored With Otto Schwarz Award

Since 2012, the Otto Schwarz Award has recognized leadership in the plasma protein therapeutics industry and related scientific fields. This year’s recipient, Herbert Dichtelmüller, Ph.D., was recognized posthumously for his contributions to pathogen safety and his significant contributions to improving the safety profile of plasma protein therapies.

Dr. Dichtelmüller, who worked for Biotest AG, died in February 2015. His son, Cornelius Dichtelmüller, accepted the award at this year’s Forum, saying, “I would like to thank all of you for supporting my father’s work. He would have been very proud today.”

The Otto Schwarz Award was created in honor of Dr. Schwarz, one of the founders of the International Plasma Products Industry Association (IPPIA), the association representing the manufacturers of plasma protein therapies, and the forerunner of PPTA. As one of the first Chairs of IPPIA, he recognized the importance of developing an industry view and was the first to recognize the importance of qualified donors and how to best apply nucleic acid amplification test (NAT) technology. PPTA is pleased to recognize his legacy through the Dr. Otto Schwarz Award.

NEWS FROM AROUND THE GLOBE

as were the challenges of obtaining patient access to plasma protein therapies around the world. All patient groups expressed their focus on access, advocacy, education, awareness and research. Some groups expressed the importance of finding a cure for their respective diseases and increasing support for patient registries.

“We try to build relationships and teach patients to be good stewards of their own care,” said Val Bias, NHF president and CEO.

Marcia Boyle, IDF president and founder, echoed that, saying: “We give patients a voice and teach them to advocate for themselves.”

HFA Executive Director Kimberly Haugstad agreed. “There can’t be enough overlap when it comes to advocacy,” she said.

Of his organization, Alpha-1, John Walsh, CEO and president, praised all of the patient groups for working together: “We are committed to working with other plasma-user organizations.”

During the Changing the Global Perspective on Compensation: Focus on Patient Need panel, Dennis Young, vice president, Global Plasma Sourcing, Baxalta, praised industry for the advances it’s made, saying, “The changing of perception happens one mind at a time.” In that same panel, Cristiana Spontoni, an expert in EU biotechnology, pharmaceuticals, and medical devices, explained that in regards to compensation “we must be sensitive to cultural issues because in the end we want safe plasma for the world.”

The International Perspectives: Access to Care Panel covered issues that included: increasing primary immunodeficiency (PID) diagnoses in Germany, the importance of newborn screening; political issues surrounding the blood banks in the Netherlands and the high price that hospitals pay for blood; the vast challenges facing India as it tries to increase not only the plasma supply but the quality of it as well. The difficulty in getting patients diagnosed was also highlighted; and a journey through some PID case studies from Japan and the effect of treatments.
During his panel, Shinji Wada, PPTA Source Board of Directors Chairman and president/CEO of Grifols Plasma Operations, shared his enthusiasm for the industry’s response to the global challenges it faces. Calling the challenges “opportunities,” Mr. Wada cited the FDA’s draft guidance on MSM, nomogram, Ontario legislation, and Rome Declaration among a spate of global issues the industry has faced in the last year. “We are making progress,” he said. “Serious, serious progress.”

Whitney Goulstone, director, communications, Canadian Immunodeficiencies Patient Organization (CIPO), presented “Protecting Patient Access in Ontario: A Patient’s Voice.” A PID patient herself, Ms. Goulstone took the audience through CIPO’s advocacy efforts opposing legislation banning compensated plasma donation in Ontario. Although the legislation passed in 2014, she said that the patients and advocates in Canada will continue to fight on behalf of access and highlight support for compensated plasma collection.

Two donors took time to speak to the audience about their dedicated donation routines and the pride they take in saving lives. A 20-year-old college student who has donated more than 80 times at the BioLife Plasma Center in Harrisonburg, Va., told the crowd, “It is great to learn about the people who are in need of my plasma and that some of the people are close to home.”

Another donor, a 43-year-old military officer who has been deployed several times, said he donates twice weekly whenever possible at the Biomat USA Frederick center, a Grifols facility in Frederick, Md. He shared how he has seen firsthand the necessity of plasma during war. “Without plasma and without the life-saving benefits, they would not have made it off the battlefield,” he said.

During his presentation, “A Scandal in Geneva: National Self-Sufficiency & The WHO,” Dr. James Stacey Taylor urged stakeholders in every facet of industry to demand better evidence when policymakers declare self-sufficiency as the best way for countries to take care of their citizens in regards to blood and blood products.

“When a country which pursues national self-sufficiency in blood or plasma or any other medical product that it can import cheaper, it’s wasting its health care resources on an ideological, ideologically-motivated policy,” said Dr. Taylor. “In human terms, this means that it is not helping its patients in the way that it should. It’s spending money badly.”

The Forum opened with a moment of silence for Dr. Víctor Grífols Lucas, a founder of Grifols and innovator known for his work on plasmapheresis. He passed away on June 1, 2015, and was remembered for his valuable contributions to the industry.