

# THE SOURCE



THE MAGAZINE OF THE PLASMA PROTEIN THERAPEUTICS INDUSTRY

Summer 2009

## The Evolution of Safety in Source Plasma Collection

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**Leaders Gather in Paris for IPPC 2009**

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**JMF Recognizes Industry at Spring Ahead Gala**

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**Florida Launches Comprehensive Hemophilia Management Program**

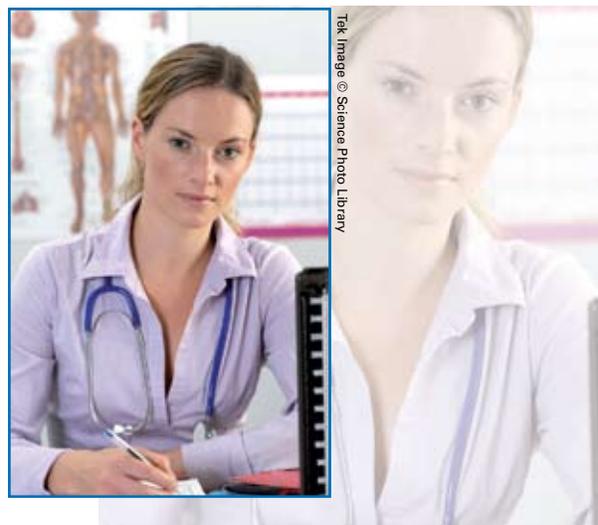
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USA/Canada  
Tel: 858 453 9177  
Fax: 858 453 9189  
info@thebindingsite.com

THE BINDING SITE GmbH  
Germany/Austria  
Tel: +49 (0)6202 9262 0  
Fax: +49 (0)6202 9262 222  
office@bindingsite.de

THE BINDING SITE  
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Managing Editors  
Sybille Beck  
Kym Kilbourne

*THE SOURCE is published four times a year by PPTA, 147 Old Solomons Island Road, Suite 100 Annapolis, MD 21401 Phone:+1.202.789.3100 email: [thesource@pptaglobal.org](mailto:thesource@pptaglobal.org)*

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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 magazine 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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Design and Production: [www.bonotom.com](http://www.bonotom.com)

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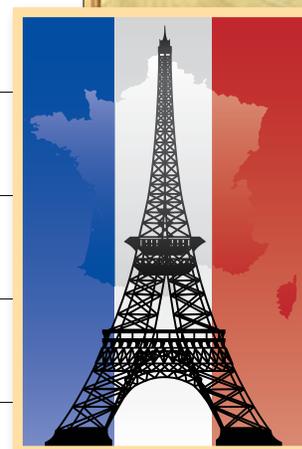
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# IN MY VIEW

## PATIENTS NEED FREEDOM OF CHOICE

**LIFE IS FULL OF CHOICES.** In early childhood, choices are made for us, but as we get older and grow to adulthood, we must learn to make our own decisions. These decisions often reflect personal opinions that we strongly believe in, despite the fact that family and friends warn us about the possible negative consequences if our choices are ill-advised. As everyone knows, many decisions could have been better and some of them we regret ever making.

There are situations in life where no wrong decisions can be made. Swimming without proper instruction is not a good thing to do; driving a car without a license is a no-no; and flying without training and a license is asking for serious trouble. Sometimes people choose to make such irresponsible decisions and must accept the consequences. We learn from our mistakes, gaining wisdom that follows us through life.

But what about decisions that are made for us even after we reach adulthood? Usually, we accept and follow these rules because we are safer, such as laws mandating seat belt use in cars or wearing helmets on motorcycles. Sometimes, however, the decisions that are made for many of us do not result in a better life, but a reduced standard of living and greater pain. There are many people with genetic or acquired conditions that require life-long medical treatment. Each of these individuals wants to decide the favored treatment options in tandem with the help of their physician. Any restriction that affects the availability of a therapy takes away a patient's ability to decide what treatment they will choose. Freedom of choice means that patients and physicians can influence the decisions responsible for the quality of the lives of the patient in need.

There are however many situations where freedom



Jan M. Bult  
PPTA President

of choice does not exist. Treatment availability is restricted by:

**Barriers to trade:** Countries limit the import of licensed therapies for non-scientific reasons.

**Tenders:** Countries restrict the availability of licensed therapies to only one or a few thereby limiting choice. When a new tender is awarded it may lead to a situation that patients have to switch to another therapy without having a choice.

**Preferred drug lists:** If a preferred drug list leads to rejection of other therapies, it will limit the choice of therapies, and there is a risk that some patients will not receive the therapy of their choice.

**Prior authorizations:** These authorizations are mainly in place for budgetary reasons. Any delay or refusal can lead to undesired clinical complications for already vulnerable patients.

Of course I know that everyone wants to make a claim that their situations and therapies are unique. But you know what, in the case of patients receiving plasma protein therapies, it is true. I remember the heartbreaking story of a woman with primary immune deficiency who was having difficulties in getting her life-saving therapy reimbursed. She was told by her insurance company it would be cheaper for the company if she died. She had no ability to choose. She was threatened. She was treated irresponsibly and immorally. That needs to be changed.

I have mentioned in an earlier edition of the *Source* (December 2008) that for programs (including choice) to be successful we need the cooperation of patients, treating physicians, researchers, industry, government and media.

With a successful program, choices are not taken away but made available with good reasons. I like that. ●

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# FLORIDA MCHM

## MEDICAID COMPREHENSIVE HEMOPHILIA MANAGEMENT PROGRAM

BY HOLLY BENSON

THE MISSION OF THE FLORIDA AGENCY for Health Care Administration is Better Health Care for All Floridians, and every day Agency employees are looking for better ways to serve our beneficiaries.

Because we were particularly interested in improving our services to our beneficiaries who were diagnosed with hemophilia, we launched the Medicaid Comprehensive Hemophilia Management (MCHM) Program, and it is beginning to make a meaningful difference for the people we serve.



Holly Benson

Our team saw that while we do not serve a large number of hemophiliacs, the cost associated with their care was one of the highest in the state. We began looking for ways to improve the care and recognized that traditional disease management services, without a strong pharmaceutical component, would have little impact.

We launched a new approach in April 2008 and implemented a factor pricing program with a disease management overlay through two year contracts with *Hemophilia of the Sunshine State* and *Caremark*. This new MCHM program is designed to provide specific pharmaceutical products, pharmaceutical management and comprehensive disease management for eligible beneficiaries.

One hundred ninety-seven Medicaid beneficiaries are currently enrolled in the program. Enrollment in the program is automatic for those Medicaid beneficiaries who are not enrolled in a Medicaid HMO and who meet certain criteria. To be eligible, patients must have a diagnosis of hemophilia and have prescriptions for factor product or products. Voluntary enrollment is also available for eligible beneficiaries who are dually enrolled in Medicaid and Medicare.

Once patients are enrolled, they get the benefit of coordinated care. The program develops individualized care plans and strategies with input from their primary care and specialty physicians to ensure coordination of all of the patients' services. Case managers coordinate home infusion training and services, personalized education, enhanced monitoring, and support for patients and families during hospitalization. The program works to ensure access to appropriate product and timely and accurate factor dosing. Home delivery of products and supplies is provided as well as access to all products related to factor replacement therapy including plasma-derived or recombinant factor concentrates available under the Medicaid State Plan. Staff members are culturally sensitive and the call centers have multi-lingual proficiency in English and Spanish.

Current treatment protocols are made available to primary care providers (PCPs) and participating specialty physicians on request.

The protocols are nationally recognized by leading professional experts in the field of hemophilia, reviewed by a Hemophilia Medical Advisory Panel (HMAP) and approved by the Agency. All targeted physicians, specialists and other providers receive education on treatment guidelines, and the program helps physicians develop effective patient care plans and provides reports on beneficiary adherence with treatment protocols as well as status reports addressing outcomes. Specialist referral options are provided for primary care providers and consultative support is offered during surgery including face-to-face provider consultation as necessary.

The contracted pharmacy benefit managers monitor patients for factor assay prescriptions, provide for home delivery of product and supplies including medical waste pickup and disposal, emergency delivery of product and supplies in the event of a natural disaster and delivery of protective gear and therapeutic devices. They provide patients and providers with toll free telephone access to a licensed pharmacist and a registered nurse (RN) around the clock. In addition, they act as expert resources to Agency staff, PCPs and specialty providers on up-to-date knowledge of new technology and treatments for coagulation bleeding disorders.

Finally, in an effort to ensure that the quality of care continues to improve, the Agency is working with the two vendors that provide these services to identify and determine health outcomes, cost benefits and changes in demographics and trends. By constantly evaluating the program, the Agency hopes to improve the quality of health care provided to the hemophiliacs served by the program.

The Agency strives to ensure high-quality health care for our beneficiaries, and partnerships like these can make the difference. By coordinating care with providers and including beneficiaries in treatment plans, the MCHM is making a meaningful difference for the people we serve. ●

HOLLY BENSON is Secretary of the Florida Agency for Health Care Administration

# PROF. JOHANNES OLDENBURG HONORED AT IPPC WITH HILFENHAUS AWARD

**PROF. JOHANNES OLDENBURG WAS HONORED** by PPTA with the prestigious Hilfenhaus Award at the 2009 International Plasma Protein Congress (IPPC) in Paris, France, for his outstanding contribution in the fields of immuno-haematology and transfusion medicine.

Named after Dr. Joachim Hilfenhaus, former head of PPTA's Viral Safety Working Party who died unexpectedly 10 years ago, the Hilfenhaus Award recognizes individuals who have made an outstanding contribution to patient access to safe plasma protein therapies.

The last two award winners were Prof. Reinhold Schmidt, a leading international immunologist, and Prof. José-Luis Valverde, a well-known politician, professor, and author.

Prof. Johannes Oldenburg studied biology and medicine at the University of Bonn in Germany and has been the head of the Immunohematology and Molecular Hemostasis Departments at the Institute of Transfusion Medicine and Immunohematology since 2001.

He is also a consultant in clinical transfusion medicine. Since 1995, Prof. Oldenburg has been establishing and maintaining research groups of molecular haemostasis at the University of Würzburg in Bonn and at the University of Frankfurt.

His main fields of research are clinical trials and genetics of hereditary coagulation disorders, vitamin K cycles and Gamma-glutamyl-carboxylation.

He was a member of the "Advisory Committee for Blood" at the German Health Ministry, and was a co-chairman of the Scientific Subcommittee on Factor VIII & IX of the International Society of Thrombosis and Hemostasis. More recently, he has been a member of the Steering Committee of the International Hemophilia Inhibitor Previously Untreated Patients Study and has been on the advisory board of the Journal of Thrombosis and Hemostasis as well as for the Congress 2003 and 2005 of the International Society of Thrombosis (ISTH) and for the Congress 2004 of the World Federation of Hemophilia.

Prof. Oldenburg has received several scientific awards: in 2000, the Alexander Schmidt Award and in 2004, the Professor Landbeck Award.

He is a member of many societies including the German Association of Hemophiliacs, the Association of Interests of Hemophiliacs, the International Society of Thrombosis and Hemostasis and the American Society of Hematology. ●



Prof. José-Luis Valverde, Hilfenhaus award winner 2008 & Editor-in-Chief of the International Journal of Pharmaceuticals Policy and Law, Professor Johannes Oldenburg, Head of the Institute of Transfusion Medicine and Immunohaematology, Bonn, Germany, Charles Waller, Vice-President PPTA Europe.

# IPPC 2009

**THE INTERNATIONAL PLASMA PROTEIN CONGRESS (IPPC) 2009, held on March 3-4 in Paris, was a big success, with a record number of attendees. More than 300 people participated in the discussions and listened to high-level presentations on a wide range of topics.**

The 2009 IPPC featured panels of government, industry and academic experts discussing topics including developments in the clinical use of plasma proteins, regulatory affairs in Europe, optimizing access to therapies and obtaining the plasma needed to manufacture life-saving therapies.



**PPTA Global Board of Directors Chairman  
Larry Guiheen**

The Congress got off to a lively start with an opening session that included an informative presentation from Prof. Alain Fischer of AP-HP Necker Hospital in Paris on the role



**Brian O'Mahony of the Irish Haemophilia Society**

of reference centers in the treatment of primary immunodeficiency disease (PID). Dr. Graham Sher of the Canadian Blood Service provided details on Canadian self-sufficiency and PPTA Global Board of Directors Chairman Larry Guiheen of Baxter BioScience discussed the state of the plasma protein therapeutics industry.

In his remarks Mr. Guiheen indicated that demand for plasma-derived therapies continues to grow in the developed world

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# DRAWS RECORD NUMBER OF ATTENDEES

BY KARA FLYNN

with significant expansion opportunities in the rest of the world. In addition, he said that the global supply of plasma will grow due to industry's investment in the infrastructure of plasma collection, fractionation expansion, purification and finishing.

Various perspectives on how much plasma we need were given by speakers addressing the topic from different points of view. Brian O'Mahony of the Irish Haemophilia Society provided a patient's perspective on this topic and said that economic threats including the global recession and treatment parameters defined by costs will loom large in the next couple of years. "Coming battles will be as much about advocacy and assertiveness as availability and adequacy," he said. During his remarks, Mr. O'Mahony also took the opportunity to announce the formation of a new patient group, PLUS, which formally launched in Paris on March 2, 2009 (see article on page 14). According to O'Mahony, PLUS was created to facilitate the exchange of information towards building consensus views when possible among the organi-

zations that represent regular users of plasma-derived therapies.

Patrick Robert of the Marketing Research Bureau peered into his crystal ball and discussed global plasma demand in 2015. Presenting on new developments with the use of intravenous immunoglobulin (IVIG) for the treatment of Alzheimer's disease, Mr. Robert said the approval of IVIG for this use in possibly 2012 will "cause a surge in demand" and a "sharp increase in plasma collections and fractionation will be required." Ultimately, he said that additional plasma volume requirements may need to be obtained from source plasma collections in the U.S. and elsewhere.

The final session of IPPC 2009 was devoted to optimizing access to plasma protein therapies. Issues and challenges were presented by Larry Warren of the Alpha One Foundation, Mark Skinner of the World Federation of Hemophilia (WFH), Jose Drabwell of the International Patient Organization for Primary Immunodeficiencies (IPOPI) and PPTA President Jan M. Bult.

Mr. Warren began his presentation by discussing the need to raise awareness of alpha-1 antitrypsin deficiency in the general population, as currently most physicians are unaware of the disease and often patients are either misdiagnosed or mistreated. "Only 5 percent of patients are



**Above: Prof. Rainer Seitz, Paul-Ehrlich-Institut gives a presentation on current priorities of the EMEA Blood Products Working Party.**

**Below: IPPC 2009 Attendees. Background: Paris landmarks, the Alexandre III Bridge crossing over the Seine River with the Eiffel Tower to the left.**



properly diagnosed and those who are being treated sometimes find it difficult to obtain therapies, depending on where they live in the European Union," he said. According to Mr. Warren, to solve this problem, the Alpha One Foundation and other groups have taken to lobbying and are combining resources with other groups, including Alfa Europe.

Mark Skinner of WFH agreed with Mr. Warren and said the number one issue for most hemophiliacs is proper diagnosis and treatment. In order to combat this scenario, he said the WFH is implementing national care programs in target countries. Mr. Skinner indicated that both recombinant and plasma-derived products are crucial given that the supply of either alone is insufficient and both therapies have robust safety records. But he said demand is increasing with new markets and increased utilization, so it will be important to expand manufacturing capacity and eliminate hurdles to market entry.

Jose Drabwell also agreed with remarks made by earlier presenters on this panel and said she feels it is important to bring the issue of patients' involvement to the attention of those who are working on providing healthcare. "There needs to be closer collaboration between academic researchers, industry, doctors and patients," she said. "Ultimately, there needs to be increased visibility of these disorders. A patient who has the benefit of a safe, effective and continued regime of treatment will become a contributing member of society."



PPTA President Jan M. Bult discussed some of the challenges currently facing manufacturers including barriers to trade, collection of plasma and tax exemptions. Countries like China that has Article 49, a pharmaceutical law, which bans products made from plasma collected outside of China, and Japan that has discriminatory labeling requirements and self sufficiency that unfairly supports local manufacturers, are preventing therapies from reaching patients. "What is needed is the active involvement of five parties including patients, physicians, researchers, industry and government," he said. Mr. Bult said the conditions for a level playing field include transparent financial transactions with no hidden subsidies. Additionally, there should be equal application of tax systems to all licensees of plasma protein therapies. "Until these things exist, it will be difficult for patients to obtain much needed therapies," he said.

Delegate feedback of IPPC 2009 was very positive and a solid program, high-level speakers, a truly dynamic location and an impressive number of relevant attendees combined for the most successful event in PPTA's history.

The IPPC 2009 presentations are available for download for all delegates from the website: [www.ippc2009.com](http://www.ippc2009.com). ●

KARA FLYNN is PPTA's Director of Global Communications

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## IPPC Special Session Focuses on vCJD

**F**OLLOWING PANEL PRESENTATIONS given on the first day of the International Plasma Protein Congress (IPPC), PPTA sponsored a special extra session on variant Creutzfeldt-Jakob Disease (vCJD) in which patients, regulatory authorities and plasma protein therapeutic manufacturers were given the opportunity to voice their views on the issue of safety of plasma-derived therapies. In addition, members of the audience were permitted to ask questions or raise any pertinent issues. The discussion came following an announcement in the United Kingdom (UK) in late February that a patient with hemophilia was found to harbor the abnormal vCJD protein upon autopsy. In a series of brief presentations, officials, including Rainer Seitz from the European Medicines Agency (EMA) and Basil Golding from the U.S. Food and Drug Administration (FDA), provided remarks on the information that is known from the case in the UK. In addition, patient representatives including Brian O'Mahony of the Irish Haemophilia Society, David Watters of the International Patient Organization for Primary Immunodeficiencies and Mark Skinner of the World Federation of Hemophilia gave their



**David Watters**  
of the **International Patient Organization for Primary Immunodeficiencies**

perspectives and shared their concerns during this public discussion. The special session was moderated by PPTA's Senior Director, Global Access, Prof. Albert Farrugia. PPTA President Jan M. Bult concluded the discussion with brief remarks noting that industry is taking this situation very seriously and will continue to be in communication with stakeholders on this matter. For more information on vCJD, please see "PPTA Backgrounder: Variant Creutzfeldt-Jakob Disease (vCJD) and the Safety of Plasma Protein Therapies" on PPTA's website: <http://www.pptaglobal.org>.



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# PPTA HOSTS WORKSHOP PRECAUTIONARY

**PARIS, THE CITY OF LIGHT**, served as the host city for a workshop exploring the precautionary principle and its influence on the manufacture and access of plasma protein therapies on March 2. The meeting was held in conjunction with the International Plasma Protein Congress (IPPC) and brought together key opinion leaders in blood safety decision making. Audience members were invited to participate in the discussion to generate common views on the best ways of applying the influential concept of the precautionary principle to current practices.

By hosting the workshop, PPTA sought to explore the arena of modern public policymaking and its evolution over the past 25 years to include the concept of the precautionary principle, where the state of scientific knowledge indicates uncertainty from potentially harmful events. Some fields in which the precautionary principle has been utilized in the past several years have ranged from food safety and global warming to persistent or acute pollution and the extinction of species.

According to Prof. Albert Farrugia, PPTA's Senior Director, Global Access, and the chair of a panel of expert speakers at the workshop, the concept has been applied vigorously in the areas of blood and plasma products, where layer after layer of safety has been built into product delivery systems with the intent of generating the highest margin of safety, with some proponents advocating "zero risk."

Panel speakers at the four hour event included Prof. Jean-Hugues Trouvin, chair of the European Medicines Agency (EMA) Biotechnology Working Party; Dr. Graham Sher of Canadian Blood Services; Dr. Reiner Laske of CSL Behring; Brian O'Mahony of the Irish Haemophilia Society; Prof. Marc Turner of Scottish National Blood Transfusion Service and Dr. Thomas R. Kreil of Baxter BioScience.

In his opening remarks, Prof. Farrugia said that use of the precautionary principle with regard to the plasma protein therapeutics industry sometimes has tended to increase costs and affect access to products, but this has been viewed as acceptable because of the damages of emerging risks. The precautionary principle had been interpreted in various ways, but common features included the need to anticipate harm through pre-emptive actions and a shift from absolute evidence of the effect of such actions to a review of their effect after implementation.

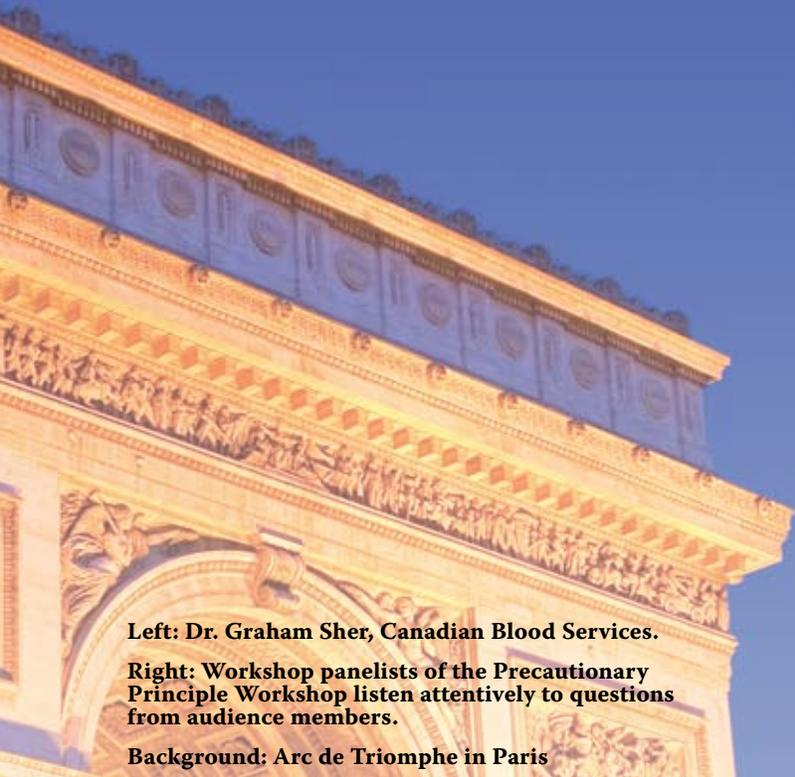
Prof. Marc Turner, Clinical Director of the Scottish National Blood Transfusion Service, discussed the United Kingdom's (UK) experience in dealing with the threat of variant Creutzfeldt Jakob

Disease (vCJD) transmission through blood as knowledge evolved over the years. He described how succeeding precautionary measures were introduced as more information became available on potential transmission modes, including the selection of plasma sourced from outside the UK for fractionation purposes, the introduction of leucoreduction for all blood donations and the use of imported plasma for transfusion to children. As more evidence accumulated regarding actual transmission to patients and the possible prevalence in the UK population was assessed, further precautionary measures are now under review, including the importation of red cells and the introduction of prion filters and screening tests. Prof. Turner expressed some reservations on how the recent case of vCJD infection in a hemophiliac was handled by the UK authorities and media, and he strongly advocated a transparent, open, balanced and timely interaction with media.

Mr. O'Mahony of the Irish Haemophilia Society said actions should be based on current scientific evidence and in the best interests of patients who use the products and not based on nationalism and politics or outdated concepts of safety. "Decisions not based on science have had major ramifications in the past on the hemophilia community," he said. Citing the period in the early 1980s when he says there were barriers to action on blood policy,

# ON THE PRINCIPLE

BY KARA FLYNN



**Left: Dr. Graham Sher, Canadian Blood Services.**

**Right: Workshop panelists of the Precautionary Principle Workshop listen attentively to questions from audience members.**

**Background: Arc de Triomphe in Paris**



Mr. O'Mahony said a general lack of understanding, some political considerations and people in denial led to human immunodeficiency virus (HIV) infection rates in the 1980s.

According to Dr. Sher of Canadian Blood Services, the precautionary principle and precautionism in general have dominated our thinking for the past 15 years. "Costs are spiraling out of control and there is a need to restore equilibrium through a sound understanding of the science of safety and risk analysis," he said. "A good risk management practice should reflect the appropriate balance between evidence and caution and articulate the scientific, economic and political bases for blood safety decisions."

Prof. Trouvin described the process utilized by the French authorities encountering the then unknown risk of vCJD transmission through blood and plasma products in France. An assessment of the risks relied on what scientific data was available and the French authorities felt that the measures introduced in their country were less conformant to the precautionary principle but relied more on risk analysis given the medical importance of the products and the lack of an alternative route. It was felt by the French authorities this was a pragmatic interpretation, not immune from the risk of being excessive but embedded in transparency to the end users.

Both Dr. Kreil and Dr. Laske pointed to some of the current safety procedures used in the manufacture of plasma-derived therapies including donor center selection, where acceptable ranges of epidemiological data are reviewed, lookback and traceability for donors; testing of the production pool; and virus reduction to ensure the safe manufacture of therapies.

Some of the conclusions reached during the workshop by participants included the following:

- applications of the precautionary principle in its entirety using all the features including constant review and updating of measures to merge into scientific developments is crucial for optimal decision making in blood safety.
- a merging of precautionism and evidence-based decision making is possible if it is accepted that risk should be as low as reasonably achievable.
- the communication of risk and its management is as important as the actual science. ●

KARA FLYNN is PPTA's Director of Global Communications

# PPUG MEETING BRINGS STAKEHOLDERS

BY JOHAN PRÉVOT

STAKEHOLDERS JOINTLY MET IN PARIS to discuss the latest developments and key issues facing the plasma protein therapeutics community in Europe. The Plasma Protein Users Group (PPUG) met on March 2 in conjunction with the 2009 International Plasma Protein Congress (IPPC). Representatives from eight patient organizations, physician and nurse representatives as well as PPTA and industry representatives took part in a lively discussion on the latest industry developments, European Union (EU) health policy developments and risk communications.

PPTA staff provided a summary of plasma protein therapeutics distribution and plasma collection trends. Participants were informed that the supply of immunoglobulin and coagulation factors has continued to increase during 2008, as well as plasma collection both in Europe and the United States. An increase of more than 25 percent in high-quality plasma collected by PPTA members in 2008 testifies to the commitment of PPTA member companies to ensure optimal patient access to plasma protein therapies.

The outcomes of two EU health policy events jointly organized by patient, physician and industry representatives at the European Parliament in 2008 on rare plasma-related disorders were then reviewed. Several important recommendations were made during these two meetings. The need to increase diagnosis rates for rare plasma-related disorders, to improve patient access to plasma protein therapies, to address the varying treatment levels in the different EU member states, to differentiate between

blood and plasma in upcoming EU policies and a proposal to create a European Parliament Interest Group

PIDJ0E / ISTOCK

# TOGETHER IN PARIS



**Above: PPUG Members and industry representatives met in Paris to discuss key issues of plasma protein users in Europe. Background, left: Sacre Coeur Cathedral in Paris**

on Rare Plasma-Related Disorders were among the important recommendations, which led to the launch of a European Parliament Call for Action on Rare Plasma-Related Disorders.

In a related development, patient organizations representing patients affected by rare plasma related disorders have decided to create a new patient group platform called PLUS to ensure their views are appropriately reflected in relevant EU policies (see article on page 14). It was agreed that these positive developments would contribute to a better recognition of the specific issues affecting the plasma protein stakeholders in the EU political arena but would also help to address these as-

pects in upcoming relevant EU legislation including the Council Recommendation on Rare Diseases, the proposed Directive for Cross-Border HealthCare and the "Pharma Package."

The meeting was also the opportunity to have an open discussion on the recent information released by the United Kingdom's (UK) Health Protection Agency (HPA) regarding the variant Creutzfeldt-Jakob Disease (vCJD) abnormal prions, which were found in the spleen of an elderly hemophilia patient in the UK during post-mortem examination. Mr. Brian O'Mahony, Chief Executive of the Irish Haemophilia Society, provided a presentation looking at Risk Communications and vCJD in the context of the current situation in the UK. In his



presentation, Mr. O'Mahony explained the importance of timely communication to patients and the necessary risk communication plan that should be put into place to avoid uncontrolled release via the media as this can lead to unnecessary anxiety and confusion among the patients concerned. Charles Waller, PPTA's Vice President Europe, highlighted PPTA's position with regard to this new development. The PPTA position statement can be found on PPTA's website [www.pptaglobal.org](http://www.pptaglobal.org).

At the conclusion of the meeting, it was agreed that the

increased collaboration between European stakeholders has contributed to enhance the awareness of the unique issues facing this community in the EU. With several legislative dossiers coming up in 2009 and the European Parliament's elections around the corner, the PPUG will continue to provide a valuable platform through which industry and stakeholders can tackle common issues and work together to support greater patient access throughout Europe. ●

JOHAN PRÉVOT is PPTA's Director, Health Policy Europe



## PLUS GROUP OFFICIALLY LAUNCHES

SEVERAL PATIENT ORGANIZATIONS attending the 2009 International Plasma Protein Congress (IPPC) in Paris took the opportunity to organize the first meeting of a newly created European patient group platform, which brings together patients treated with plasma protein therapies. The Platform of Plasma Protein Users or PLUS – was officially launched on March 2. The meeting was an opportunity to agree on the terms of reference and the membership of this new patient group coalition.

PLUS currently consists of the following patient organizations: Alpha-1 Foundation Europe, the European

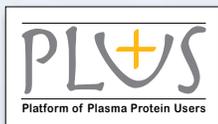
Haemophilia Consortium, the GBS/CIDP Foundation International, the International Patient Organization for C1-Inhibitor Deficiencies, the International Patient Organization for Primary Immunodeficiencies, the ITP Support Association and the World Federation of Hemophilia.

As rare plasma related disorders are increasingly gaining recognition in the European Union (EU) political arena, PLUS has been created to ensure that relevant EU policies, actions and discussions appropriately reflect the views of the patients who are directly affected by these disorders.

### Official Statement from PLUS

**A NUMBER OF DISPARATE, INHERITED OR ACQUIRED**, serious or life-threatening conditions are routinely treated with plasma products. This includes Haemophilia, Primary Immune Deficiency, Alpha 1 Antitrypsin Deficiency, Guillain Barré Syndrome, Hereditary Angiodema, Idiopathic Thrombocytopenic Purpura and von Willebrand disease. The conditions vary enormously in the level of recognition, diagnosis and treatment. Together, these conditions account for some 90,000 known patients in Europe and a probable prevalence of 380,000.

The conditions are disparate, but the main therapies used in all these conditions are manufactured from human plasma. The organisations that represent the patients with these conditions are acutely aware that diagnosis is insufficient for many of the conditions and access to therapy needs to be increased and optimised. Patients in Europe who rely on plasma-derived therapies deserve the op-



portunity to have access to treatment and the possibility of freedom from the life threatening consequences of lack of treatment.

The organisations representing these patients are concerned that directives, guidelines and recommendations which have a major impact on their access to safe and effective therapy have been and continue to be promulgated in Europe without reference to them. This is unacceptable. Our voices, as the users of these life-saving and enhancing therapies, must be heard and we must be consulted when measures are being drafted which will have a major impact on our access to therapy. We further recognise that it is impractical to ask the EU Commission at any level to meet regularly with each of the separate organisations. However, recognising that we share a common and vital interest in the optimum access to the safest and most efficacious plasma-derived therapies, we have formed a broad coalition of seven organizations of plasma users-PLUS.

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# THE EVOLUTION OF SAFETY IN SOURCE PLASMA COLLECTION

BY JOSHUA PENROD AND MARY GUSTAFSON

**HUMAN PLASMA, INCLUDING SOURCE PLASMA**, is the genesis for most plasma protein therapies. The millions of liters collected in the U.S. and Europe yearly sustain the lives of thousands of people worldwide. Fractionators process source plasma collected from more than 1,000,000 donors into numerous therapies, including immune globulins (IG), clotting factor concentrates, including Factor VIII and Factor IX, albumin, and other critical proteins. For the lives saved by these therapies, we should be grateful for our dedicated plasma donors. And for these reasons and the importance of the plasma itself, keeping donation a safe and enjoyable experience is of central importance.

Plasma donation today is safe for the donor and performed in an atmosphere that provides a donor-friendly experience. From collection centers that radiate a welcome, efficient, and friendly operating environment to highly monitored procedures designed to ensure that the plasma donation process is as safe as possible, donors have rightly come to expect a high degree of customer service from donation centers. Indeed, the plasma donation experience is predicated on the evolution of safety of the donation process itself, which helps foster a donor's commitment to a lifetime of donation.

This article will examine and summarize several areas (donor screening, automated plasmapheresis, and industry standards) in which donor safety has advanced. Advancement in these areas, coupled with comprehensive industry quality system, and regulatory oversight in both the U.S. and Europe, represent the safeguards in plasma collection today.

## Donor Screening

Prospective donors are greeted at the plasma center with a request for personal identifying information. This private information, including government-issued identification cards, permanent address and a photograph, may seem "too much information" for some. However, this information is necessary

to ensure that the donor can be positively linked to his donated plasma. This link is necessary so that important information about the donor's health can be transmitted to him if necessary.

The prospective donor's information is checked with the National Donor Deferral Registry to determine whether the individual was deferred in the past because of positive test results. If that is the case, the person will not be accepted.

The donor next is asked to provide information to questions from a health history assessment tool. The questions cover the donor's general health, medical history, medication history, and lifestyle. The questions are understandably intrusive. But honest and accurate responses to these questions are necessary to make sure that the donation process does no harm to the donor as well as to ensure that the donor does not harbor infectious agents that may be transmissible through plasma. The questionnaire, as well as other screening interactions, are conducted privately to ensure confidentiality.

At the donor's first donation and annually, the center's medical personnel perform a limited physical examination. The center





**The most significant advancement in the safety of plasma collection is the automated plasmapheresis device. Before automation, a donor's whole blood collection container was removed from the area, centrifuged to separate the plasma from the red blood cells, and the donor's red blood cells were returned to the donor manually...**

physical is not intended to replace routine medical care nor is it intended to diagnose any condition. However, through examination of the donor's systems, i.e., head and neck, chest, extremities, abdomen, and reflexes, conditions that would prevent the donor's safe donation may be detected. The donor is also asked to provide his "informed consent" for donation after the donation process, testing, and risks of the donation process are explained to him.

At every donation, the donor's vital signs, i.e., blood pressure, pulse, temperature, are obtained, and the donor is weighed. The donor must have normal vital signs in order to donate. The donor's weight is used to calculate the amount of plasma that may be collected safely from the donor. The donor's finger is pricked to obtain a small amount of blood to determine the donor's red blood cell volume (hematocrit) and total protein. While there is minimal red blood cell loss in the plasmapheresis process, monitoring the hematocrit initially and over time is a measure of the donor's general health. Protein monitoring is important to ensure that plasma proteins, harvested during the donation process, are replaced as occurs in donors who maintain a healthy diet and lifestyle.

Following the successful completion of the screening process, the donor moves to the donation area, which may contain anywhere from a handful of donation beds to dozens. After the center staff situates the donor on a donation bed, the staff member will perform another check to ensure that the donor has been screened and that the donation station is properly prepared. The automated plasmapheresis device is then prepared for use, the phlebotomy is performed, and the plasmapheresis process is underway.

### Automated Plasmapheresis

The most significant advancement in the safety of plasma collection is the automated plasmapheresis device.

Before automation, a donor's whole blood collection container was removed from the area, centrifuged to separate the plasma from the red blood cells, and the donor's red blood cells were returned to the donor manually; this increased the risk of unmatched red cells being improperly returned. With the automated plasmapheresis process introduced in the 1980s, this type of incident can not occur as the donor's blood never leaves the circuit between the donor and the automated device. At any one time, only a small amount of blood (extracorporeal volume) is held outside of the donor's body and in the machine. Tubing

and other plastic goods used in the plasmapheresis process are disposable and used once only. The system itself is monitored by a computer and carefully calibrated to ensure proper func-



tioning and a smooth donation process. The devices have alerts and alarms that signal any interruption or aberration from the normal process. The automatic device incorporates safety in two critical areas: first, components exposed to bodily fluids are not reused and second, it eliminates the risk of human error in returning red blood cells to donors.

After the donor has completed his donation, the "disconnect" occurs. At this point, the trained staff will observe the donor, checking for signs of physical distress. All plasma donation centers have well-trained staff and are equipped to handle any emergencies, though adverse events are rare. Nevertheless, a watchful eye remains upon him for several minutes, after which the donor is allowed to leave.

### Industry Standards

As a part of the International Quality Plasma Program (IQPP), certified centers are required to adhere to standards that help to further enhance the donation experience. These eight Standards comprise the IQPP, which has been built around areas identified by the industry as opportunities for improvement, not currently addressed by regulation.

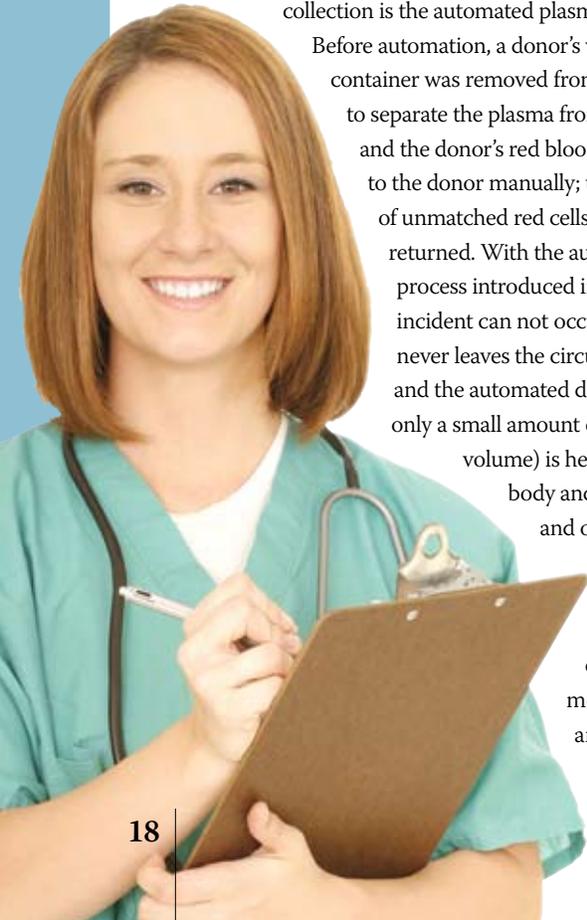
- Use of the National Donor Deferral Registry
- Qualified Donor Standard
- Donor Education Standard
- Professional Plasma Collection Facility Standard
- Community-Based Donor Standard
- Quality Assurance Standard
- Viral Marker Standard
- Personnel Education and Training Standard

Three particular standards enhance the donor's experience and aid in further enhancing the safety of plasma collection. The Professional Plasma Collection Facility Standard sets guidelines for operational flow through the center, in addition to appearance and general upkeep. The Personnel Education and Training Standard helps to solidify center staff professionalism through training, education, and quality requirements. The Donor Education Standard helps educate donors about high-risk behaviors, and also encourages donor wellness through emphasizing the importance of a balanced diet and smoking cessation.

### Summary and Conclusions

In all, the donation process is a complex but efficient process that enables donors to be screened and examined to donate and to exit the facility in an orderly, easy-to-follow manner. The automated plasmapheresis process is an extraordinarily safe and effective method of obtaining plasma from a donor and stands as the central pillar of safety in plasma donation. The well-trained plasma center staff, in conjunction with regulatory requirements, best industry practices, and industry standards, creates an environment in which plasma collection is not just performed, but perfected. ●

JOSHUA PENROD is PPTA's Vice President, Source and MARY GUSTAFSON is PPTA's Vice President, Global Regulatory Policy



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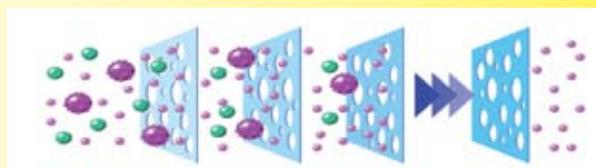
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If I can stop one heart  
from breaking  
I shall not live in vain;  
If I can ease one life  
the aching,  
or cool one pain,  
Or help one fainting robin  
unto his nest again  
I shall not live in vain.

—Emily Dickinson



JMF honored some of the "Dream Makers" during the Gala. Industry leaders honored pictured left to right: Larry Stern, Talecris; Wolfgang Marguerre, Octapharma; Victor Grifols, Grifols; Peter Turner, CSL Behring; Gregor Shultz, Biotest AG; and Joy Amundson, Baxter BioScience. JMF cited their generous support, compassion and commitment to providing life-sustaining and life-saving treatments.

# JMF Recognizes Industry at “SPRING AHEAD” Gala 2009



Jeffrey Modell



Vicki and  
Fred Modell

**THE JEFFREY MODELL FOUNDATION (JMF)** was created 22 years ago by Fred and Vicki Modell in memory of their son Jeffrey, who lost his fight against primary immunodeficiency (PID), a genetic condition that is chronic, serious and often fatal. In a speech given at the 2009 "Spring Ahead" Gala on April 23, Fred told the audience that Jeffrey never met another child with his disease, they never met parents in similar situations and doctors did not know what was wrong. What a difference two decades can make! Much is known now about PID with 52 JMF Diagnostic Centers across the world. Many deficiencies are known and today a relatively simple screening test exists that can detect Severe Combined Immune Deficiency (SCID) in newborns.

**Fred and Vicki Modell believe strongly in their mission:**

*"The Foundation's primary mission is to continue to advocate for the earliest possible diagnosis. That is why we are reaching public health laboratories in the states to advance newborn screening as we have already done in Wisconsin and Massachusetts. The importance of screening and reaching primary care physicians is the key to early diagnosis."*



**Dawson, the first baby whose life was saved by the test to detect SCID, with his happy parents and his physician, Dr. James Verbsky.**

During the annual Spring Ahead event in New York, many individuals who were instrumental in making many dreams come true were recognized. A highlight of this evening was when the first baby whose life was saved by the test to detect SCID was introduced to the audience. Last year, the state of Wisconsin introduced a SCID screening test for all newborns born after January 1, 2008. After a few months, baby Dawson was detected with a gene defect that resulted in severe bacterial infections from birth due to defective function of neutrophils and lymphocytes. In September 2008, on Jeffrey's birthday, Dawson received a bone marrow transplant and the immune defects have been corrected. Dawson is fully recovered and has a future. In addition to Dawson, several other newborns with life threatening disorders were identified by the screening program.

Dr. James Verbsky, MD, Ph.D, Assistant Professor in Pediatrics at the Children's Hospital of Wisconsin, is working with the SCID screening program and was recognized as a Dream Maker who is, "making dreams come true in the United States," during the Gala.

Other Dream Makers came from Morocco, Brazil, the United States, Israel, Hungary, Japan, Germany and Canada.

No foundation can work without its Board and all members were simultaneously honored and recognized by the audience.

Another highlight of the evening was when the leaders of the plasma protein industry were recognized for manufacturing life-saving immune globulins therapies. It was the first time that so many industry leaders were together at such an event, quite an accomplishment given the complicated travel schedules of these individuals. All companies have done enormous work on the development of immune globulins and the associated clinical research necessary to make these therapies available to the many patients in need of these life saving treatments. The recipients of the JMF awards were Joy Amundson (Baxter BioScience), Gregor Schulz (Biotest), Peter Turner (CSL Behring), Victor Grifols (Grifols), Wolfgang Marguerre (Octapharma) and Larry Stern (Talecris).



**Rose Bult and Gregor Shultz dance at the Gala, which celebrated "Dream Makers."**

At the beginning of the evening, a special recognition was given to Dr. Holmes Morton, pediatrician, Director and Founder of the Clinic for Special Children in Strasburg, PA, serving the Amish and Mennonite Communities. The Clinic has become recognized internationally for innovative studies in the diagnosis and treatment of genetic disorders, and for the discovery of the genetic basis of problems within the Amish and Mennonite populations. Dr. Morton nicely described how he views his work:

*"Special children are not just interesting medical problems, subjects of grants and research. Nor should they be called burdens to their families and communities, they are children who need our help and if we allow them to, they will teach us love. If we come to know these children as we should, they will make us better scientists, better physicians and thoughtful people."*

The event brought together so many people that together can advance the knowledge about PIDs. Jeffrey did not die in vain. His spirit is with us. ●



**The festive atmosphere also included children performing.**

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# PPTA WORKSHOP IN CHINA

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FOCUSES ON MANUFACTURING OF  
PLASMA PROTEIN THERAPIES

BY JOSHUA PENROD



BEST-PHOTO, TERRAXPLORER, BLACKRED / ISTOCK

## PPTA HOSTED THE WORKSHOP, MANUFACTURING OF PLASMA PROTEIN THERAPIES:

Building Quality from Start to Finish, on February 12-13th in Beijing, China. Over 80 individuals from local industry and the Chinese government attended. PPTA and its member companies designed the workshop with the goal of increasing the awareness of the high-quality and safety of European and American industry and its products. This was a crucial step in the industry's ongoing efforts to help ensure that patients around the world are able to access needed therapies. It was also critical to demonstrate that all imported therapies produced by PPTA members and regulated by the competent regulatory authorities are safe.

### Day One

The first day of the workshop included welcoming statements and introductions from both industry and Chinese participants.

Dr. Xue Bin from the China Center for Pharmaceutical International Exchange (CCPIE) welcomed the participants to the meeting. He explained that it was through meetings and workshops such as this one that fruitful dialogue and a path forward can be found. He expressed his desire for an open discussion and a vigorous exchange of ideas.

PPTA President Jan M. Bult opened the meeting and also welcomed all the participants. He described the nature and scope of the Association, along with its member companies, and their activities. He noted the importance of respecting the public policy initiatives advanced by all countries, but emphasized the importance of securing access to all therapies to patients in need. He also reminded the audience that there were vast

**IN THE BACKGROUND:** The Great Wall of China stretches over 4,000 miles from Shanhaiguan in the east to Lop Nur in the west, along an arc that roughly delineates the southern edge of Inner Mongolia.

**RIGHT:** Audience members at PPTA's Workshop in China on Manufacturing of Plasma Protein Therapies.



北京



# 學壽商

Mary Gustafson, PPTA Vice President, Global Regulatory Policy; Alan Chit, HPC International; and Linda Alms, U.S. Food and Drug Administration. Below: Dr. Jonathan Knowles, CSL Behring



numbers of patients, all around the world, who were under- or undiagnosed in their conditions and also in need of government policies that favor access to treatment. Mr. Bult closed by thanking the commitment of donors of both blood and plasma and highlighted the contribution of all donors to saving and improving lives.

## Speakers and topics discussed during Day One:

- **Ms. Linda Alms**, of the U.S. Food and Drug Administration (FDA), explained the statutory and regulatory structures under which the FDA operates and governs the plasma industry.
- **Dr. Jean Emmanuel**, of the Safe Blood International Foundation, presented on the journey that policymakers must take to provide access to safe therapies. Dr. Emmanuel noted that the workshop itself and the current situation in China presents a unique opportunity for policymakers to have a direct and immediate impact on its regulatory system.
- **Ms. Mary Gustafson**, PPTA's Vice President, Global Regulatory Policy, described the importance of developing a quality donor base; these elements include selection, screening, education, and qualification. Ms. Gustafson noted that the donor and the quality systems governing donation provide the foundation to all safety



and quality initiatives used by the industry along the chain of operations.

- **Dr. Doug Lee**, of Talecris Biotherapeutics, gave an overview of the testing paradigms used by the industry. The single largest point of importance of testing is that it helps ensure the safety and quality of the donor, the donation, and the finished product. The testing, in its many forms, including serology and Nucleic Acid Tests (NAT), the testing of the donor and in-process testing, occupies one of the largest niches of quality in the industry.
- **Mr. Jim Yang**, of Baxter BioLife, gave an overview of the plasma collection process itself. He highlighted areas of the collection process, including donor health parameters, such as weight, blood pressure, and pulse, and the operations occurring on the donor floor. These ranged from donor identification and venipuncture to arm preparation and disconnection.
- **Dr. Zhu Yong Ming**, President of the Shanghai Blood Center, presented "Blood Collection and Testing in China, Now & Future." Dr. Zhu highlighted many areas within this talk, including the current collection patterns of blood and plasma in China, along with testing practices. Of special note, plasma center numbers in China have declined significantly over the past 15 years, due to a variety of reasons. Dr. Zhu noted that this situation has resulted in a "shortage of all plasma derivatives."

• **Mr. Shinji Wada**, of Biomat/Grifols, discussed the final steps of plasma collection, following the donor's completion of the plasmapheresis process. Mr. Wada detailed the aseptic technique of handling the donation and the samples, sample collection, methods of testing, plasma freezing and storage, and freezer validation. He noted that all of these areas are critical points of control that help ensure product quality.

During the panel discussion concluding Day One, the speakers fielded a variety of questions, ranging from basic foundations of the quality process and Good Manufacturing Processes (GMPs) to handling supply issues in China. There was also a long exchange of ideas regarding the handling of intermediates, final product, and dossier verification. Following the panel discussion, the meeting adjourned until the next morning.

## Day Two

Jan M. Bult opened Day Two with a presentation that focused on the importance of partnerships. Industry, physicians, government authorities, and patients should work together to find a way to secure access to safe and efficacious therapies; this includes the importance of having early diagnosis and choices for treatment.

These same ethical principles apply, irrespective of country or the government's decisions about the administration of health care.

### Panelists for Day Two were:

• **Dr. Jonathan Knowles**, of ZLB Plasma, who spoke on logistics and global supply chain management within the industry. This presentation described the complex system used by the industry to ensure a steady supply of high-quality, safe starting material and the production process.

• **Prof. Wang Jing Xing**, of the Institute of Blood Transfusion, gave an overview of the industry in China, focusing on plasma collection, storage, and transport in China. He included discussions of the epidemiology of hepatitis B in China, noting this and other ongoing challenges in the country.

• **Dr. Herbert Dichtelmüller**, of Biotest Pharmaceuticals, spoke on pathogen safety, detailing the PPTA member companies' many successful efforts and its commitment to product safety. His presentation demonstrated the safety of PPTA member company products, particularly focusing on manufacturing and pathogen inactivation and removal steps.

• **Dr. Claudia Nardini**, of Kedrion, described the manufacturing process itself. Her presentation gave an overview of the processes used in successful companies to create high-quality, safe products acceptable for use around the world.

• **Dr. Bai Jian Shi**, of the National Institute for the Control of Pharmaceutical and Biological Products (NICPBP), discussed the usage of the finished therapeutics in China. He noted the improvements in technology used in China and that the authorities and industry in China are constructing a very good, high-quality system in China.

• **Mr. Erick Sjöberg**, of Octapharma, finished off the specific area presentations with a discussion of a complete quality system. His presentation gave an overview of the many elements and considerations for a quality system within the areas of plasma collection and manufacture.

The day-ending panel discussion focused on various technical topics such as bar coding and labeling, and also included several exchanges related to increasing the image of the industry and the profile of plasma donation.

## Results

The feedback PPTA received from the meeting focused on the goodwill generated by the event, countered with the reality that the road leading to full patient access in China is a long one. China is a complex society, made more complex by the rapid rate at which the Chinese economy is growing and its integration

into the global marketplace. It is clear from several of the comments and the discussion during the roundtable dialogue, that there is a large amount of work to be done in terms of education and cultural understanding. These gaps are not just at the scientific or technical level, but in being able to describe and understand a thorough regulatory and quality structure in which industry functions and government agencies provide oversight.

PPTA believes that this workshop consolidated the industry's presence

in China for further discussions, which will ultimately lead to better access to therapies for patients in China. ●

JOSHUA PENROD is PPTA's Vice President, Source

**A significant decline of plasma centers in China has resulted in a "shortage of all plasma derivatives."**

—Dr. Zhu Yong Ming



# PATIENT AND PROVIDER NEEDS

BY KYM H. KILBOURNE

IN LATE FEBRUARY, Jeff Allen, Ph.D., the executive director of Friends of Cancer Research spoke at PPTA's Stakeholder meeting about comparative effectiveness research and provided perspective not only from his work with rare cancers, but also as a steering committee member for the Partnership to Improve Patient Care (PIPC), which is actively working on this issue. PIPC's mission (PPTA is a member) is to raise awareness about the value of well-designed comparative effectiveness research (CER), the important role of continued medical innovation as part of the solution to cost and quality challenges in health care, and the need to ensure that proposals to expand the government's role in CER are centered on patient and provider needs.

Since that meeting, the issue has progressed further and with the \$1.1 billion allocated for CER in the American Recovery and Reinvestment Act (ARRC) of 2009, things are beginning to move and move quickly. "What we are seeing now is that a lot of people are recognizing what an opportunity this is given financial resources that were allocated in

the recovery bill," Dr. Allen said. The funds are allocated for specific CER research projects or infrastructure. The timeframes are tight in the stimulus bill, and some of the smaller elements are ramping up already. For example, the Institute of Medicine (IOM), part of the National Academy of Sciences and whose mission is to advise the nation to improve health, is starting

to take public input on what the priorities could be, and this is due at the end of June.

According to Dr. Allen, the priorities for the PPCI include making sure core principals are woven into whatever the vehicles are going forward. Two things being looked at:

1. Money in ARRC and processes established by the Federal Coordinating Council, which was established by the Recovery Act to help coordinate research and guide investments in CER. The lion's share of the money is for high priority projects or infrastructure.
2. The second track has Congress looking at a long-term sustainable system to do this type of research. The Recovery Act provides a one-time sum and there has been a great deal of interest in sustainable research in the scope of health care reform.

## ISSUE BACKGROUND

### Comparative Clinical Effectiveness Research

H.R. 1, THE AMERICAN RECOVERY AND REINVESTMENT ACT OF 2009 includes additional funding for comparative effectiveness research (CER) and provides incentives and penalties to spur the widespread adoption of interoperable health information technology systems. The legislation provides \$1.1 billion in additional money for CER—\$400 million to the National Institutes of Health, \$400 million in discretionary spending for the Secretary of Health and Human Services (HHS), and \$300 million for the Agency for Healthcare Research and Quality (AHRQ). Although several federal agencies have been conducting CER for more than a decade and despite the efforts of the Health Care Financing Administration (now the Centers for Medicare and Medicaid Services (CMS), cost-effectiveness analysis has generally not been used for coverage policy decisions. Moreover, in January 2006, CMS expressly stated that it does not consider costs in reviewing treatments for the purpose of making National Coverage Determinations (NCDs). CMS contends, however, that its local contractors have the authority to consider cost effective-

ness and adopt "least costly alternative policies" in setting local coverage determinations (LCDs). Least costly alternative policies state that a Medicare contractor will not pay the additional cost of a more expensive item if a clinically comparable item costs less. This policy could be especially problematic for drugs used to treat rare diseases for medically supported off-label indications.

Moreover, Congressional intent of the initial funding given to AHRQ in the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) to conduct comparative clinical effectiveness research specifically states in the MMA conference report that CMS "may not use data from the research conducted to withhold coverage of a prescription drug, to mandate a national standard, or require a specific approach to quality measurement and reporting." Any language accompanying legislation in the 111<sup>th</sup> Congress that provides increased funding for comparative clinical effectiveness research should proscribe that CMS must primarily focus on advancing an individual patient's medical outcome—rather than cost.

SLOWGOGO / ISTOCK



# MEET THE PPTA STAFF



## BRIDGET ELIS

**MY NAME IS BRIDGET ELIS.** I am PPTA's Assistant Director, Regulatory Policy. I have worked for three and a half years at PPTA.

In my position, I work closely with Mary Gustafson, PPTA's Vice President, Global Regulatory Policy. My responsibilities include evaluating and reporting on industry issues relating to regulatory policy and assisting in developing regulatory policy for the Association through the Regulatory and Compliance Policy Steering Committee (RPSC)

I also work with PPTA's North America staff when legislative issues affect the U.S. Food and Drug Administration (FDA).

### **Tell us about your background.**

I was born and raised in Maryland and am proud to call it my home state. I attended the University of Maryland College Park where I obtained a Bachelor's of Science degree in Marine Biology. After graduation, I left my wetsuit behind, took a job at a law firm in D.C. and decided to become a lawyer. I moved to North Carolina, where I obtained a law degree from Campbell University School of Law. During law school, I worked at the U.S. Attorney's Office for the District of Columbia, Appellate Division and was President of Women in Law. I am admitted to practice law in the states of North Carolina and Maryland. I met my husband in high school and we will be married for 10 years this June. We have two beautiful daughters, Georgia and Lila. In my spare time, I enjoy spending time with my family, sewing and running.

### **What is your proudest professional achievement at PPTA?**

Shortly after I started in 2005, a global threat of an influenza pandemic began to arise. There was a large amount of misinformation being circulated and it became necessary for the plasma protein therapeutics industry to create a mechanism for delivering accurate and up-to-date information. To that end, I worked to create a multi-faceted Pandemic Preparedness website that contained information on global pandemic resources, the latest news, key documents and planning checklists. PPTA members expressed appreciation for PPTA's quick response to this issue and the comprehensiveness of the website.

### **What is most rewarding about working in this industry?**

Knowing that we are helping people – the policy we develop helps to ensure the safety and quality of the products people rely on. ●

"I think the biggest thing now is that both chambers acknowledge the need for sustained commitment to this kind of research," Dr. Allen said. "Right now, there are no great feedback systems for medical decision making."

Dr. Allen believes we need to figure out how to conduct research and answer first the toughest and most outstanding questions to gain evidence to make decisions. "Studies designed to address high-cost drugs are not the starting point and are not appropriate for CER now," Dr. Allen said.

PPTA supports comparative clinical effectiveness research that empowers patients and their physicians with the most accurate and efficacious treatment designs. The Association also hopes that policymakers support legislative proposals and statutory language that recognizes that patients suffering from rare, chronic, and debilitating diseases, disorders, and medical conditions, such as those treated with plasma protein therapies, deserve the best treatment available as determined by the individual patient along with his physician. Thus, any new information gleaned through studies and data analysis should not affect the ability of these patients to access their preferred therapies that have proven to be clinically effective in their treatment.

PPTA will continue to monitor discussion on CER and any legislation that arises from it, including how patient access to plasma protein therapies may be affected. ●

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EDITOR'S NOTE: JON MCKNIGHT, Assistant Director, Federal Affairs, PPTA, contributed to this article.

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KYM H. KILBOURNE is the Assistant Director, Communications, North America.

# NEWS

## PLASMA PROTEIN NEWS FROM AROUND THE GLOBE



Congresswoman Anna G. Eshoo



Congressman Jim Langevin



Senator Byron Dorgan



Senator Olympia Snowe

### UNITED STATES

► Representatives Anna G. Eshoo (D-CA) and Jim Langevin (D-RI) and Senators Byron Dorgan (D-ND) and Olympia Snowe (R-ME) introduced the Health Insurance Coverage Protection Act (H.R. 1085; S.442) on February 13, 2009. The legislation, will set a \$10 million minimum lifetime cap on health insurance, with future increases based on inflation. PPTA is highly supportive of this legislation and will work closely with the plasma protein therapies user community in advocating for its successful passage.

► PPTA and the patient communities have been working to pass Standards of Care legislation in Minnesota that would protect patient access to their medically appropriate therapy from cost containment strategies used by payers. Sen. Kathy Sheran of

Mankato and Rep. Kim Norton of Rochester introduced identical legislation on January 29, 2009. Sen. Sheran's Senate File 339 was passed by the Senate Committee on Health, Housing and Family Security on March 25, 2009 as amended to require the Board of Pharmacy to create standards of pharmaceutical services for individuals needing plasma protein therapies based on recommendations from patient medical advisory committees.

This is the first time any Standards of Care legislation for people with primary immunodeficiency diseases, alpha-1 antitrypsin deficiency and von Willebrand disease has passed out of any committee in the nation. After passage, S.F.339 was referred to the Senate Committee on State and Local Government Operations and Oversight. House File 410 is currently in the House Committee on Health Care and Human Services Policy Oversight.

The work in Minnesota with patient advocates, national consumer organizations and PPTA state affairs represents a concerted and collaborative approach to work on these patient-led initiatives, with PPTA playing a supporting role. In addition to significant lobbying support, PPTA also worked to promote the need for the legislation along with a human interest story angle with the local media, using a local public relations firm to connect with reporters that cover issues at the Capitol and to hit key media outlets. As a result, a story about advocate Kathy Antilla and her teenage son, Isaac, who has primary immunodeficiency disease, appeared in the *Isanti County News*, and alpha advocate Julie Knutson was interviewed by the *St. Paul Pioneer Press* (as was Sen. Sheran) and on camera together with infusing for WCCO, the CBS broadcast affiliate, for a story that ran on April 23. Another story ran on May 2 in the *Mankato Free Press*. Visit [www.pptaglobal.org](http://www.pptaglobal.org) to view a link to the WCCO piece.

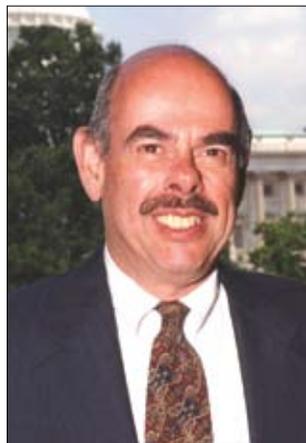


Kathy Antilla and her son Isaac

► House Energy and Commerce Committee members, Anna Eshoo (D-CA), Jay Inslee (D-WA) and Joe Barton (R-TX) along with 66 other co-sponsors introduced the "Pathway for Biosimilars Act." Highlights of the bill include 12 years of data exclusivity to the makers of brand biotech and additional two years if a new indication is approved that offers a



**Congressman Nathan Deal**



**Congressman Henry Waxman**



**Congressman Jay Inslee**



**Congressman Joe Barton**

significant improvement in the treatment, diagnosis, or prevention of disease within eight years after the biologic is initially approved. The bill does provide a mechanism for the Food and Drug Administration (FDA) to determine that biological products are interchangeable; however, FDA must issue guidance advising that it is feasible in the current state of scientific knowledge to make a determination of interchangeability for that product class. This aforementioned provision is favorable to PPTA because plasma-derived therapies and recombinant blood clotting factors products raise significant scientific challenges to provide for an abbreviated application process.

› **The 94th FDA Blood Products Advisory Committee (BPAC)** met in Gaithersburg, Maryland. FDA sought advice of the Committee on the appropriate manufacturing standards for plasma collected from whole blood donors to make injectable plasma-derived products. The Committee voted unanimously in support of the framework for the standards proposed by FDA for collection, freezing, storage and

labeling for concurrent plasma and component plasma. The standards will be based on five categories of concurrent/component plasma that delineates different freezing, storage and shipping requirements. The BPAC also focused on recruitment and informed consent issues associated with the collection of plasma for manufacturing use by blood centers. Additional topics included: HBV NAT testing for transfusable components with the BPAC agreeing with FDA that donors with apparent vaccine breakthrough HBV infections (HBV NAT positive with anti-HBs) should be presumed infectious pending further studies and that HBV NAT screening of blood donors would be beneficial; and potential testing strategies for *T. cruzi* infection in blood donors.

› On April 28, 2009, **PPTA** ran the 8-page advertorial in Politico newspaper and launched the microsite [www.Politico.com/preservepatientaccess](http://www.Politico.com/preservepatientaccess) that contains the same content as the print piece. This advertorial provides information to policymakers and key stakeholders about plasma protein therapies, the patients and diseases they treat and how they are different from traditional chemical pharmaceuticals. It conveys messages regarding the need to protect patient access and the uniqueness of the patient groups and specialized therapies, and uses rare disease language to enhance our argument. Because Politico.com is one of the most widely read online newspapers in the country, with nearly 4 million visitors per month, the reach of this information is tremendous.



## EUROPE

› **The European Commission** is consulting on the draft revision of the "Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products." This technical revision has been undertaken to take into account advancement of science in the area of transmissible encephalopathies, as well as the evolving situation regarding **Bovine Spongiform Encephalopathy (BSE)** across the world.

› PPTA's French affiliated association, previously known as **AMDSA**, has recently changed its name to officially become **PPTA France** (Association des Entreprises des Protéines Plasmatiques Thérapeutiques). A new logo was designed and a new website is under construction. The name change will allow PPTA France to be better aligned with the "PPTA brand" and reflects the willing-

ness of the French association to support and make progress on PPTA's global strategic priorities by implementing them in the local environment. Importantly the new name also will help to clearly differentiate plasma protein therapies from labile blood products, which remains a significant challenge in the French political arena particularly on issues related to compensated plasma donations.



**French President Nicolas Sarkozy**

➤ **PPTA France** recently met with **French President Nicolas Sarkozy's Health Adviser, Mr. Raphaël Radanne**, to discuss the amendment, which was recently lodged by a French Member of the Parliament, Mr. Rolland. The so-called "Rolland Amendment" seeks to confirm the public health mission of the French National Fractionator, LFB, by including it into French law. This amendment, if passed, could provide the LFB with a tool to defend their dominant

position and the anti-competitive advantages that they currently benefit from in France. Not surprisingly, Mr. Radanne indicated the support of the French government to this amendment. As it will be extremely difficult to challenge the amendment in this context, PPTA France will soon meet to consider its position and alternative options to tackle the existing market access barriers in France.

➤ Mr. Wolfgang Marguerre, the founder of Octapharma, was granted "les insignes de Chevalier de la Légion d'Honneur," France's highest military and civilian Medal of Honor, by the French Minister of Health and Sports, Madame Roselyne Bachelot-Narquin. The title was granted in recognition of Mr. Marguerre's entrepreneurial spirit as Chairman and founder of a leading European plasma fractionator. In her presentation of the award to Mr. Marguerre,

Madame Bachelot-Narquin also referred to his strong association with the State of France through his ancestors, his MBA studies at the Institut Européen d'Administration des Affaires (INSEAD) and the fact that he and his family lived for several years in France. She further commemorated the fact that Octapharma is a major employer in the region of Alsace currently employing 330 people and intending to hire another 30 later this year. In his acceptance speech, Mr. Marguerre expressed his gratitude for having received the Medal of Honor and thanked the employees of Octapharma for their contribution to the success of the Octapharma.

➤ Article 4(1) (a & b) of Commission Regulation (EC) No 1234/2008 of November 24, 2008 concerning the examination of variations to the terms of marketing authorizations for medical products for human use and veterinary medicinal products establishes that the Commission shall, after consulting the Member States, the Agency and interested parties, draw up guidelines on details of the various categories of variations and on the operation of the procedures laid down in Chapters II, III and IV of the Regulation. With this public consultation, Directorate General for Enterprise and Industry intends to consult all stakeholders on a contribution to the preparation of the above mentioned guidelines. This contribution is an input from the EU Variation Task Force coordinated by EMEA and it will form the basis for the preparation of the Commission guidelines.

➤ The EU Member States have approved the new Commission Directive amending, regarding advanced therapy medicinal products, Annex I to Directive 2001/83/EC. The draft Directive was put to vote at a meeting of the Standing Committee on Medicinal Products for Human Use. The text now enters a three-month period of scrutiny by the European Parliament and Council, before it can be formally adopted by the Commission and enters into force.

➤ The European Medicines Agency published the draft "Guideline on Plasma-Derived Medicinal Products. This guideline replaces the Note for Guidance on Plasma-Derived Medicinal Products." CPMP/BWP/269/95, rev.3 dated January 25, 2001. ●

## GLOSSARY OF TERMS

**BPAC** – Blood Products Advisory Committee  
**CCPIE** – China Center for Pharmaceutical International Exchange  
**EMEA** – European Medicines Agency  
**EU** – European Union  
**FDA** – U.S. Food and Drug Administration  
**HIV** – Human Immunodeficiency Virus  
**HMAP** – Hemophilia Medical Advisory Panel  
**HPA** – Health Protection Agency  
**IG** – Immune Globulins  
**IPOPI** – International Patient Organization for Primary Immunodeficiencies

**IPPC** – International Plasma Protein Congress  
**IQPP** – International Quality Plasma Program  
**IVIG** – Intravenous Immunoglobulin  
**ISTH** – International Society of Thrombosis and Hemostasis  
**MCHM** – Comprehensive Hemophilia Management Program  
**PCPs** – Primary Care Providers  
**PID** – Primary immunodeficiency disease  
**PLUS** – Platform of Plasma Protein Users  
**PPUG** – Plasma Protein Users Group  
**WFH** – World Hemophilia Federation  
**vCJD** – Variant Creutzfeldt-Jakob Disease

# EVENTS

## UPCOMING CONFERENCES & SYMPOSIUMS

### 2009

<b>July 6–7</b>	6th IABs Symposium on Advances in Transfusion Safety <i>Cambridge, U.K.</i>
<b>July 11–17</b>	XXII Congress of the International Society on Thrombosis and Haemostasis (ISTH) <i>Boston, MA, U.S.A.</i>
<b>September 11–13</b>	European Haemophilia Consortium Annual General Meeting <i>Vilnius, Lithuania</i>
<b>September 15–18</b>	42nd Annual Meeting of the German Society for Transfusion Medicine and Immunohaematology (DGTI) <i>Rostock, Germany</i>
<b>September 24–25</b>	Sixth Global Forum on the Safety and Supply of Treatment Products for Bleeding Disorders <i>Montreal, Canada</i>
<b>October 24–27</b>	AABB Annual Meeting <i>New Orleans, USA</i>
<b>October 25</b>	PPTA Source Business Forum <i>New Orleans, USA</i> PPTA members only
<b>October 26–27</b>	10th Workshop EPPOSI on Partnering for Rare Diseases Therapy Development <i>Brussels, Belgium</i>
<b>October 29–31</b>	61st Annual Meeting of the National Hemophilia Foundation (NFH) <i>San Francisco, CA</i>

### 2010

<b>March 16–17</b>	International Plasma Protein Congress <i>Berlin, Germany</i>
<b>May 22–25</b>	56th Annual Meeting of the Scientific and Standardization Committee of the ISTH <i>Cairo, Egypt</i>
<b>June 15–16</b>	Plasma Protein Forum <i>Reston, VA, USA</i>
<b>June 26–July 1</b>	XXXIst International Congress of the ISBT <i>Berlin, Germany</i>
<b>July 10–14</b>	Hemophilia World Congress <i>Buenos Aires, Argentina</i>
<b>September 11–13</b>	Annual General Meeting of the European Hemophilia Consortium <i>Vilnius, Lithuania</i>
<b>October 7–10</b>	XIVth Meeting of the European Society for Immunodeficiencies <i>Istanbul, Turkey</i>
<b>October 9–12</b>	AABB Annual Meeting <i>Baltimore, USA</i>
<b>October 10</b>	Source Business Forum <i>Baltimore, USA</i> PPTA members only



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#### ASIA & OCEANIA

Asahi Kasei Medical Co., Ltd.  
Planova Division  
1-105 Kanda Jinbocho  
Chiyoda-ku, Tokyo 101-8101, Japan  
Tel: +81-3-3296-3780  
Fax: +81-3-3259-5725  
[planova\\_jp@om.asahi-kasei.co.jp](mailto:planova_jp@om.asahi-kasei.co.jp)

#### NORTH AMERICA

Asahi Kasei Medical America, Inc.  
Long Island Branch  
1600 Stewart Ave., Suite 602  
Westbury, NY 11590, USA  
Tel: +1-516-620-3130  
Fax: +1-516-620-3135  
[planova\\_us@om.asahi-kasei.co.jp](mailto:planova_us@om.asahi-kasei.co.jp)

#### EUROPE

N.V. Asahi Kasei Planova Europe S.A.  
Rue Colonel Bourg, 122  
1140 Brussels, Belgium  
Tel: +32-2-526-0500  
Fax: +32-2-526-0510  
[planova\\_de@om.asahi-kasei.co.jp](mailto:planova_de@om.asahi-kasei.co.jp)

N.V. Asahi Kasei Planova Europe S.A.  
Cologne Office  
Hansaring 82  
50670 Cologne, Germany  
Tel: +49-221-2720-803  
Fax: +49-221-3974-868  
[planova\\_de@om.asahi-kasei.co.jp](mailto:planova_de@om.asahi-kasei.co.jp)