

THE SOURCE

THE MAGAZINE OF THE PLASMA PROTEIN THERAPEUTICS INDUSTRY

SPRING 2008

PPTA LOOKS AHEAD IN 2008

Congressional Outlook for 2008

**Jeffrey Modell Foundation
Establishes Center in Japan**

Interview with FDA's Mark Weinstein





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THE BINDING SITE INC,
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
France
Tel: 04.38.02.19.19
Fax: 04.38.02.19.20
info@bindingsite.fr

THE BINDING SITE
Spain
Tel: 902027750
Fax: 902027752
info@bindingsite.es

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Editor
Kara Flynn

Managing Editors
Sybille Beck
Kym Kilbourne

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PPTA, 147 Solomons Island Road
Annapolis, MD 21401
Phone: +1.202.787.3100
email: thesource@pptaglobal.eu

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and/or reprint contents of
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to the managing editor at
thesource@pptaglobal.eu

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THE SOURCE magazine may contain
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Editor's Note: Your eyes are not deceiving you. *The Source* has a new, bolder and more eye-catching look. What's inside has not changed. There is much to appreciate in this first issue of 2008. We're peering into the crystal ball and looking at what's ahead this year. In addition, there is an informative interview with FDA's Mark Weinstein and an article that celebrates the opening of the latest Jeffrey Modell Foundation Center in Japan. Our look may be different, but the important issues have not changed—and *The Source* content remains informative.



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NEWS FROM JAPAN GIVES PATIENTS HOPE

“It is unfortunate but true that in these times, patients are denied access to therapy even though it is available in sufficient quantities. I felt shocked and saddened by this revelation. It is not what you expect in any developed country.”

I AM WRITING THIS COLUMN IN JAPAN,

the day after the opening of the new Jeffrey Modell Center in Tokyo. The complete story follows later in this issue. During one of the several presentations at this event, I heard a story from a patient organization representative about patients suffering from primary immune deficiency. There was one story about a 39-year-old male, who died after yet another bout of pneumonia in a long string of illnesses. The patient was diagnosed, but due to national treatment policies, he did not receive enough intravenous immunoglobulin treatment to raise his immunoglobulin level to where it should be.

It is unfortunate, but true that in these times, patients are denied access to therapy even though it is available in sufficient quantities. I felt shocked and saddened by this revelation. It is not what you expect in any developed country.

This and other patient stories illustrate how important it is to continue educating policymakers about the consequences of therapy guidelines that are based on cost containment and not on the effectiveness of the treatment. Combine that with the negative aspects of the political goals in Japan to achieve self sufficiency, and the result is that more patients will have to suffer before things get better.

What a contrast with the state of Wisconsin, where as of January 1, each newborn will be tested for severe combined immune deficiency (SCID). Undiagnosed, most children die within 12 months. The policymakers in Wisconsin deserve great recognition for their leadership in fighting this disease.

Why is it sometimes so difficult to do the right thing? Failing to diagnose immunodeficiency diseases when the diagnostic tools are available, restricting access to therapies due to financial barriers, or denying prophylactic treatment to persons with hemophilia



Jan M. Bult

forces countless individuals to live a restricted life of pain and disability. In Japan today, there are about 1,400 registered patients with primary immune deficiency, and Japanese medical experts know that there are many more. A more realistic number is five to 10 times higher. The question has been how to find, diagnose and treat these patients. High-profile patient advocate groups and the Jeffrey Modell Foundation Riken Center in Yokohama are pivotal in filling this need. More about the opening is on page 14.

The news coming from Japan is hopeful. The advanced research carried out at the Riken Institute, coupled with the diagnostic tools provided by the Jeffrey Modell Foundation clinic, are giving the Japanese people, as well as the citizens of the world, new hope. I am concerned, as always, because there is still so much work to do. ●

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ITALY: FACTS ABOUT ALBUMIN

ALBUMIN PERSPECTIVES: A TRADITIONAL THERAPY WITH

BY DR. GIOACCHINO DE GIORGI

TRY TO LOOK AT ALBUMIN as one of the most intriguing adventures in the health care industry.

Born in the 1940's as a "war drug" (a plasma substitute suitable to be transported and reconstituted in overseas battlefields) its use quickly spread through emergency rooms and surgical facilities. Later, as an iperoncotic solution, it became an immediately bioavailable protein source for critically ill patients. Now, albumin is in a position to play new roles, most of them still largely unexplored (Fig. 1). As a stabilizer of blood's physical environment, a marker of disease and independent predictors of mortality in many conditions, buffer, carrier of metabolites and drugs, scavenger and antioxidants reservoir, albumin currently seems to be used in many fields of medicine—an "old" drug with a virtually limitless potential.

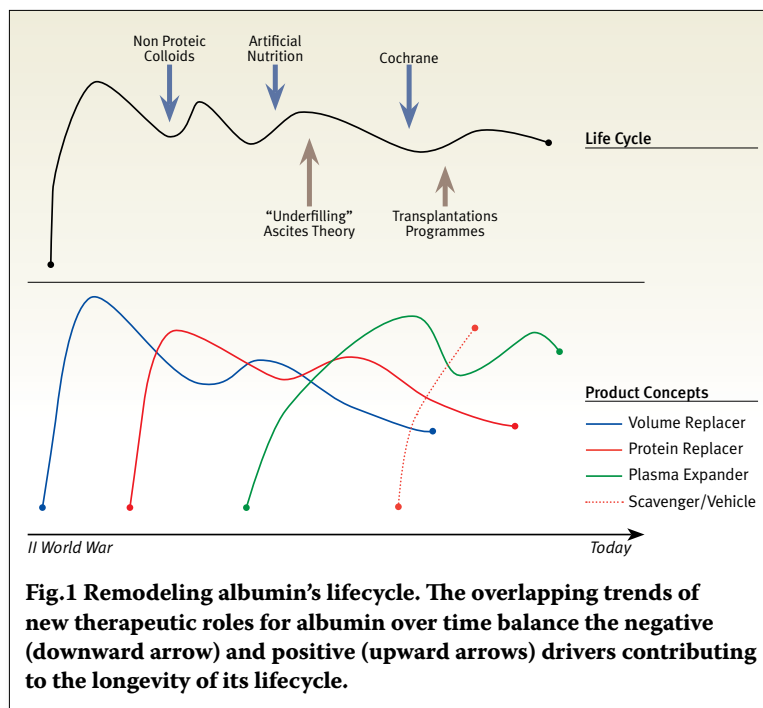
1998 was the "annus horribilis" for albumin

The Cochrane report (i.e. Cochrane Injuries Group Albumin Reviewers), released that year, stated that "its use should be reviewed," contributing to conjecture that albumin is expensive, useless and possibly a harmful drug. In Italy, albumin prescriptions for home-care use were restricted by law to a very low-level of hypoalbuminemia: 2.5 g/dl, regardless of the individual's clinical condition. This appealing number soon became the universal "rule of thumb" for all hospital guidelines and all therapeutic indications causing a dramatic drop.

Hepatologists were the first physicians to react. A national consensus conference by Delphi method came to the conclusion that hypoalbuminemia doesn't directly correlate with the severity of cirrhosis, a consequence of chronic liver disease, and the likelihood of ascites (fluid retention in the abdominal cavity) recurrence. Also, they agreed that this restriction to albumin therapy resulted in a cost-increase rather than a saving when analyzed in a more comprehensive perspective, with increased hospitalizations and longer hospital stays (Fig. 2). In the following years, several Spanish and Italian groups demonstrated that albumin administration in cirrhosis promptly increases the effective arterial volume, relieves ascites and decreases the risk of renal failure, increasing survival up to 30 percent. It took another five years for the international scientific community to endorse these results, and for North American scientists to confirm the Italian and Spanish studies in the "end stage" phases of ascites.

To try to defend albumin in Italy was a hard task

In 2002, we started a qualitative market research report to identify the most represented clinical indications for albumin, and understand a physician's motivation or resistance when using albumin. The conclusions were somewhat surprising—albumin wasn't just seen as costly, but mainly as a "silent" drug:



UNLIMITED POTENTIAL

STATEMENT	% AGREE	% DISAGREE
Appropriateness of albumin treatment		
Albumin administration in hospital reduces the length of stay	77	9
Albumin treatment at home		
hypoalbuminemia < 2.5 is not the sole parameter to start treatment. A more complex evaluation is needed	71	17
Albumin home care improves health conditions and the response to diuretic, decreasing the recurrence of ascites	86	9
Albumin home care reduce the resort to hospitalisation	79	9
Criteria to start albumin therapy		
Hypoalbuminemia < 2.5 cannot be the sole criterion to start therapy.	66	29
At least other three important criteria exists: <ul style="list-style-type: none"> • patient's general conditions • signs of hypovolemia • ascites non responsive to diuretics 	80	8

Fig. 2. The place of albumin on the care of patients with cirrhosis and ascite. Main statements from the Italian consensus conference on albumin indications in cirrhosis with ascites (% of agreement on the total of interviewed physicians).

Reproduced from Ascione A, De Luca M, Di Costanzo GG: "Albumin in home care treatment: clinical rationale and organisational aspects." In "Albumin: from volume expander to drug." Cepi, Rome 2007.

an easy target to competitors and hospital budget cutters, and was viewed as being undefended. Physicians were persuaded by a positive perception of albumin as "a multi-purpose protein, irreplaceable by other substitutes" rather than a mere plasma or protein surrogate (Fig. 3), and this was not by chance. We were seeing a heritage of strong and positive physicians' attitudes toward albumin's therapeutic value.

From Hygea to Hydra

A multidisciplinary panel of eight outstanding clinical opinion leaders (Italian Group of Experts on Albumin or IGEA from the name of the Greek health goddess) was tasked to redesign and enforce the clinical rationale for albumin in its different indications, to start an institutional medical information campaign. In cooperation with the Italian Society of In-

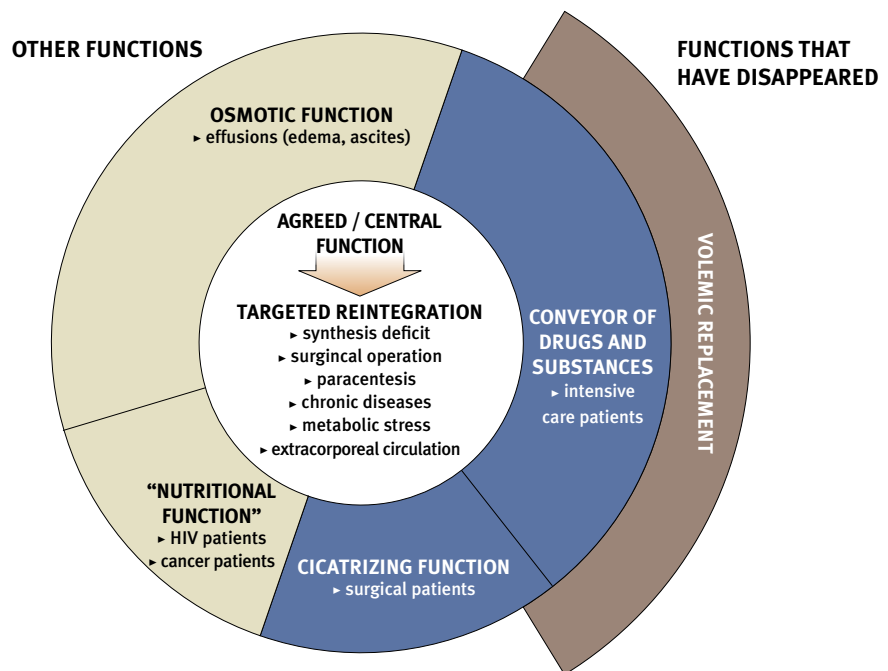


Fig. 3. Why physicians use albumin. The main therapeutic expectation resides in a central function agreed by the different specialists, both in acute and chronic disease: to reintegrate an otherwise irreplaceable protein.

Source: Eurisko, health research department: "Albumin: imagery, usage driver, development potential." 2003.

“...Albumin currently seems to be used in many fields of medicine—an ‘old drug’ with a virtually limitless potential.”

WHAT MATTERS IS THE “QUALITY” OF VOLUME

- Crystalloids → 2/3 out • edema
• acidosis
- Colloids → coagulation
- Albumin → none of the above
→ possible benefits (sepsis, cirrhosis)

Fig.4. A practical approach to choice of fluid for volume replacement. Drawbacks of the alternative fluids and possible benefit of albumin drive the choice according to the individual patient condition.

(Courtesy of Prof. Luciano Gattinoni (from “Albumin, Volume Expander or Drug?” SMART National Symposium on Anaesthesia, Resuscitation and Intensive Care. Milan, May 28, 2005.)

ternal Medicine, and their President Prof. Mannuccio Mannucci, a series of conferences were prompted and collected in the monographic volume *Albumin: from Volume Expander to Drug* distributed in 10,000 copies.

The most valuable outcome of IGEA was a new medical concept for albumin: no longer just a plasma substitute, but a multi-faceted drug. Also, when used as a volume expander (the daily case in critically illness), albumin deserves a special place. If you don’t

simply consider the volume effect but the quality of volume, the cheaper non-proteic surrogates are more likely to induce side reactions (as alterations in blood pH, renal function and coagulation), which cannot be justified by cost savings (Fig. 4). In cooperation with the Italian Congress for Anaesthesia, Resuscitation and Intensive Care (S.M.A.R.T.), a cycle of conferences were held on the biological effects of fluid replacement, which had a very large audience. Today, by initiative of its chairman, Prof.

with the aim to drive the debate on albumin efficacy throughout all the Italian regions. For this project, an outstanding medical faculty designed a problem-based-learning approach to teach by theoretical lectures and practical cases how to use this valuable therapeutic resource.

Use of Albumin in Italy

It is important to stop seeing albumin as a commodity, but rather to regard it as a unique specialty, a multi-function therapy that still has a lot to give. At the same time its use is threatened by a difficult scenario: restrictive guidelines are still in place, cost-containment policies, which still identify albumin as the main target, and the negative trends have not concluded.

The present and the future of albumin is a matter of commitment and requires hard scientific input and continuous resources to be invested. ●

Acknowledgments: The IGEA panel (Prof. Paolo Angeli, Dott. Antonio Ascione, Prof. Luigi Bolondi, Prof. Luciano Gattinoni) and Prof. Mauro Bernardi for having enthusiastically contributed to the development of the scientific project which owes its accomplishment to their irreplaceable help, and Prof. Pier Mannuccio Mannucci for his continuous help and precious advice in the realization and publication of the scientific conferences.

I am indebted to Dr. Riccardo Vanni for his support in this project as in other professional activities.

DR. GIOACCHINO DE GIORGI is the marketing and medical affairs director of Grifols Italia.



Dr. Gioacchino De Giorgi

Luciano Gattinoni, a large scale, randomized trial to evaluate the efficacy of albumin versus saline in severe sepsis will be carried out with a fund from the Italian Medication Agency (AIFA).

In 2007, a new educational campaign, the IDRA project (from the Italian acronym of Regional Didactic Initiative on Albumin), was started under the patronage of the Italian Federation of Internal Medicine,

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Tel: +81-3-3259-5723
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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

EUROPE

N.V. Asahi Kasei Planova Europe S.A.
Rue Colonel Bourg, 122
B-1140 Brussels, Belgium
Tel: +32-2-526-0500
Fax: +32-2-526-0510
planova_de@om.asahi-kasei.co.jp

N.V. Asahi Kasei Planova Europe S.A.
Köln Office
Hansaring 82
D-50670 Köln, Germany
Tel: +49-221-2720-803
Fax: +49-221-3974-868
planova_de@om.asahi-kasei.co.jp

HEALTH CARE DEBATE HEATS UP DURING U.S. ELECTION YEAR

BY RYAN FADEN

THE KAISER FAMILY FOUNDATION ESTIMATES that there are 46.5 million uninsured Americans. Of this total, 9.4 million are children. As a result of the growing ranks of the uninsured, universal health care is one of the top domestic policy issues for the 2008 Presidential elections. In fact, a recent survey found that 68 percent of U.S. adults support a requirement that all residents obtain health insurance, with government subsidies for those who cannot afford coverage. Of course, the devil lies in the details. States have often played the role of “laboratory” to develop solutions to major public policy issues. In fact, in 2007 close to two-thirds of the states considered some plan to address the uninsured. Among those, at least 20 were comprehensive approaches to ensuring universal access to health care coverage. Three states, Massachusetts, Maine and Vermont, currently have programs in place, and many other states have looked to the Massachusetts plan as a model.

Universal Health Care in California: Framing the Issue

As the most populous U.S. state, California faces significant challenges in ensuring universal access to health care coverage. This is compounded by the fact that California also has the seventh highest uninsured rate in the country. Recent estimates by the California government show that 6.6 million Californians lack health insurance—approximately 15 percent of the population. By comparison, this is more than the entire population of Massachusetts (6.3 million). Of those lacking insurance in California, 1.3 million are children. The California proposal passed the Assembly late in 2007, but stalled in the Senate and faces major obstacles in the coming months. Specifically, here are some of the key concerns:

- 1) Should residents be required to buy insurance, and if so what can be done about people who cannot afford the coverage;
- 2) Are tax breaks preferable to direct subsidies for lower income workers;
- 3) How much should companies be fined that refuse to offer insurance to their employees;
- 4) How much to tax doctors and hospitals to raise money for subsidies;
- 5) Whether to require insurance companies to issue coverage to individuals, regardless of their age or pre-existing medical conditions; and finally
- 6) Funding.



Proposal Highlights

When assessing universal health care proposals, plans essentially fall into two categories. One is a single payor system in which the state functions as the sole payor for all health care services. This model would resemble some plans in other industrialized countries and raises important concerns about price controls and other mechanisms that could have negative effects on the biotechnology and pharmaceutical industries and patient access. The other approach involves so-called coverage expansions of both the existing public and private systems. The Massachusetts plan and the California proposal Assembly Bill X1 1 (this connotes the first bill of the first extraordinary session of the 2007-08 California Legislature) include an individual mandate requiring every citizen in the state to have insurance. Among the key characteristics of the California expansions are:

- 1) Coverage for all children at or below 300 percent of the federal poverty level (FPL), regardless of immigration status;
- 2) Extension of Medi-Cal coverage to 19 and 20 year olds up to 250 percent of FPL;
- 3) Coverage for low-income parents of children on Medi-Cal and childless adults between 100 and 250 percent of FPL;
- 4) Subsidized coverage for parents otherwise not eligible for Medi-Cal and childless adults between 100 and 250 percent of FPL; and
- 5) A program for childless adults who are citizens, nationals, or qualified immigrants with incomes up to 100 percent of FPL.

One key point in terms of funding the plan is securing federal financial participation (FFP) for the subsidized coverage. As a reference point, the federal government currently pays on average 60 percent of all dollars spent on Medicaid and 72 percent of those for the State Children's Health Insurance Program (SCHIP).

Reforming Health Insurance

The California proposal also includes a number of health insurance reforms. Most important among these reforms is the requirement for guaranteed issue and

renewal, which means that all carriers who sell individual coverage must offer, accept and renew such coverage to all individuals regardless of age, health status, or claims experience. This requirement could be especially important for users of plasma protein therapies who have experienced difficulties with insurance—particularly when changing jobs or after exceeding life-time maximums.

The proposal also would establish a new California Health Care Cost Quality and Transparency Committee for the purpose of statewide data collection, measurement and analysis of health care costs, quality and outcomes. This entity might discuss quality of care and standards legislation aimed at the plasma protein therapies community. It should be noted that AB 8, which was the other leading health care proposal vetoed by the Governor, includes a requirement that the California Health Services Agency conduct a review of best practices related to the care and treatment of patients with high-cost, chronic conditions. This could be highly important for users of plasma protein therapies and an issue for the community to raise in future discussions with the California legislature.

Outlook

One of the major obstacles to enacting the plan is financing. Ultimately, this will be the most important test for the proposal as the financing mechanism will be voted on by Californians in November. Because of its large and diverse population, any movement on universal health care in California could presage further development both in other states and nationally as well. PPTA is engaged and focused on this very important issue and will continue to update members through *The Source* and other communication mediums. ●

Note: California ABX1 1 failed in the state's Senate Health Committee in late January.

PPTA SOURCE TACKLES INITIATIVES NEW AND FAMILIAR IN 2008

BY JOSHUA PENROD

THE PPTA SOURCE DIVISION has a number of new and ongoing initiatives for 2008. These range from responsive actions, such as to the U.S. Food and Drug Administration's (FDA) Proposed Rule on Donor Eligibility, to proactive campaigns, such as the improvement of the Source industry's public profile and image. With the dedication and expertise of the PPTA staff and member company personnel on Association committees and task forces, optimism flows, anticipating great results for the industry and all stakeholders.

UDHQ

The PPTA Uniform Donor History Questionnaire (UDHQ) Task Force has completed its response to the FDA evaluation of the industry's UDHQ. It is expected that PPTA and member companies will have to perform some studies to generate data demonstrating the new instrument's effectiveness. After the FDA's review of these data, we are hopeful that the UDHQ will be accepted by regulatory authorities and industry participants, as we are very confident in its increase in efficiency and effectiveness as a donor screening tool.

Proposed Rule

In December 2007, the FDA released the long-awaited proposed rule on donor eligibility. As expected, the proposed rule is comprehensive and covers a large number of processes used in both whole blood and Source Plasma collection enterprises. The proposals are many and varied; the FDA has specifically invited industry comment on a number of areas, such as the utility and administration of donor deferral registries. Already PPTA, working with allied sectors, has been successful in persuading the FDA to allow industry further time to comment; the deadline for comments on the proposed rule has been delayed until August.

Importantly, the FDA also has included language that would attempt to include at least two of PPTA's long-standing standards: the Qualified Donor and

Inventory Hold. We currently are analyzing the implications of this addition, though at this time it is believed that a number of the important subtleties of those standards has been omitted.

A large number of technical changes and requirements also have been introduced by the proposed rule, which affect both the whole blood and source plasma sectors. These include parameters for monitoring donor weight to blood pressure requirements, to adverse event reporting and the aforementioned donor deferral registries. We look forward to our participating committees providing valuable counsel and guidance in crafting what will be a very thorough industry response to the FDA's proposals.

Industry Image

The PPTA Source Image Task Force has begun to lay the foundation for a large industry campaign with the goals of enhancing the public profile and image of the Source Plasma collection industry. In conjunction with this, the Task Force has identified key messages and audiences, and is in the process of creating new tools and material for use by the Source membership. These tools include a website dedicated to plasma donation, and a "toolkit" of resources that can be used by members in local communities to build awareness about the importance of plasma donation and the thousands of lives saved by the efforts of our industry.

PPTA has released a number of revised standards to the IQPP program for public comment.

Project Eastwards

With the continuing global importance of a safe, high-quality Source Plasma donor population, the industry has looked into potential donor areas, such as European Union member states in Eastern Europe. This project would educate stakeholders, including politicians, physicians, patients, and regulators, on intrinsic differences between whole blood for transfusion and plasma for fractionation, as well as discuss the legal environment in the new European Union member states. This is to be accomplished through ongoing dialogue with regulators in those member states, development of an educational toolkit, and a workshop for discussing these and other important, related issues.

SIPLA Implementation

The Study on Intensified Plasmapheresis (SIPLA) has been a long-term investment of time and resources for the plasma collection industry in Europe, working toward furthering a policy of safe plasma donation volumes, while increasing the flexibility more than what has been historically available under the requirements. This project is designed to implement higher donation frequency and volume as well as maximum yearly donation volume in the European Union.

Epidemiology

The Plasma Master File Task Force is continuing its diligent work in managing the issues of plasma center epidemiology and the European Plasma Master File, brought to fore by the Epidemiology Guidance Document. Several discussions are planned, and PPTA with consultants at Westat, Inc., is generating data-driven policy for advocacy to European regulatory policy-makers.

Business Forum Montreal

PPTA has reserved a location for the 2008 Business Forum, to be held in Montreal, Quebec, Canada, on October 5, 2008. By this time, PPTA's comments to the FDA proposed rule will be completed, along with progress on a number of the projects described above; these findings will be communicated to the Source membership at this meeting. In addition, routine reports on the state of the Association also will be communicated.

International Quality Plasma Program

Starting early in 2008, PPTA has released a number of revised



International Quality Plasma Program

The Worldwide Standard for Plasma

standards to the IQPP program for public comment.

The Viral Marker Standard, Education of Donors, Professional Medical Facility Criteria, and Qualified Donor Standards all have been enhanced by the IQPP Standards Committee and Source Board of Directors. The public comment period will run for 60 days, after posting of the proposed changes, and PPTA anticipates constructive feedback from the industry and stakeholders regarding the changes.

Further, the Standards Committee will be examining new opportunities for the IQPP program. A number of ideas have been brought to the attention of the Committee and the Board, and will be under active consideration. If any industry member or stakeholder has concepts to share with the Committee for its consideration, PPTA would welcome them.

Lastly, as mentioned previously, the FDA proposed rule contains language that would propose to absorb some of the industry standards in a federal regulation. The Regulatory Committee is currently studying the ramifications of these changes, and will comment as appropriate regarding these proposals. ●

INTERVIEW

DR. MARK WEINSTEIN

BY MARY GUSTAFSON

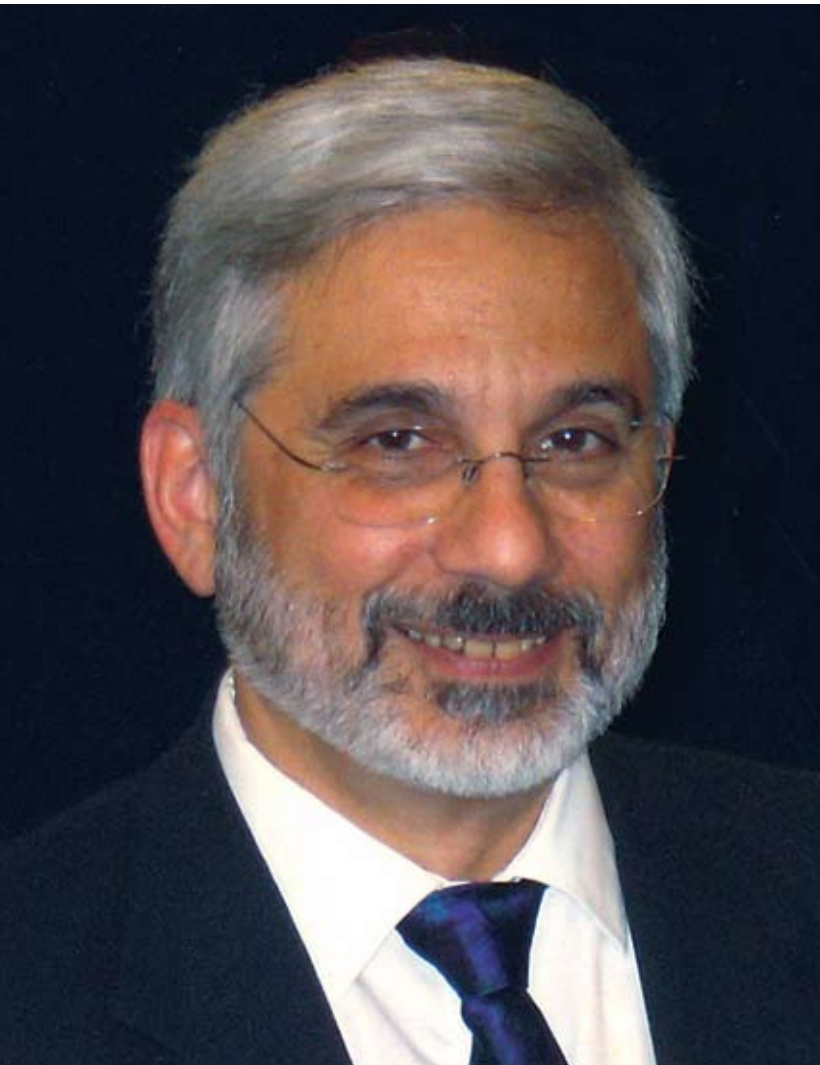
MARK WEINSTEIN, PH.D, is the Associate Deputy Director, Office of Blood Research and Review (OBRR), Center for Biologics Evaluation and Research (CBER), U.S. Food and Drug Administration (FDA). His duties include overseeing mentoring and training in OBRR, acting as an FDA liaison to manufacturers, trade organizations, regulatory agencies, and consumer groups, and helping to develop risk communications, written and physical standards, guidance documents, and policy. Dr. Weinstein has organized workshops on Factor VIII inhibitors, fibrin sealants, patient notification of withdrawals and recalls, rare plasma protein disorders, and plasma standards, among others.

Dr. Weinstein joined the FDA in 1993, and has served as Chief, Laboratory of Hemostasis, Deputy Director, and Director, Division of Hematology in OBRR. He received his bachelor's degree from the State University of New York, Binghamton, his Ph.D. in chemistry from the University of California, San Diego, and postdoctoral training at the University of Washington, Seattle. Prior to joining the FDA, Dr. Weinstein had academic appointments at Boston Veterans Administration Medical Center, Boston City Hospital, and Boston University School of Medicine, where he conducted research on plasma proteins, including Factor VIII, von Willebrand factor, and fibrinogen.

What is FDA doing to help industry develop products to treat rare bleeding and clotting disorders?

Consumer advocates have strongly urged the development of products to treat bleeding and clotting disorders that affect very small patient populations, and this desire has been supported by recommendations of the Advisory Committee on Blood Safety and Availability. One of our challenges is to help industry find a path forward

that is not overly burdensome, but can still assure the safety and efficacy of these products. One step we took in 2005 was to organize a workshop that discussed the need for such products, different regulatory pathways to licensure, registries and databases to identify patients for clinical trials, product reimbursement, and incentives for product development. Following this workshop, a number of manufacturers developed products to treat some of these disorders, but there are still large gaps.



FDA is now actively working with a number of groups including the Centers for Disease Control (CDC) and the American Thrombosis and Hemostasis Network (ATHN) to develop databases that will help to identify patients with rare bleeding and thrombotic disorders, improve our understanding of the natural history of these diseases, and help in post marketing surveillance. We are also piloting a program with the European Medicines Agency (EMA) for providing parallel scientific advice to companies that are seeking to market products in the U.S. and the European Union. This program has the potential to optimize product development and avoid unnecessary testing replication or diverse testing methodologies. This is particularly advantageous when dealing with products for very small patient populations.

Do you think relations among consumer groups, the FDA and industry have improved over the years?

When I was asked to attend my first dinner meeting with the National Hemophilia Foundation in 1994, I wasn't sure whether I was being asked to speak or to be the first course. In the wake of the AIDS epidemic of the 1980s, patients were very concerned about product safety and quite mistrustful of the FDA and industry. Concerns were heightened at that time because of the relatively frequent recalls and withdrawals of products due to viral contamination, manufacturing defects, and fear about the theoretical potential of Creutzfeldt Jakob Disease (CJD) infectivity. Relations have improved a great deal over the years as the number of withdrawals and recalls have dropped through advances in viral clearance, a better understanding of CJD infectivity, and better adherence to current good manufacturing practices. In addition, and maybe equally important, FDA and industry have been more transparent in decisionmaking processes and information exchange with consumers. FDA has done this in several instances by inviting patient advocates to participate as special government employees and members of advisory committees in discussions of issues that we know will be of particular concern to consumers. One recent example of this was in the

development of our risk communication message about the extremely small theoretical potential of plasma derivatives to transmit variant CJD. Likewise, PPTA has helped to improve consumer confidence by supporting the voluntary patient notification system regarding recalls and withdrawals, through frequent stakeholder meetings, and through the monthly reports on product distribution. It is tempting to become sanguine about this improved relationship. However the recent concerns that consumers have raised about the definition of U.S. plasma and a perceived increase in industry compliance difficulties, have shown how fragile this relationship is. Paradoxically, because there have been relatively few recalls or withdrawals in the last few years, some consumers believe that FDA oversight has become lax. FDA and PPTA must constantly strive to improve communications with consumer groups to maintain their trust.

On September 27, 2007, Congress passed the FDA Amendments Act (FDAAA), which updates the Food Drug and Cosmetic Act. What is CBER doing to implement the Act?

FDAAA has eleven provisions (Title I to Title XI) that cover many aspects of FDA's regulation of drugs, devices, and biologics (including blood and blood components) including strengthened provisions for post-marketing surveillance, quality oversight of pediatric studies, and increased public transparency of the regulatory process. Since many of the provisions of FDAAA went into effect immediately, CBER has been putting a great deal of effort into building documents and procedures that will help us to comply with the new statutes. These include: 1) developing a Clinical Trials Certification form (required to be included with all regulatory submissions to CBER as of December 27, 2007); 2) developing procedures to post the full content of some drug and biologics approval packages on the CBER web site; 3) providing review of PREA pediatric study plans submitted by sponsors to a central Pediatric Review Committee (PeRC). Many of the FDAAA provisions apply to biologics manufacturers, so familiarity with the FDAAA requirements is important to all of us in the biologics community. ●

PPTA has helped to improve consumer confidence by supporting the voluntary patient notification system through frequent stakeholder meetings, and through the monthly reports on product distribution.

JEFFREY MODELL FOUNDATION



Fred and Vicki Modell

*The Riken RCAI Institute is one of seven Riken scientific research centers in Japan researching biosciences and physics. The Riken Institute began as a private foundation for industrial plants in 1917. From this simple beginning, Riken has evolved into a renowned multi-disciplinary research entity with locations throughout Japan and at the Max Planck Institute of Immunology and Infection, German Rheumatism Research Center, Singapore A * STAR, La Jolla Institute of Allergy and Immunology, INSERM Pasteur Institute and Harvard University. Former and current directors of Riken include two Noble Laureates. Satellite centers are located at the Massachusetts Institute of Technology, Brookhaven National Laboratory in New York, Singapore and the United Kingdom. Ancillary Riken RCAI initiatives emphasize international research with monetary support to foreign scientists and invite young post-graduate investigators from around the world to lecture in Japan and collaborate with their Japanese counterparts.*

Celebrating 20 years of advocacy and research for patients suffering from PID, JMF strives to educate the public, medical community and legislators about immunodeficiency diseases and maintains a database accessible worldwide, providing information on patients, their diagnosis and therapy. Fred and Vicki Modell founded the first center one year after the death of their son, Jeffrey, from primary immunodeficiency disease. They constructed the foundation on four main cornerstones comprising research, physician education, patient support, and public awareness and advocacy. Joining the phalanx of JMF centers last year, six new diagnostic centers were opened in Milwaukee, Seattle, San Francisco, Oxford University (United Kingdom), Sao Paulo (Brazil), and Tokyo. Additionally, in 2007, JMF was pivotal in starting the first program in the United States to screen newborns for SCID using an inexpensive, easy-to-administer test in the state of Wisconsin.

BY ROSE NOYES

ON TUESDAY, JANUARY 15, 2008, two powerhouse fighters in the war against primary immunodeficiencies formally celebrated the opening of their combined facility bringing the diagnosis and treatment of every baby born in Japan and around the world afflicted with primary immunodeficiency (PID) closer to realization. The Jeffrey Modell Diagnostic and Research Center for Primary Immunodeficiencies at the Riken RCAI Institute in Yokohama, Japan is the 37th Jeffrey Modell Foundation (JMF) center in the world and the first of its kind in Japan. This partnership was formally inaugurated with a press conference where JMF founders Fred and Vicki Modell co-signed documents detailing the working relationship between the JMF and Riken. Also signing were Riken RCAI Director Dr. Masaru Taniguchi and Riken President Dr. Ryoji Noyori (2001 Nobel Laureate in Chemistry). The day-long event capped nine months of planning and building-initial talks between Riken and JMF began in March 2007.

The morning session was highlighted with speakers numbering among them pre-eminent researchers and a patient advocacy group speaking about the role of the new center and its mission. The Modells' briefly explained three main objectives of the collaborating centers: finding patients; diagnosing their specific PID and intervening with life-saving treatments. Additionally, the Jeffrey Modell Diagnostic and Research Center at Riken will educate the medical and public sector about PID's; build a comprehensive immunodeficiency database, including the registration of PID patients; push for neonatal screening of every newborn for severe combined immunodeficiency (SCID); research the mechanisms and causes of immunodeficiency diseases; and work in collaboration with a worldwide network of research facilities and universities to identify therapies and find the cure for every PID. Another speaker, Mrs. Keiko Nagai, a spokeswoman for a Japanese patient advocacy group, the Society TSUBASA, told the emotional stories of some of the patients she represents. In one, a 39-year old man with X chromosome linked Agammaglobulinemia (XLA) died of pneumonia because he could not obtain treatment in a large enough dosage to raise his gamma globulin level. He suffered from over 200 episodes of pneumonia throughout his life. The therapy guidelines followed by his doctors were set by governmental agencies. Mrs. Nagai's own son's PID went undiagnosed through his infancy, during which he contracted numerous ear infections that required frequent, sometimes day-long visits to the hospital. The initial diagnosis of PID occurred only after a chance screening of her son's immune system in the emergency room of another hospital by a specialist familiar with PID. Her ex-

CELEBRATES OPENING IN JAPAN



Dr. Taniguchi, Dr. Noyori, and Fred and Vicki Modell announce the opening of the new Jeffrey Modell Foundation Center in Tokyo.

periences and others motivated Mrs. Nagai to found the TSUB-ASA society, with the goal of providing guidance, education, advocacy, and a sense of brotherhood to other PID patients in Japan. At the end of her story, Mrs. Nagai said her simple wish for every family with an immunodeficient patient would be to have the ability to enjoy a fulfilling life. Mrs. Nagai was confident that the new center would be instrumental in improving PID patients' quality of life. Expectations were high from all participants that real breakthroughs in positive government involvement, medical profession awareness, and patient quality of life would be realized in Japan with the new facility's opening.

After a lunch break, participants toured the impressive lab facilities. Dr. Ishikawa from the Riken Unit for Disease Model, explained the humanized mouse model, an important research tool to study the human immune system and leukemic stem cells. Another highlight was the astounding single molecule image from the Riken's fluorescent microscope. It was evident to all that the facilities at Riken represent state-of-the-art, cutting edge technology.

The afternoon signing ceremony concluded the official session. Following the press photographs, everyone attended a dinner and reception. Mr. and Mrs. Modell were very eloquent about their expectations and praise for the combined centers. Mr. Modell enumerated the requirements for success in the fight against PIDs. He explained there must be the combined effort and involvement of five parties, including patients, physicians, experts, industry and government. He described the link between a recent victory in Wisconsin and hope for a similar outcome in Japan. The JMF was instrumental in starting a pilot program in the

state of Wisconsin where every newborn is screened for SCID by governor's order. Both Mr. and Mrs. Modell were adamant that the three fundamental objectives to find patients, diagnose their PID and provide life-saving treatments would be realized in Japan, as well as in the United States and the world, through the combined efforts of all. Addressing the need for increased availability of therapies with increasing numbers of new patients in Japan, Mr. Modell stated, "We are not going away, we will be back to make sure therapy is available." Mrs. Modell added, "We will find the patients, then convince the government that the therapies are needed."

The opening of the Jeffrey Modell Diagnostic and Research Center for

Primary Immunodeficiencies is an important medical milestone. For the founders of JMF, Vicki and Fred Modell it is a bittersweet stepping stone in a series of stepping stones to rid the world of the misery of PID. In a conversation with PPTA President Jan M. Bult, Vicki Modell described how she believes Jeffrey would react to the success and renown of the foundation that bears his name. Jeffrey would say, that he always knew he wasn't alone. And so it is that because of the tireless efforts of the JMF centers worldwide, combined with advocacy groups, medical professionals, and researchers, a groundswell of public awareness, industry capability and government involvement can make a positive difference for those suffering from immune deficiency disorders. Many more patients are now diagnosed and have renewed hope and know that they are not alone. ●



Jeffrey Modell Centers around the world.

4TH FOURTH EUROPEAN CONFERENCE ON RARE DISEASES



BY JOHAN PRÉVOT

A **UNPRECEDENTED PUBLIC CONSULTATION BY THE EUROPEAN COMMISSION** regarding rare diseases was launched at the 4th European Conference on Rare Diseases November 27-28, 2007 in Lisbon, Portugal. The event, attended by more than 400 delegates as well as PPTA staff, was organized by The European Organization for Rare Diseases (EURODIS), under the sponsorship of the Government of Portugal in the context of the European Union Presidency, and with the support of the European Commission.

The conference was chaired by Mr. Terkel Andersen, former head of the European Haemophilia Consortium, President of EURODIS and by Prof. Torrent I Farnell, Director of the Dr. Robert Foundation in Spain and member of the Committee on Orphan Medicinal Products (COMP).

Mr. Antoni Montserrat from the European Commission's DG Sanco Health Information Unit kicked off the meeting with a presentation on the new European action on rare diseases. Mr. Montserrat stressed that despite the good progress that has been made in the field of rare diseases in recent years, only one out of 27 European Union member states (France) has implemented a Rare Diseases National Plan in its healthcare policies. Participants were informed that based on the outcomes of the consultation, the European Commission will draft a Communication outlining recommendations and pointing to concrete actions aimed at improving the lives of rare diseases patients in the European Union. It is expected that a Council Recommendation will follow the Commission Communication some time during the French European Union Presidency, which will be effective July through December 2008.

A roundtable debate chaired by Ms. Christel Nourrissier (EURODIS) followed the presentation, during which the need to promote equal prevention, diagnosis, access to treatment, quality of care and better education on rare diseases for young

Bianca Pizzera, Chairperson of IPOPI and founder of the Italian Patients Organisation for Primary Immune Deficiencies





Lisbon, Portugal

physicians throughout the European Union was highlighted.

The second session of Day 1 focused on enhancing member states' rare diseases policies. Dr. Ségolène Aymé, Orphanet and Chair of the European Commission's Task Force on Rare Diseases, provided a broad overview of the various public health policies for rare diseases that are being implemented by several member states. Dr. Aymé emphasized that there had been an increasing number of national and regional initiatives across the European Union in last few months, such as more research funding, empowerment of patient organizations, better availability of orphan drugs, and the creation of centers of reference and public information measures. Her presentation was followed by an overview of national research policies in the field of rare diseases and collaboration between member states by Dr. Brigit Wetterauer with the German Ministry for Research and Education. Dr. Wetterauer highlighted the important role played by the European Research Area (ERA)-NET plan, which aims to step up the cooperation and

coordination of research activities carried out at the national or regional level in the member states and associated states, through the networking of research activities, and the development and implementation of joint activities.

The remainder of Day 1 featured sessions on Promoting National Centers of Expertise and European Reference Networks and on Mobility in Europe: Framing Healthcare Pathways to Patients' Needs. Mr. Yann Le Cam, Director of EURORDIS, presented the results of the "Eurordiscare3 study that looked at patients' expectations concerning access to health services. The study showed, among other conclusions, that the first barrier to care for patients with rare diseases in the European Union was the lack of referral to specialist physicians, followed by family income. In his presentation, Jaroslaw Waligora, with the European Commission's DG Sanco, looked at the issue of patient mobility and revealed the outcomes of a recent European Commission study that showed that 57 percent of European Union citizens stated that they were

Professor Farnell expressed his desire to see 27 national rare diseases plans by the time of the next Rare Diseases Conference in 2009.



Ms. José Drabwell, Vice-Chairperson of IPOPI and Mr. Terkel Andersen, President of EURORDIS with Bianca Pizzera, Chairperson of IPOPI

open to travel to another member state to get their treatment.

The morning of Day 2 of the conference, included parallel workshops on Recent Advances in Quality Assessment Relevant to Rare Diseases, New Initiatives in Member States for Rare Diseases and Addressing All Patient Needs Beyond Medical Care. The parallel sessions were followed by plenary sessions on Making the Most of the EU Research Policy and Shaping Future Policies for Orphan Medicines and Advanced Therapies. Participants were informed that the European Commission, the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) have adopted a common application form for sponsors seeking orphan designation of medicines in the European Union and U.S. This initiative is aimed at simplifying the process of obtaining orphan status for medicines intended for rare diseases in both jurisdictions.

Dr. François Meyer from the French High Health Authority (HAS) reported on the outcomes of a workshop organized by the HAS on timely and equitable access to orphan drugs across European Union member states, which showed many inequalities in patient access to these medicines depending on the member state in which they live. The need to improve the current knowledge of the natural history of rare diseases and to

improve health technology assessment of orphan drugs was emphasized. In his concluding remarks to the conference, Prof. Farnell reminded participants of the importance of the European Commission's Communication on rare diseases, which will be a new tool to advocate for the rare diseases community. Prof. Farnell also stressed that while rare diseases require specific actions and initiatives at the national level, they also need a true European Union dimension and international perspective. Finally, he encouraged the collaboration between all stakeholders and expressed his desire to see 27 national rare diseases plans by the time of the next Rare Diseases Conference in 2009.

Alpha-1 Patients Decide to Establish Association in Portugal

The 4th European Conference on Rare Diseases was followed by a satellite meeting of the Alpha-1 Spanish Association (Alfa-1 España) organized by Ms. Shane Fitch, Chair of Alfa-1 España) that was aimed at exchanging information with local Portuguese alpha-1 patients and physicians. Among the meeting's conclusions was the decision to create an Alpha-1 Patient Association in Portugal that Mr. and Mrs. Pyrrait, who are parents of an alpha-1 patient, will set up in the coming months. ●

WHO HOSTS 8TH GCBS MEETING IN GENEVA, SWITZERLAND



World Health Organization

BY JAN M. BULT

THE GLOBAL COLLABORATION FOR BLOOD SAFETY (GCBS) held its 8th meeting on Dec. 5-7, 2007 in Geneva, Switzerland. The GCBS was set up to create a mechanism for better information exchange on blood safety issues. The secretariat of the GCBS is organized by the World Health Organization (WHO) in Geneva. Though the main focus is on areas related to blood safety, there are many areas of overlap with the plasma collection industry. Therefore, it is important to be represented to ensure that the interests of the plasma collection and fractionation industry are well taken into account. Each participant has to apply for membership and make a presentation on its activities before being accepted. Participants come from blood banks, regulatory agencies (e.g. the U.S. Food and Drug Administration, European Medicines Agency, European Directorate for the Quality of Medicines, Council of Europe, Paul-Ehrlich Institute), patients, donors, transfusion organizations (e.g. the International Society of Blood Transfusion) and industry associations representing fractionation and collection industry (e.g. PPTA, International Plasma Fractionation Association, European Blood Alliance, PPTA Source, American Association of Blood Banks). At the last meeting, the following recommendations were accepted:

RECOMMENDATIONS

1 GCBS participants will review and consider supporting initiatives for the implementation of the finalized recommendations of the WHO Global Consultation, Ottawa, June 2007.

(i) GCBS participants should review the recommendations from the WHO Global Consultation, Ottawa, June 2007 to address the Millennium Development Goals (reducing child mortality, improving maternal health, preventing HIV/AIDS and malaria) related to blood safety through.

- Focus on the donor
- Establishing the evidence base, especially relating to advocacy
- Linking advocacy for blood needs with broader health outcomes
- Implementing the most relevant recommendations.

(ii) Support from GCBS participants to blood services in individual countries should, as far as possible, take account of the advantages of integration with other



RECOMMENDATIONS *continued*

health strategies: e.g. HIV/AIDS, maternal and child health and malaria.

(iii) GCBS participants offering support should work with WHO to identify priority countries where systematic country assessments can be undertaken and priority interventions implemented.

2 GCBS established a task group to develop decision models applicable to the leading concerns in different country settings as a strategic approach to ensuring universal access to safe and effective blood transfusion, consistent with the United Nations Millennium Development Goals.

The task group should:

- (i) Through suitable country level inquiries, identify relevant policy questions for countries in different settings.
- (ii) Establish clear linkages between the objectives of the decision models and the Millennium Development Goals.
- (iii) Identify existing data sources and analytic tools to support the decision models.

(iv) Describe pilot programs for the evaluation of the decision models at country or local levels.

(v) Identify candidate funding sources for the pilot initiatives.

3 GCBS participants agreed to collaborate on a project to:

(i) Generate evidence on the role of transfusion strategies in preventing malaria-related mortality and morbidity in women and young children.

(ii) Investigate the clinical utility of testing strategies on blood donors and donated blood to prevent malarial transmission by transfusion.

4 Considering the importance of hemovigilance as an element of Quality Management for blood programs, GCBS participants engaged in hemovigilance networking, agreed to cooperate in the dissemination of established definitions and, where feasible, tools of hemovigilance applicable in different settings.

GCBS tasked interested participants to convene and participate in a meeting to:

GLOBAL COLLABORATION FOR

BY CHARLES WALLER

“**V** **EIN TO VEIN**” was the title of a PPTA-hosted workshop that provided a curtain-raiser event on the eve of the 8th General Meeting of the Global Collaboration for Blood Safety (GCBS) in Geneva, Switzerland in December 2007.

The workshop was designed to be particularly relevant and helpful to GCBS participants from the developing world. It provided attendees with an overview of key aspects in the preparation and delivery of safe and efficacious plasma proteins. Presentations considered the collection of high-quality plasma for fractionation, state-of-the-art production, regulations, clinical aspects and new therapies. Attendees at the workshop came from South America, Africa, Asia and the Middle East.

Impressive industry speakers included the chairman of PPTA's



Dr. Thomas Kreil

(i) Identify existing gaps and potential duplication of initiatives for a global hemovigilance network.

(ii) Consider strategies for:

- Local monitoring of complications of donations and transfusions
- International benchmarking of rates of donation and transfusion incidents
- Rapid alert systems.

5 GCBS participants endorsed the concept of the development of an aide-mémoire on transfusion practices at the bedside.

(i) GCBS participants agreed that the single most important safety measure at the bedside is the correct identification of the patient and the unit to be transfused.

(ii) A task group was formed to compile these concepts into a draft aide-mémoire to be circulated to GCBS participants for comment and to be followed by clinical consultations.

6 Recognizing the adverse impact of supply instability on the availability of safe blood and the barriers to effective procurement and contracting, GCBS participants concurred that steps should be taken to ensure uninterrupted supplies of reagents, diagnostics and consumables for blood services.

(i) GCBS participants requested that WHO more actively engage with the relevant agencies and organizations involved in procurement practices and contract development for essential reagents, diagnostics and consumables to establish effective mechanisms to ensure stable supplies.

(ii) GCBS participants proposed the development of an advocacy tool to address procurement practices and contract development in order to prevent interruptions to supplies of essential reagents, diagnostics and consumables.

(iii) GCBS participants requested WHO assistance to develop and disseminate appropriate specifications for critical reagents, diagnostics and consumables. ●

For more information, please go to:
<http://www.who.int/en/>.

BLOOD SAFETY

Pathogen Safety Steering Committee, Dr. Thomas Kreil (Baxter); Dr. Steve Petteway (Talecris), who previously chaired the Association's Pathogen Safety Steering Committee; Dr. Reiner Laske (CSL Behring), chair of PPTA's European Regulatory Affairs Steering Committee; Dr. Fabrizio Fabrizzi (Kedrion) from PPTA's Clinical Affairs Working Party, and PPTA President Jan M. Bult.

Each year, the GCBS comes together in the spirit of genuine collaboration to share experiences to help improve blood safety globally. For understandable reasons, the focus is usually on transfusion issues, but as countries become more economically advanced, many nations are considering how best to treat those people in their country that need plasma proteins. PPTA was delighted to host this workshop. We provided an informal opportunity for experts from the developing world to ask questions and discuss challenges they are facing. Positive responses from participants convinced us that we should plan something similar for the next GCBS meeting. ●



Dr. Reiner Laske

CONGRESSIONAL OUTLOOK FOR 2008

BY JAY GREISSING

A S THE SECOND SESSION OF THE 110TH CONGRESS BEGINS, many lawmakers are positioning themselves for successful reelection campaigns. Because 2008 is a presidential election year, the likelihood of passing any meaningful legislation becomes even more challenging on Capitol Hill.

Even a soothsayer would have difficulty predicting which, if any, healthcare issues will be able to gain momentum as Democrats attempt to lose the stigma of leading a “do-nothing Congress.”

According to *Real Clear Politics*, the approval rating of Congress now is lower than the current approval rating of President George W. Bush. Democrats will wrestle with whether to adopt the challenging strategy of obtaining bipartisan support for their initiatives in an election year, or the strategy of initiating “the blame game” with Republicans in anticipation of winning the White House and increasing their margin in the Senate. While it is unclear which overall strategy will prevail, the follow-on biologics debate is one significant healthcare initiative which is impacted by election-year politics in 2009. The poll numbers, however, will ultimately decide the fate of the majority of this year’s legislative action.

Currently, the House of Representatives is made up of 232 Democrats and 199 Republicans, with four seats currently vacant. In the Senate, there are 49 Democrats and 49 Republicans with two independents, Sens. Joe Lieberman (I-CT) and Bernie Sanders (I-VT), who caucus with the Democrats. While the margin in the House has afforded these lawmakers the ability to pass some meaningful, comprehensive legislation during the First Session of the 110th Congress, the margin in the Senate has proven to be a major hurdle, because of the filibuster and the inability to override Presidential vetoes. Given the ability to engage in political and procedural gamesmanship, the reauthorization of the State Children’s Health Insurance Program (SCHIP) nearly suffered the same fate as the comprehensive medical liability reform legislation that repeatedly died in both the 108th and the 109th Congresses.

Will the Margins Change?

The party that wins the Presidency in 2008 will very likely determine whether the margins in the two Houses of the legislative branch increase or decrease. For instance, the 2008 election could possibly shore up the current 33 seat deficit for House Republicans, if the Republican Party was able to hold onto the Presidency and if that candidate brings in other Republicans from districts around the United States. Conversely, the elections may cement another political landslide for the Democrats, if they can bring

their nominee into the White House. Interestingly, if Democrats take back the White House in 2008, maintain their substantial margin in the House, and significantly increase their margin in the Senate, it would be the “perfect storm” to set the table for a “smorgasbord” of Democrat-inspired legislative initiatives in 2009. As always, voter turnout will be one driving factor in the election outcome. If the recent primaries are any indication, particularly the South Carolina Democratic primary, the U.S. could see record voter turnout on election day.

One key question is whether Democrats will continue in a pattern of stong voter turnout and remain able to engage voters enough to return to the polls this year. While the presidential candidates from both parties attempt to position themselves as candidates of change in order to excite the American public, frontrunners are beginning to emerge from each party. The lack of frontrunners and the poor congressional approval ratings may signal that voters are once again, apathetic.

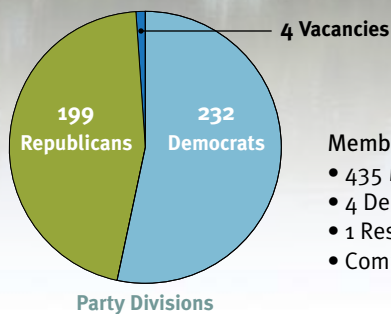
Retirements and scandals could also play a significant role in the 2008 election. For example, in 1994 Republicans were aided in their takeover of Congress by the fact that 20 Democrat incumbents retired, rather than seek reelection. Unless the seat is in a highly partisan district, an open seat in the House is more likely to switch parties than a race with an incumbent. Because of the staggeringly low congressional approval ratings, open races in a competitive district could very likely switch parties. Currently, 18 Members of the House, 16 of whom are Republicans, are retiring at the end of 2008. Five other House Members, including the entire New Mexico delegation, are running for the Senate. In addition to Sen. Pete Domenici’s (R-NM) seat, four other Senate Republicans are retiring. Further, although Senator Trent Lott (R-MS) recently retired, he has already been replaced by Roger Wicker (R-MS).

Elections to Push Most Legislation to 2009; Makes Way for More Hearings

As the campaign trails begin to heat up, presidential and congressional candidates will raise a plethora of healthcare issues, but it is likely that very little legislation will move until 2009. According to key staff from both the House and the Senate, the congressional



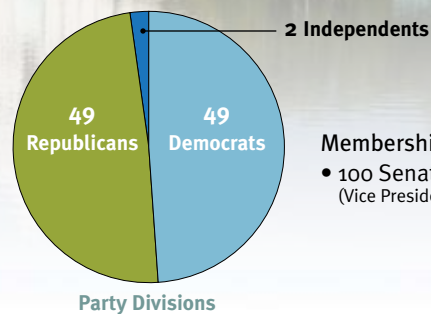
HOUSE



- Membership:**
- 435 Members
 - 4 Delegates
 - 1 Resident
 - Commissioner

Party Divisions

SENATE



- Membership:**
- 100 Senators
(Vice President votes in case of a tie)

Party Divisions

committees that oversee the Medicare and Medicaid programs will focus their attention on conducting hearings on the Medicare program for the purpose of examining its successes and how it can be improved. In addition to this oversight, exploring comprehensive Medicare reform strategies is a top priority for Senate Committee on Finance Chairman Max Baucus (D-MT). The prices of prescription drugs and the value of drug discount programs could be among the topics explored in the House of Representatives.

Additionally, the safety of prescription drugs will continue to be an issue in this election year. Lawmakers will continue efforts to protect consumers from counterfeit drugs and rogue Internet pharmacies. Although Congress passed legislation in September that directs the U.S. Food and Drug Administration (FDA) to develop “standards for the identification, validation, authentication, and tracking and tracing of prescription drugs” and, by March 29, 2010, “develop a standardized numerical identifier to be applied to the drug at the point of manufacturing and repackaging at the package or pallet level,” lawmakers are committed to continuing their pursuit of more comprehensive legislation—some of which would preempt state drug pedigree laws. As a result of the recent negative publicity surrounding professional baseball players, wrestlers, and football players purchasing copious amounts of steroids, human growth hormone, and additional hormone replacement therapies from Internet pharmacies without prescriptions, Congress also is determined to take the necessary steps to curb this epidemic.

A Physician Fix this Year Is Likely

Because physicians are scheduled to take a 10.6 percent pay cut from the Medicare program beginning on July 1, 2008 and an additional 6 percent cut beginning on January 1, 2009, Congress will likely be committed to moving at least one piece of health-care legislation during this election year. The vehicle for the phy-

sician fix is, however, uncertain. Although this legislation could move as a free standing bill, it could also be attached to a FY 2009 budget reconciliation bill or an economic stimulus package that currently is being drafted. Some congressional staffers have opined that the Senate Budget Committee will have difficulty producing a budget resolution, the absence of which does not allow for a reconciliation bill.

Federal Spending to Balloon

The Medicare Payment Advisory Committee recently recommended that Congress increase Medicare payments to physicians in 2009 by 1.1 percent. Such an increase will cost \$10 billion over the next five years. Recent reports also have suggested that the Senate Finance Committee is going to pursue an 18 month physician fix that would cost between \$12 and \$15 billion over the next five years. Regardless of which plan the committee adopts, it clearly must find significant budgetary offsets.

Owing to costs associated with the physician fix, healthcare legislation that would require additional expenditures, without an offset, will likely have very little chance of success this year. Such a landscape could make passage of H.R. 2914, the IVIG Medicare Access Act of 2007, very challenging. H.R. 2914, which is sponsored by Rep. Kevin Brady (R-TX), is an important piece of bipartisan legislation that will ensure Medicare beneficiary access to intravenous immunoglobulin. Rep. Brady currently has 35 co-sponsors on this bill. The Immune Deficiency Foundation has done an outstanding job leading Congressional advocacy on this important piece of patient access legislation

As the campaign season enters full swing, the predictions of the political pundits notwithstanding, critical issues will continue to affect the plasma protein therapeutics industry...some things will never change. ●

NEWS

PLASMA PROTEIN NEWS FROM AROUND THE GLOBE

› **The West Virginia Office of Pharmacy Services** sent a letter to PPTA agreeing with the Association's assertion that the West Virginia Medicaid program was inappropriately reimbursing alpha-1 proteinase inhibitors at the generic rate of AWP -30% instead of the brand rate of AWP -15%. The letter states that providers may "reverse and resubmit any claims paid in error for up to one year from date of service." This decision is a clear victory in furthering PPTA's objective of ensuring access to plasma protein therapies. It may also have value as PPTA addresses reimbursement issues in other states. The letter is available on PPTA's website at www.pptaglobal.org.

› The **European Medicines Agency** (EMA) has published the draft *Addendum on the Replacement of Rabbit Pyrogen Testing by an Alternative Test for Plasma Derived Medicinal Products* for consultation. The deadline for comments is June 30, 2008. The text will be an addendum to the *Note for Guidance on Plasma-Derived Medicinal Products*, which is currently under revision. The addendum also makes reference to alternative methods to Limulus amoebocyte lysate (LAL) testing such as Monocyte Activation Tests

(MAT), leaving more flexibility to manufacturers. The addendum has been developed in coordination with the European Pharmacopoeia expert group 6B. After many years of extensive lobbying by PPTA and its membership on this issue, the addendum represents a big step forward in the right direction.

› **The U.S. House of Representatives** overwhelmingly approved a \$5.3 billion Medicare reform package negotiated by the U.S. Senate at the end of the 2007 congressional session. Under the Senate compromise package, the scheduled 10.1% Medicare cut for physicians was staved off for another six months where they will now receive a 0.5% update through June 2008. Most notably, PPTA was successful in helping to thwart any budgetary offsets that would include an increase to the Medicaid Drug Rebate Program for drugs and biologicals, including plasma protein therapies. However, as the physician fee update will need to be revisited by Congress in the upcoming months, PPTA will remain diligent in its efforts to oppose any potential increase to the Medicaid Drug Rebate that lawmakers will look to use to pay for another physician fee update and/or other Medicare expansion programs.



› **In Germany**, an advisory board of the sick funds and the **Ministry on Health** has recently published its list of 80 diseases that should be considered specifically when discussing the internal sick fund cost transfers (depending on the different risk structure of the insurants between the compulsory sick funds). In the related press communication of the Ministry on Health, hemophilia was the first disease mentioned. Although—on the first view—this has no direct influence on any treatment reimbursement, it shows the importance of hemophilia-related costs to sick funds.

› The **U.S. Food and Drug Administration (FDA)** has announced that effective December 27, 2007 every human drug, biologic and device product application submitted to the agency must include a certification form in order to comply with the provisions of the Food and Drug Administration Amendments Act to 2007. The certification must indicate that all requirements of section 402(j) of the Public Health Service Act, as amended by the FDAAA of 2007 have been met. The certification should include, if applicable, the National Clinical Trial numbers. In addition, expanded information on clinical trials and their results must be submitted to the clinical trials data bank.

› The regulatory experts from the European Union and Canada will be able to exchange confidential information about the authorization and safety of medicines. Confidentiality arrangements were agreed upon between the **European Commission and the European Medicines Agency (EMA)** and the **Health Products and Food Branch of Health Canada** at a bilateral meeting in Brussels in December 2007. The partners will be able to exchange confidential information, for instance on safety issues with marketed medicines and therapeutic products being developed or considered for authorization.

› The **World Health Organization (WHO)** added subcutaneous immunoglobulin to the recently published *First Essential Medicines List for Children*, along with intravenous and intramuscular immunoglobulin

and coagulation factors. This success is due to the great commitment of **Dr. Helen Chapel** of the **International Union for Immunological Societies (IUIS)**.

› Manufacturers of plasma therapies met with the **United Kingdom's Purchasing and Supply Agency (PASA)** in the first of what is predicted to be a quarterly meeting to review the supply and availability of immunoglobulin following the introduction from July 1, 2007 of a new purchasing "framework agreement." The agreement was intended to ensure predictability of supply. After five months, Primary Care Trusts have actually ordered 15 percent less than they said they would in the framework agreement.

The associated introduction of new clinical guidelines has further restricted use in neurological and other indications. Believing some of the current discrepancies between predicted and actual ordering of immunoglobulin PASA has proposed extending the July 1, 2007 framework agreement. Some manufacturers expressed reservations about the new arrangements.

› In Japan, the government and plaintiffs in the **hepatitis C lawsuits** agreed on blanket relief measures for those infected by blood products. The plaintiffs and Health Minister Yoichi Masuzoe signed the deal on January 15, 2007. The government acknowledged its responsibility and offered compensation. The law covers persons who contracted hepatitis C after using fibrinogen and factor IX, regardless of when the drug was administered. The plaintiffs will receive compensation commensurate with their conditions and it will range from 40 million yen to 12 million yen.

› The FDA has issued a notice to inform companies that the **Direct-to-Consumer (DTC)** television advertisement user fee program will not commence because the necessary user fees for the program were not "provided in advance in appropriations Acts" as required by the FDAAA of 2007 and the previously issued notice establishing user fee rates for the program for fiscal year 2008 is being withdrawn.



› The **European Federation of Pharmaceutical Industries and Associations** published a report about a conference at the European Parliament. The report concluded that Europe needs a comprehensive health information strategy to enhance citizens' and patients' access to high-quality health and medicines information from a variety of sources. The Conference, which was co-hosted by the three European Parliament representatives in the EU High-Level Pharmaceutical Forum – Françoise Grossetête, Dagmar Roth-Behrendt and Jorgo Chatzimarkakis, brought together European decision-makers from all EU institutions, doctors, pharmacists, patients, regulators and more than 100 stakeholders with a variety of different backgrounds.

› The **European Commission's** ad hoc group for the development of implementing guidelines for **Directive 2001/20/EC** relating to good clinical practice in the conduct of clinical trials on medicinal products for human use, chaired by the Commission services, has adopted recommendations on various ethical aspects of clinical trials performed in children. These recommendations will contribute to the protection of children who are the subject of clinical trials. Furthermore, the recommendations are intended to facilitate a harmonized application of rules on clinical trials across the European Union and thereby facilitate the conduct of clinical trials in the EU.

› The **Alabama Medicaid Agency** has decided to adopt standards of care for management of hemophilia and a reimbursement mechanism that should help ensure access to therapies for residents of Alabama. Alabama's adoption of these regulations represents an important development for the bleeding disorders community and the goal of ensuring access to high quality care. PPTA believes that the activities that occurred surrounding this issue, including coalition building, open lines of communication with regulators, and achieving consensus on comments and messaging represent a valuable case study and precedent in addressing future reimbursement proposals in the states.

› PPTA staff provided a presentation at a recent lunch meeting organized by **Dr. Miroslav Mikolasik, Member of the European Parliament (MEP)**, at the European Parliament in Brussels, on "Plasma protein therapies in the treatment of rare diseases." The programme of the meeting also included a presentation by Mr. David Watters, International Patient Organization for Primary Immunodeficiencies (IPOPI) on behalf of the Plasma Protein Users Group (PPUG) an informal platform of plasma protein community stakeholders in Europe on "Living with plasma protein disorders," as well as a presentation by Mr. Antoni Montserrat, European Commission, on the upcoming European Commission Communication on Rare Diseases. Several MEPs as well as industry, patient and European Commission representatives attended the meeting. Amongst the conclusions of the meeting, it was agreed that EU actions should be initiated to encourage and improve diagnosis rates, access to plasma protein therapies and treatment levels which vary from country to country, awareness and education campaigns and the recognition of the unique nature of plasma protein therapies in national healthcare policies. ●

MY NAME IS LAURELLA GANEY. I am PPTA's Manager of Accounting. I will be celebrating my 10th anniversary this summer working for PPTA.

My responsibilities include overseeing the day-to-day financial transactions and the proper functioning of the Association's accounting processes. It includes maintaining the internal controls and supervising one accounting associate in the accounts receivable and accounts payable function. In my role, I oversee the billings of membership dues and several programs of PPTA including the National Donor Deferral Registry, International Quality Plasma Program, Quality Standards of Excellence, Assurance and Leadership, the Patient Notification System and data gathering, as well as the control of expenses incurred by the Association. My duties also include the full financial reporting of the Association's activities including the month-end closings and the reporting of variances. I ensure that all journal entries are properly recorded, reconciliations are completed in a timely fashion and that any issues or discrepancies are resolved. My work in the finance department provides budget support as well as sales and use tax support and tax filings. In addition, I also supervise the annual external financial audit of the Association and provide any necessary audit documentation, worksheets and reconciliations. My responsibility is primarily to ensure the accurate and timely processing, recording and presentation of the monthly and yearly financial statements of PPTA.

Tell us about your background.

I was born in the U.S., but my family is from Switzerland so I have dual citizenship. At a very young age, we moved to Basel, Switzerland where I attended primary school. German was the spoken language at home there. My father's career opportunities brought my family back to the Washington D.C. area where I found myself learning English all over again. In order to quickly learn the language, my parents, who both speak three languages fluently, spoke English to us at home. After high school, I attended the University of Maryland and obtained my Bachelor's of Science degree in accounting. I am also a Certified Public Accountant. After graduating college, I accepted a position as an internal auditor for Gannett Co. Inc. where I traveled significantly auditing the subsidiaries of Gannett, which included various newspapers, TV stations, radio stations and outdoor advertising sites. Traveling several weeks out of month for several years took a toll on me, so I transferred into the consolidation department there. After Gannett, I worked for Thomson CSE, Inc., a French defense electronics company and Atlantic Graphics Inc., a Komori offset printing press dealer. All positions were in the accounting field, which has ultimately led me to this position at PPTA.



I've been happily married for nearly 17 years. My husband, Steve, and I have two wonderful daughters Delena and Selia, ages 12 and seven. They keep me contentedly very busy in my free time with their "on the go" schedules between school activities and sports. When I'm not working in the office, I thoroughly enjoy volunteering for various activities and events at their schools.

What is your proudest professional achievement?

The accounting department is continuously changing as PPTA grows. The consolidation of two associations, the American Blood Resources Association (ABRA) and PPTA, presented interesting challenges in the financial reporting of the Association. The accounting department also underwent a full accounting software conversion a few years back, which I had managed to ensure a smooth transition. I'd have to say that my proudest professional achievement is keeping up with the challenges that these changes bring to the department in order to ensure the accurate and proper financial reporting of PPTA.

What is most rewarding about working in this industry?

Although I personally don't have direct contact with the patients that we as an Association and the members serve, it is rewarding to know that my fellow colleagues are helping patients in need of the life-saving therapies that our members produce. It is also gratifying to know that we are making a difference to secure access to therapies for all patients. ●

EVENTS

UPCOMING CONFERENCES & SYMPOSIUMS

2008

March 4-5	PPTA International Plasma Protein Congress 2008 <i>Warsaw, Poland</i>	June 19-22	13th International Congress on Infectious Diseases <i>Kuala Lumpur, Malaysia</i>
March 16-19	International Conference on Emerging Infectious Diseases (ICEID) <i>Atlanta, Georgia, USA</i>	September 6-9	32nd Annual Meeting, American Association of Tissue Banks <i>Chicago, USA</i>
March 18-21	28th International Symposium on Intensive Care and Emergency Medicine <i>Brussels, Belgium</i>	September 12-14	European Haemophilia Consortium (EHC) Annual Meeting <i>Dublin, Ireland</i>
April 7-9	48th Annual Scientific Meeting of the British Society of Hematology incorporating the 6th Bi-Annual-BFM Leukaemia Symposium <i>Glasgow, Scotland</i>	September 16-19	41st Annual Meeting of the German Society for Transfusion Medicine and Immune-hematology (DGTI) <i>Düsseldorf, Germany</i>
April 9-12	American Society for Apheresis 2008 Annual Meeting <i>Galveston, Texas, USA</i>	October 5	PPTA Source Business Forum <i>Montreal, Canada</i> PPTA Source Members only.
June 1-5	Hemophilia World Congress <i>Istanbul, Turkey</i>	October 4-7	AABB Annual Meeting and TXPO <i>Montreal, Canada</i>
June 7-12	XXX International Congress of the International Society of Blood Transfusion (ISBT) <i>Macao, China</i>	October 7-11	11th International Conference on Thalassemia and Haemoglobinopathies and 13th International Conference on Thalassemia for Patients and Parents <i>Singapore</i>
June 12-15	13th Congress of the European Hematology Association (EHA) <i>Copenhagen, Denmark</i>	October 16-19	XIIIth Meeting of the European Society for Immunodeficiencies (ESID) <i>'s-Hertogenbosch, The Netherlands</i>
June 17-18	PPTA Plasma Protein Forum 2008 <i>Washington, D.C., USA</i>		

2009

June 4-7	14th Congress of the European Hematology Association <i>Berlin, Germany</i>
October 24-27	AABB Annual Meeting <i>New Orleans, USA</i>

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You are cordially invited to attend the Plasma Protein Therapeutics Association's 2008 Plasma Protein Forum (PPF) at the Washington Marriott in Washington, D.C. Millions of people worldwide rely on plasma-derived and recombinant analog therapies to improve and save their lives. Consumers, physicians, caregivers, regulators and policymakers, and industry representatives strive to create a market that supports innovation, quality and access to plasma protein therapies. These groups will come together to discuss the key issues facing the industry today and in the future during the 2008 Forum.

The industry continues to be influenced by national and international dynamics. The 2008 PPF will address policies and regulations that impact consumers' access to life-saving therapies in thought-provoking and engaging sessions. Now, more than ever, the plasma protein therapeutics community must work together to assure patient access. This commitment to the community is steadfast and inspires new solutions to the challenges of today and tomorrow.

Highlights of the 2008 PPF include panel discussions on:

- U.S. Food and Drug Administration Amendments Act: Breaking It Down
- FDA's "Requirements for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use" Proposed Rule: An Overview
- Global Access to Care Initiatives: International Perspectives
- Plasma's Journey: From Human to Biologic
- PPTA Global Board of Directors: Vision of the Industry
- Primary Immunodeficiency Access Imperatives
- Securing the Future: Energizing New Leaders
- The Importance of Access to Care: Overcoming the Hurdles

Join us June 16-18, 2008 in our nation's capital! There is no better opportunity to meet and network with members of the plasma protein therapeutics industry. Pre-conference registration opens Monday, June 16, 2008 at 5:00 p.m. In addition, meet your colleagues at the "Registration Hospitality Suite," which will be open from 5:00 p.m. to 7:00 p.m. – there is no better place to meet, greet, and enjoy a refreshment. Register now and together let's continue to demonstrate our collective "Commitment to the Community!"

Julie A. Birkofer
Vice President
PPTA North America

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