

THE SOURCE

THE MAGAZINE OF THE PLASMA PROTEIN THERAPEUTICS INDUSTRY

Fall 2008

Leading Advancements in Life-Saving Therapies

Leaders Gather
in Washington, D.C.
for the Plasma
Protein Forum

Interview
with Val Bias:
New CEO of
the NHF

Dr. Shigeaki Nonoyama:
Working to Cure PIDD



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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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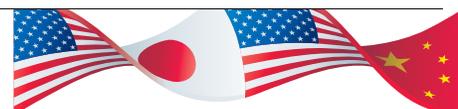
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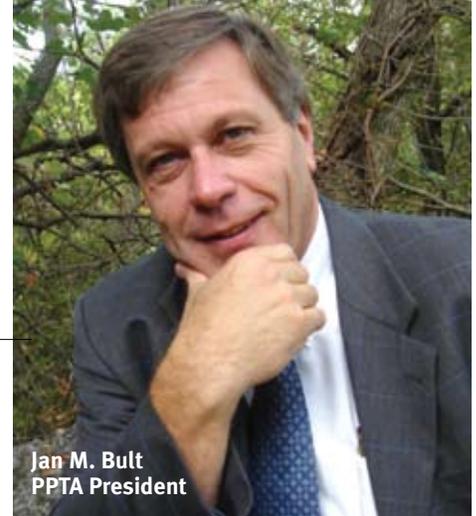


These companies have earned QSEAL certification. The PPTA QSEAL program is a promise to stakeholders worldwide, that the highest levels of care were invested into the production of these unique life-saving therapies.

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IN MY VIEW

LET'S LEVEL THE PLAYING FIELD, PART II



Jan M. Bult
PPTA President



IN THE LAST EDITION OF THE SOURCE (In My View, Summer 2008)

I wrote about the need for leveling the playing field. I used, as an example, the situation in The Netherlands where the organization Sanquin has a dual responsibility. Sanquin is responsible

for the collection of blood and distribution of blood components to the hospitals, while at the same time using recovered plasma (produced as a by-product of blood collection) for the manufacture of plasma protein therapies. The prices of blood components for transfusion in The Netherlands are more expensive than in the surrounding countries, giving rise to the thought that there is a (government supported) cross-subsidy which can be considered unfair competition. Government support is provided, because the Dutch Ministry of Health (DMOH) provides oversight of Sanquin and approves the budget.

Sanquin has responded to that article and in the spirit of transparency, Sanquin's reply is printed on pages 3-4.

I have known Dr. Paul Strengers as a well respected professional from the many international meetings he and I have attended. Therefore, I am surprised that nowhere in his response to my column is there any attempt to debate my main message. Rather than responding emotionally, I prefer to stick to the facts.

As mentioned before, Sanquin is responsible to the Dutch Ministry of Health (DMOH). Interestingly, two years ago the Australian authorities were reviewing their local fractionation arrangements. They welcomed input from different sources worldwide. The DMOH's submissions to the report (Review of Australia's Plasma Fractionation Arrangements) as well as the submissions from other sources are publicly available at the following website: [http://www.health.gov.au/internet/main/publishing.nsf/Content/8CE33B4219AF4C8CCA2572270005BE65/\\$File/32%20-%20The%20Netherlands.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/8CE33B4219AF4C8CCA2572270005BE65/$File/32%20-%20The%20Netherlands.pdf)

Here are quotes from the DMOH's recommendations:

"...Any introduction of competition would mean that the existing provider would have to examine its fixed costs. If the existing service loses part of the market, it may have to, for example:

- Close facilities or lower standards of staff conditions
- Contract out the testing entirely

I am sure that the Dutch Ministry does not suggest that this would apply to Sanquin if competition increases, but if the plasma used for fractionation would be available to all manufacturers in an open market situation, I am sure that a serious examination of fixed costs would be necessary!

Another quote from the DMOH:

"The full range of plasma products should be available without limitation for the patients. The determination of the appropriate therapy for the patient should only be made by the physician. Since plasma therapies are not always interchangeable, denying access to any therapy could endanger the patient's health."

I applaud the DMOH for this clear view and could only wish that the same approach would be taken by all countries. If there is a critical comment, than it can only be that some of our member companies would be able to produce more therapies out of the plasma because of the technology being used.

Last quote from the DMOH: *"Obtaining plasma products from a single provider could lead to considerable risks. The continuation of plasma products has to be guaranteed and plasma derivatives shortages should be prevented..."*

This statement is undeniably true. It underscores the importance of an open market which exists in The Netherlands. But why is it that the plasma collected in The Netherlands can only be provided to one organization and is not available on the open market? The best guarantee for stable supply is that plasma is available from all sources. In case a contract would be made, that contract would ensure that plasma from Dutch donors would be manufactured and returned to The Netherlands.

In summary, the costs for blood components in The Netherlands is important to all stakeholders because it directly influences the acquisition costs for plasma for fractionation. Because the DMOH has oversight of Sanquin and approved their budget, it is clear that these two activities are related. Also, directing the flow of plasma to one company produces a source monopoly. Sanquin is therefore operating in a "protected" area with sole access to plasma without full transparency of their acquisition costs. This is unfair competition and not what we expect in a level playing field. The therapies produced by Sanquin and the company itself have a good reputation among stakeholders. What is also required is transparency and fairness in business practices. ●



Response of Sanquin on the column of PPTA President, Mr. Jan M. Bult in "The Source" of summer 2008

Chalk dust

In his column in 'The Source' of summer 2008, PPTA President Jan M. Bult is emphasizing the need for a level playing field. He presents the organization for blood collection and manufacturing in The Netherlands, his home country, as an example where, in his view, the same rules do not apply for all.

It is an interesting article that shows that Jan is positioning himself quite high by criticizing strongly the Dutch Parliament that has approved the Dutch Law on Blood Supply which forms the basis of the Dutch structure of blood collection and manufacturing, and the Dutch Ministry of Health and Welfare that is supervising Sanquin in order to have Sanquin's operations in compliance with this Law. His paper is unfortunately sometimes incorrect and it should be clarified that CAF-DCF in Brussels is an independent Belgium organisation, owned by Sanquin, the Belgium Red Cross and LFB, and therefore it is also incorrect that the budget of CAF-DCF should need approval of the Dutch Ministry of Health and Parliament. Jan should know that since the year 1839, Belgium and The Netherlands are two different States.

Another misunderstanding in the paper of Jan is the fact that his indicator model is based on the assumption that the sales of IVIG should be able to carry all the cost of a liter of plasma. In The Netherlands and Belgium, recovered plasma from voluntary non-remunerated donors is used to produce a variety of products that together carry the cost of raw material and manufacturing. In this way, Sanquin can offer not only a safe supply but also manufacture plasma products at cost and subsequently offer the plasma products to the Dutch health care market. Besides, it should be noted that the price level mentioned by Jan is from contracts concluded some time ago during a period when competitors were offering IVIG in The Netherlands at exactly these sales prices or lower. Indeed, currently, such prices are low as compared with those in the US and elsewhere. Sanquin, however, in contrast to competitors, has not shifted its IVIG sales to those "high price regions" due to its commitment to supply its Dutch customers. Thus, the fact that the not-for-profit organization Sanquin has no shareholders expecting maximal dividends or shareholder value is an advantage for the health care system.

Sanquin contributes to the containment of the national health budget by offering its plasma products at relatively low prices and more importantly it is able to act according the European Blood Law in its efforts to reinforce confidence in the safety of the blood transfusion chain and to promote Community self-sufficiency through voluntary unpaid donations.

Sanquin Blood Supply
Foundation respects
the fundamental
principles of the
International
Red Cross. 



Since CAF and Sanquin are two different organizations, it is not wrong that Sanquin, located in the Netherlands, should not pay taxes for an organization in Belgium.

In summary, the article of Jan Bult reminds me of the tennis player John McEnroe who playing in a level field had long discussions with the umpire on whether the ball was in or out. His wrong views created hot debates, but it was in fact only chalk dust.

Dr. Paul Strengers
Medical Director
Sanquin Blood Supply Foundation
Division of Plasma Products

Amsterdam, July 1, 2008

Sanquin Blood Supply
Foundation respects
the fundamental
principles of the
International
Red Cross. 

PLASMA PROTEIN FORUM



Members of PPTA's Global Board of Directors discuss their vision of the industry. Pictured from left to right: Jan Bult, PPTA; Gregor Schulz, Biotest; Larry Guiheen, Baxter BioScience; Paul Rosenthal, PPTA Counsel; Wolfgang Marguerre, Octapharma; Peter Turner, CSL Behring; and Joel Abelson, Talecris Biotherapeutics.

BY KYM KILBOURNE

LEADERS GATHER IN WASHINGTON, D.C. FOR THE PLASMA PROTEIN FORUM

Plasma industry leaders gathered in Washington, D.C. for the annual Plasma Protein Forum in June. The event drew more than 300 representatives from member companies, government agencies, patient advocacy groups, physicians, consumers and policymakers. These attendees took part in the two-day meeting that featured panels on global access to care, regulatory requirements, plasma collection and fractionation, as well as perspectives from three consumers. The Forum ended with a unique opportunity for participants to hear from several members of PPTA's Global Board of Directors, who discussed their vision of the industry.

PPTA Global Board Chairman Larry Guiheen with Baxter BioScience opened the Forum with a discussion of the state of the industry, focusing on critical themes including access to care; reimbursement; self-sufficiency and its affect on care; breaking down trade barriers; and the importance of research and development.

Matt Stinger, a 25-year-old consumer from Pennsylvania with severe hemophilia A, offered a compelling presentation on the morning of the first day regarding the benefits that medical technology have made in his life. Stinger is an emergency room nurse at Children's Hospital of Philadelphia, where he is able to use his personal experience with hemophilia to relate to parents

LEADERS GATHER IN WASHINGTON, D.C. FOR THE



Gordon Naylor, CSL Behring; Ileana Carlsile, Biotest Pharmaceuticals Corporation; and Dr. Nathan Roth, Talecris Biotherapeutics discuss plasma's journey from collection to life-saving therapy.

Jacob Beal, a nine-year-old boy from Ohio with primary immunodeficiency disease (PIDD). Beal showed remarkable poise in explaining how he copes with PIDD and how he is working with the Jeffrey Modell Foundation to help raise awareness about the disease in his home state. He noted his luck in living close to a wonderful hospital and thanked everyone at the Forum for giving him the opportunity to remain healthy—including his doctor who was in attendance—and donors who contribute to the therapy he takes. Like a typical boy of his age, Beal talked about swimming and spending time with his family, including his older brother who



Nine-year-old Jacob Beal wowed attendees with his presentation about life with primary immuno deficiency disease.

and children with rare and serious diseases that he treats. Because of the advancements in therapies available to him, Stinger, who began his treatment with cryoprecipitate, now infuses himself three times a week with a recombinant factor therapy. Stinger explained that he and his family became advocates for the bleeding disorders community when he was diagnosed and have been involved with camps for children with serious, chronic diseases for years. Stinger said, "I knew it was my calling to give back to these kids," and expressed how much he enjoyed his work at the hospital. In closing, Stinger offered his thanks for medical advancements and to plasma donors who have made it possible for him to lead a "normal" life.

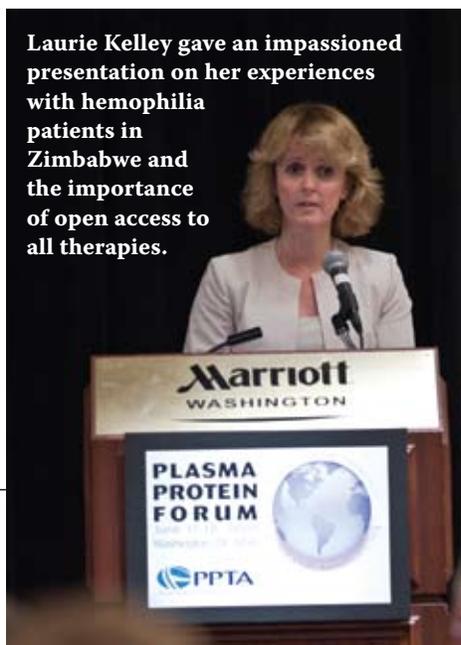
Another Forum highlight came from

holds his hand every time he receives his shot at home—saying, "I like staying at home, rather than going to a clinic for my shots."

Laurie Kelley, President of LA Kelley Communications, began her presentation on the importance of access with compelling video footage from a recent trip to Zimbabwe, a southern African nation embroiled in a humanitarian crisis, with tremendously high inflation, unemployment and poverty, and in which "healthcare has collapsed." The poignant footage of her visit underscored the needs of hemophilia patients in the country, where she met with individuals who shared their difficulty accessing therapies and treatment.

Kelley continued her presentation by stating that the greatest threat to the community is, "access to freedom of choice for product," highlighting

Laurie Kelley gave an impassioned presentation on her experiences with hemophilia patients in Zimbabwe and the importance of open access to all therapies.



PLASMA PROTEIN FORUM

treats to reimbursement and the complexities of the industry. Her discussion of practice of hiring Pharmacy Benefit Managers to control costs paints a “grim picture of healthcare in this country.”

On the regulatory front, a panel of U.S. Food and Drug Administration (FDA) experts broke down specifics of the 2007 Food and Drug Administration Amendments Act (FDAAA) and answered questions about how this legislation increased FDA’s

control over drugs once on the market and how the agency is implementing key provisions of the Act, including drug pedigree, track and trace methods and Radio-Frequency Identification (RFID). Addition-



Marcia Boyle, Chairman and CEO of the Immune Deficiency Foundation; Dr. Eveline Mauser-Bunschoten with the Van Creveldklinik Department of Hematology, University Medical Center Utrecht; and Laurie Kelley, LA Kelley Communications presented a panel on access to care.

process it undergoes from donation to a final therapy, the Forum ended with a first-of-its kind panel comprising several members of the PPTA Global Board of Directors. These leaders shared their perspectives regarding a number of



Pictured left to right are Catharine Beal (Jacob’s mother), Fred Modell, co-founder of the Jeffrey Modell Foundation, Jacob Beal and Julie Birkofer with PPTA.

ally, PPTA members in another Forum panel offered preliminary thinking with respect to the FDA Proposed Rule on Requirements for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use.

Gordon Naylor, with CSL Behring who is Chairman of the PPTA Source Board of Directors, opened the second day of the Forum, which also offered an entertaining and informative presentation about building awareness among young people with bleeding disorders from Shelly Mattson, a youth leader with the National Hemophilia Foundation who has von Willebrand Disease.

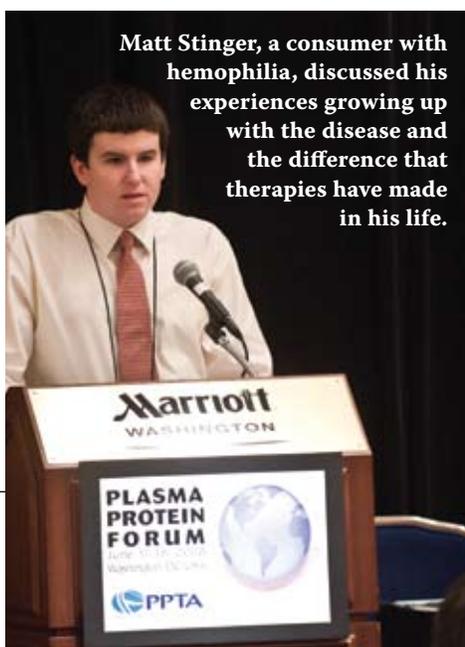
After presentations on overcoming hurdles to global access to care and a discussion of the importance and value of plasma and the complex

important issues facing the industry, including patient access, market trends, regulatory harmonization, intravenous immune globulin (IVIG) as a driver for plasma collection, and new indications and future therapies. The result was a lively and engaging presentation led by questions from PPTA

President Jan M. Bult that placed Forum attendees in the rare position to ask questions and hear first-hand from numerous company leaders.

Special thanks to all of the Forum exhibitors, sponsors and supporting organizations that helped make the meeting such a success. Save the date for next year’s Plasma Protein Forum in Washington, D.C. June 2-3, 2009. ●

KYM KILBOURNE is PPTA’s Manager of Communications



Matt Stinger, a consumer with hemophilia, discussed his experiences growing up with the disease and the difference that therapies have made in his life.

INDUSTRY IMAGE TOP OF MIND FOR SOURCE PLASMA COLLECTORS

BY KYM KILBOURNE

IMPROVING THE INDUSTRY'S IMAGE REMAINS A PRIORITY FOR PPTA SOURCE MEMBERS. Greater awareness of the need to continue work on image issues also was evident from the Source Board of Directors support of project funds to help improve public perception of the source plasma industry in the U.S., and discussion of extending the program to Europe.

It's a challenge to get our point of view across in media stories regarding plasma collection and the coverage the industry has seen lately is really an economic story rather than a story about plasma donation and life-saving therapies. Some media stories are more balanced than others and this underscores the need to engage with reporters to provide information about our industry and provide context for stories on plasma collection.

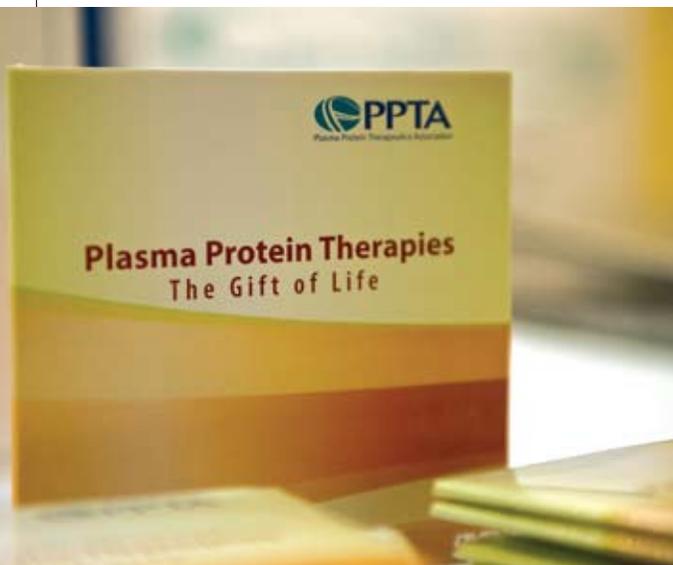
To address media inquiries, PPTA Communications staff, worked with Source and Regulatory staff to craft and share suggested media talking points that provided appropriate industry messages regarding plasma donation and the volume of donations over the last several years with members. It is important that members are consistent when it comes to information regarding the industry as a whole. These

talking points are one tool that is part of a "toolkit" of resources being developed by PPTA. Other resources include:

- A website dedicated to plasma donation that provides one-stop, credible information about the industry and guidance to current and potential donors. This site has already gone through review, but is now in the midst of a color "face lift." It is expected to launch in September.
- "Communicating Effectively with the Media" is a multimedia tutorial that will provide tips and tools on preparing for and conducting media interviews. Not intended to be full media training, it will provide member company staff and collection center employees with a short refresher before doing any press interviews.
- Plasma collection centers have the opportunity to now use the new PPTA DVD "The Gift of Life" in their centers to help educate donors and employees about the industry. The video tells the story of plasma protein therapies from donor, physician, patient and manufacturing perspectives to provide a full picture of the complex industry and highlight the value of donors in the production of life-saving therapies. Contact PPTA for information about obtaining copies of this new resource.

More projects are being explored such as establishing an awareness week or month, creating a community relations guide and PPTA's Communication staff will explore new products and projects moving forward. Look for more information in the *Source* as the Industry Image Campaign unfolds in the next several months. ●

KYM KILBOURNE is PPTA's Manager of Communications



"The Gift of Life" is available to members and stakeholders by contacting PPTA's communications department.

GBS/CIDP FOUNDATION INTERNATIONAL INTERNATIONAL LIAISONS' CONFERENCE 2008

BERLIN, GERMANY

BY EVAN R. ROTHMAN

BERLIN, THE CAPITAL CITY OF THE FEDERAL REPUBLIC OF GERMANY, is a thoroughly modern city embracing the many and varied cultures and peoples of Europe, and increasingly those of the rest of the world. With a population in excess of 3.5 million people, Berliners have made their city one of the world's most innovative through its "green" (environmental) policies. Berliners, simply put, have made it their business to help the world in any way they can.

It is fitting then that Estelle Benson, founder of the GBS/CIDP Foundation International, selected Berlin as the host city of its recent International Liaisons' Conference. Invited liaisons from the United States, Spain, Great Britain, The Netherlands, France, Belgium, Germany, Sweden, Romania, Turkey, Israel, India and South Africa descended on Berlin to discuss the various methods of developing GBS/CIDP Foundation International groups in their home countries, with the ultimate objectives of serving patients with Guillain-Barré Syndrome (GBS), Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) and its variants, with support, education and research.

Adding greatly to the significance of this conference was the attendance of PPTA, major medical companies and world-renowned medical doctors with a passion for GBS, CIDP and its variants.

Founded in the U.S. in Pennsylvania in 1980, the foundation has grown to enormous proportions with volunteers all around the world and more than 26,000 members. All members of this foundation have directly experienced GBS, CIDP or its variants, or have been indirectly affected.

The two-day conference proved a resounding success, with the newly formed GBS/CIDP Foundation International groups receiving

invaluable information, assistance and support that will enable them to provide more effective roles as liaisons in establishing support and care networks in their countries. This meeting also gave the invited delegates the opportunity to meet face-to-face, which will greatly improve future communication, support and cooperation.

Creating support groups helps patients overcome the debilitating effects of their illnesses. The volunteers who devote of their time, energies and resources bring hope, friendship and care to the patients. With a greater enthusiasm, these international liaisons will use their newly acquired skills to dynamically enhance the effectiveness and reach of the support groups in their countries.

Having personally been afflicted with Guillain-Barré Syndrome, I vowed that no other patient would experience these illnesses alone and so went about establishing a GBS/CIDP support group in South Africa. It is with this same energy and enthusiasm that every GBS/CIDP Foundation International group has been created! With this in our hearts the GBS/CIDP Foundation International groups in each of our countries are without a doubt richer and greater. ●

EVAN R. ROTHMAN is the founder of the GBS/CIDP chapter in South Africa.

Delegates at the GBS/CIDP Foundation International Liaisons' Conference in Berlin





INTERVIEW WITH VAL BIAS

NEW CEO OF THE NATIONAL HEMOPHILIA FOUNDATION

BY KYM KILBOURNE

Having devoted the past 28 years to serving the bleeding and clotting disorders community, Val Bias now takes on a new position as the National Hemophilia Foundation's (NHF) Chief Executive Officer. Learn first-hand his plans for NHF and his agenda for the year ahead.

What led you to become so involved in advocating for the bleeding disorders community?

In the late 1980s, I participated in a focus group hosted by the National Hemophilia Foundation (NHF); the focus was for men living with HIV. At that focus group, I met some of the future leaders of the bleeding disorder community: gentlemen like Don Colburn (Mass.), Dana Kuhn (Va.) and Rich Davis (Wash.). Later, we were asked to participate in a planning group for a national men's program which became the Men's Advocacy Network of the NHF (MANN). Although NHF had supported the need for such a group by creating the Women's Outreach Network of NHF (WONN) one year before the start of MANN, the men wanted more than support—they wanted acknowledgement of what had happened related to their HIV infection.

How have your other positions prior to this prepared you for your new role as CEO for NHF?

NHF is a complex organization with 48 members in our chapter structure, and we collaborate and advocate for 148 Hemophilia Treatment Centers (HTC) across the United States. I have served NHF as Chairman of the Board in 1992-1994—there I learned the structure of the organization. In 1994, I was sent to Washington to advocate for compensation for the HIV infected. We succeeded with the passage of the Ricky Ray Hemophilia Relief Act, which ultimately provided \$100,000 to each

infected person or remaining family member. In Washington, I learned about the National Institutes of Health and other agencies that work with and on behalf of the bleeding disorder community; including the National Heart, Lung, and Blood Institute (NHLBI), Centers for Disease Control and Prevention (CDC), Maternal and Child Health Bureau (MCHB), U.S. Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS). Those agencies are essential to research, prevention, clinical care, licensure and regulation, and reimbursement. I also met and worked with the Congressional offices that have traditionally understood and supported hemophilia.

Upon the successful passage of the Ricky Ray Hemophilia Relief Fund Act in 1998, I left Washington, D.C., and returned home to San Francisco. I continued my volunteer work with NHF through my role as Co-Chair of the Blood Safety Working Group. Shortly after my return to the Bay Area, I became President of the Hemophilia Foundation of Northern California, and was instrumental in rebuilding what had become a dormant organization.

During the entire span of my career in hemophilia, I have volunteered at Camp Emotion, a residential summer camp for children with bleeding disorders and known carriers. I have also volunteered or worked at every level of the organization and community, and have a steadfast commitment to service. That dedication has always been bolstered by my experience with the kids and young people in the community.

I will be proposing a collaborative working relationship with PPTA and its members with state advocacy representatives to form a coalition with an agenda to address key state issues nationwide.

Summarize your priorities as the new CEO of the National Hemophilia Foundation.

NHF and the bleeding disorder community face a serious challenge to their standard of care. With reimbursement decisions being made at the state level, hemophilia is being targeted for cost reduction and formulary limitations. With large insurers and Pharmacy Benefit Managers (PBM) moving into hemophilia care, this change is eroding the care provided by Hemophilia Treatment Centers (HTC) and the specialty care pharmacies that serve the community. I believe the bleeding disorders community is at risk of having access to their HTCs limited, and the full array of clotting factors made unavailable to them as an effect of these cost containment measures.

In order to address this and other health care issues, I intend to strengthen our chapter network through the chapter reorganization. NHF has embarked on a collaborative effort to support our chapter network by providing more direct support for staffing, equipment, technical support and training for both chapter staff and volunteers. The stronger the chapter network, the better our ability to address access to care, access to products, and adequate reimbursement in each state.

The reorganization has already succeeded in working with chapters to agree on a set of standards that will ensure similar services and support at the chapter level for each local community. I feel it is an initial step in building a stronger, better-supported, better trained chapter network. Similar services, however, does not mean a cookie-cutter approach to chapters, but rather, valuing current achievements and diversity among our local organizations.

We will renew and strengthen our relationships with the Washington, D.C. agencies who have traditionally worked with the bleeding disorders community. Already, we have worked with Sen. Byron Dorgan (S. 2706) to introduce a lifetime caps bill, which will raise the limit to \$5 million the first two years, and then \$10 million in years three and four with a cost of living increase in the future. Rep. Anna Eshoo (D-Calif.) along with Reps. Betty Sutton (D-Ohio), Jason Altmire (D-Penn.) and James Langevin (D-R.I.) have introduced H.R. 6528 a companion bill in the House.

We have already met with the FDA, and plan meetings with the other agencies while embarking on never before meetings with large insurers and PBMs to discuss appropriate and cost-effective care for people with bleeding disorders.

We will double our efforts in our role to protect the nation's blood supply for our community and all Americans.

What do you hope to accomplish during your tenure?

I hope to build the NHF into what we have dreamed about; a

responsive, service-oriented national organization that provides the leadership to achieve our collective goals as a community. I believe the bleeding disorders community must measure its progress on successful collaborations between those stakeholders, which will contribute to maintaining and increasing the standard of care. Those stakeholders include individuals living with bleeding disorders and their families, the physicians and clinicians, the government agencies that support, provide funding and lead research, and the industry that makes the products we are all dependant on for treatment of these disorders.

I want NHF to provide leadership for everyone who supports patients and our standard of care. For me, that does not mean control, but support through advocacy, research and education. Leadership is not ownership, but rather the ability to build consensus for a common goal.

With the appropriate leadership from NHF, it is my hope that the bleeding disorders community should be the hallmark for the treatment of chronic disorders—a shining example of how best to meet the needs of a diverse community. We should be supporting and increasing the quality of care from our clinicians while working with governmental agencies and industry partners to create even more effective products for the patients we all serve.

What are the NHF's legislative priorities in 2009?

As you know, lifetime insurance caps have long presented a challenge for people with hemophilia and other bleeding and clotting disorders. With annual costs for some consumers at \$200,000, \$300,000 and more, a \$1 or \$2 million dollar cap just doesn't last very long.

During NHF's Washington Days 2008, with the help of members of our Minnesota and the Dakotas Chapter, Senator Byron Dorgan of North Dakota introduced S. 2706, the Health Insurance Coverage Protection Act, which will ultimately raise all lifetime caps to a minimum of \$10 million, and then continue to provide increases based on inflation. Although our ultimate goal is to eliminate caps, this would be a huge step in the right direction. Right now, we're creating a lot of awareness on this issue, including significant media coverage. By the time this story appears, the House version of the bill will likely have been introduced. Moving this important piece of legislation forward will be the centerpiece of our federal efforts in 2009. We appreciate the support we have received on this effort from our allies in industry including PPTA, and we look forward to continuing to working closely with you as the effort goes forward.

Of course, this is an election year, and there are a lot of important things that will remain unknown until November, including who our next President will be. Our goal is to help keep healthcare

As I said before, we have some challenges to our standard of care and how we respond will determine the next five years for the community.

reform on the front burner, not only leading up to the election, but after newly elected officials at every level take office. In particular, we need to drive home the message that healthcare reform must meet the needs of all Americans, and that includes folks living with high-cost, chronic conditions.

Finally, we know that no matter what happens in the fall, a lot of what impacts access to care will still happen at the state level, so we need to pay a lot of attention to what's happening not only in state legislatures, but also at the agency levels where rules are often made. For these efforts, we rely heavily on our chapters who are on the front lines in the state, and we appreciate as well the information and other resources PPTA and our other industry allies bring to the table. Certainly, we would like to see more legislative ad-

vances on things like standards of care. At the same time, we know this will be a difficult year economically for many states, and we need to establish agendas that are realistic and take the economy into full consideration. What cannot be accomplished in some places through legislation might be achieved through negotiation. In other places, it may be all we can do to hold on to what we have. The important thing is that the entire community works together on a united front, speaking with one voice to ensure that our access to quality care is never taken away.

How do you see the needs of individuals with hemophilia changing over the next five years?

As I said before, we have some challenges to our standard of care and how we respond will determine the next five years for the community. People will need more support around insurance issues and access. That means chapter and HTC's collaborating with each to support access to dental care internists for needs other than their bleeding disorder. Adequate reimbursement has always been a challenge for access to physicians outside of the HTC treatment team.

For the first time in the history of this community we are facing geriatric care for people with bleeding disorders, a generation who will live a longer life filled with the complications of older age. We will need to focus on what happens when a person with a bleeding disorder enters long-term care in a nursing home environment.

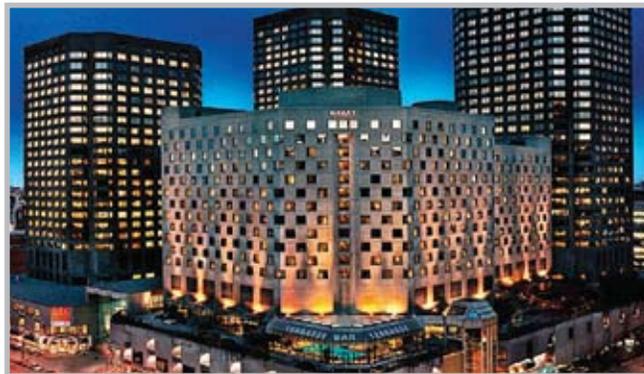
How do you believe it is best to work with industry in order to achieve common goals such as open access to all plasma protein therapies?

I believe we must strengthen that relationship as it relates to advocacy. The community should provide the leadership to ensure reimbursement and work with the industry to inspire the development of new products.

We must look to the future where there are recombinant products for von Willebrand Disease and new treatments developed for rare coagulation disorders. I believe if we don't come together on many levels, states won't pay for the fourth generation products.

I will be proposing a collaborative working relationship with PPTA and its members with state advocacy representatives to form a coalition with an agenda to address key state issues nationwide. We need to collaborate with a comprehensive agenda with solid deliverables that will allow us to protect access to care and products while maintaining adequate reimbursement. During the development of a stronger chapter network, this collaboration only makes sense to address current challenges. Perhaps through a more focused and deliberate agenda we can maintain the current standard of care for people with bleeding disorders across America. ●

KYM KILBOURNE is PPTA's Manager of Communications



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AGENDA

TUESDAY 3 MARCH 2009

Session 1: Keynote Session

- State of the Industry
- Role of the reference centers in the treatment of PID
- The precautionary principle and plasma proteins: a new approach

Session 2: Regulatory Affairs - what's up in Europe?

- Paediatric Regulatory Framework in the EU: Relevance to plasma protein therapies
- Revision of 269/95 - what has changed
- New Variations Regulations
- Counterfeit medicines - Think locally, act globally

Session 3: Rare diseases - a European Health Priority?

- European Commission actions in the field of rare diseases
- The rare diseases community priorities
- Rare diseases: the European Parliament's viewpoint
- Plasma related patient organizations
- Overview of member states public health policies for rare diseases

Session 4: Developments in the clinical use of plasma proteins

- A new perspective on the therapeutic use of albumin
- Underdiagnosis: the real cost of PID
- The role of EAHAD
- Neurological use of Ig review

WEDNESDAY 4 MARCH 2009

Session 5: Meeting clinical needs - various perspectives on how much plasma do we need

- Patient
- Physician
- European Commission
- Ethicist
- Plasma demand in 2015

Session 6: Getting the plasma we need

- Plasma collection in Eastern Europe?
- Donor compensation in the German Donation System
- Optimizing the quality of plasma
- Opening new plasma centers

Session 7: Closing session

DR. JERRY HOLMBERG

INTERVIEW

THE FIRST MEETING OF THE ADVISORY COMMITTEE on Blood Safety and Availability (ACBSA) was called to order April 24-25, 1997 by the acting executive secretary, Dr. Paul McCurdy (National Institutes of Health). Dr. Arthur Caplan, a bioethicist from the University of Pennsylvania chaired the Committee from 1997-2001. During his opening remarks, Dr. Caplan reviewed the mission of the ACBSA and commented on the important role each of the 18 members were called to serve. From the beginning, the ACBSA has been recognized for its diverse composition. The roster includes individuals with expertise in specific areas such as: bioethics experts, industry, public health law, health educators, transfusion medicine and hematology as well as consumer representatives.

The purpose of the ACBSA is essentially to provide a perspective from outside of government and to provide advice to the Secretary and to the Assistant Secretary for Health on issues ranging from blood and blood product safety and availability and supply. A July 1993 Institute of Medicine Report (IOM) commissioned by the U.S. Department of Human and Health Services (HHS) Secretary Donna Shalala focusing on the “rise of AIDS in the early 1980s and the infection of a large portion of patients with hemophilia by HIV contaminated clotting factor concentrates” was the impetus for the formation of the ACBSA. A key component of Secretary Shalala’s request was not only to look at the facts, but also the decision-making process and the coordination of blood safety activities within the government and in the government’s relationship to the other organizations that are involved with blood products. The hope of this review was to minimize the risk of any similar tragedy in the future.

Highlights from that first agenda included: “Hepatitis C and Blood Transfusion and whether the Committee should recommend a Hepatitis C “lookback”

to identify people who previously received blood from donors who now test positive for Hepatitis C.” Interestingly, PPTA’s Vice President of Global Regulatory Policy, Mary Gustafson participated in that first meeting as the FDA representative

providing the Committee with the statutory basis for the regulation of blood and blood products. Currently, Julie A. Birkofer, PPTA’s Vice President, North America serves as a voting member of the Committee. As one of six seats designated for “representatives of the blood and blood products industry or professional organizations,” PPTA has had representation on the Committee since 2003.

Dr. Caplan put forth two conditions on opening day: One was that if we were going to wrestle with fairly clear-cut issues like the ones in our agenda, that we would be able to “meet more than once” and secondly, that we “have a little bit of staff support.” I think that a little over ten year’s and over 30 meetings later, Dr. Caplan would be pleased that under guidance from Jerry Holmberg, Ph.D., the current executive secretary, the Committee is on a firm course.

Dr. Jerry Holmberg has more than 30 years in all areas of laboratory medicine, but most specifically in blood bank operations and policies. Prior to his military career, he taught senior level medical technology and pathology courses at Michigan State University and Bowling Green State University. Between 1980 and 2000, Dr. Holmberg served in the U.S. Navy, achieving the rank of Commander. During that period, he held various positions directing blood banks, blood donor centers, frozen blood bank depots, and programs affiliated with the U.S. Navy and U.S. Department of Defense. In 2003, the U.S. Department of Health and Human Services Secretary Tommy G. Thompson announced his appointment as Senior Advisor for Blood Policy and the Executive Secretary for the Advisory Committee on Blood Safety and Availability. He continues to hold that position, where he makes recommendations to the Secretary and the Assistant Secretary for Health regarding blood and blood products. Dr. Holmberg received his Ph.D. in Biological Sciences from Bowling Green State University.

What is the role of the ACBSA within the HHS?

The Advisory Committee plays an important role to the HHS as a body that provides advice and consultation on policy recommendations to the Secretary. The scope of this charge is broad and includes (1) the definition of public health parameters around safety and availability of the blood and blood products, (2) public health, ethical and legal issues related to transfusion and transplantation safety, and (3) the implications for safety and avail-



Jerry Holmberg participates in a PPTA panel discussion.

HHS ADVISORY COMMITTEE: A DECADE OF SERVICE



ability of various economic factors affecting product cost and supply.

This Committee is unique in the sense that it not only deals with science but also the sociologic, ethical, economic and legal issues that affect transfusion and transplantation safety. Experts in these areas are often requested to address the Committee to provide an understanding of the various views. Risk versus benefit and cost versus benefit are often parameters weighed into advice and recommendations to the Secretary by the Committee.

Advice and recommendations are taken very seriously, however, as with any advice the recommendations may be recognized but not implemented by the Secretary. The ACBSA has been very effective in its recommendations and since 2000 the Department has taken over 100 actions on these recommendations.

The ACBSA is chartered for two years and must be reevaluated by the Secretary for its effectiveness to continue. It is regulated under the Federal Advisory Committee Act (FACA) with annual reports. The activities of the ACBSA must be transparent and reports are available either on the Committee's web site or on the FACA web site.

Can you describe a few policy areas where you feel the ACBSA has played a pivotal role and had a high impact?

One of the most notable policy areas that was based on an early recommendation of the Advisory Committee is Hepatitis C (HCV) Lookback. Once either a donor or potentially implicated recipient is diagnosed with HCV, the tracking of products either backwards from the recipient to the donor or from the donor to the recipient is required. Although it has taken over a decade to fully implement, both the U.S. Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) have final rules on HCV Lookback. These final rules took years of coordinating language between the Secretary's two operating divisions (CMS and FDA).

The ACBSA has also had a great impact on the availability of intravenous immune globulin (IVIG) for those patients with warranted clinical indications. The recommendations to the Secretary have resulted in thousands of hours of internal review and formal reports to the Secretary. Collaboration with various public health operating divisions and CMS has led to a better understanding of factors influencing availability and access to IVIG. Although IVIG access has not been completely resolved in all cases, reimbursement for IVIG and associated services has been improved through CMS' understanding of the issues identified in the ACBSA recommendations.

What issues do you believe will be addressed at upcoming ACBSA meetings?

It is difficult to look into the crystal ball and determine the issues that the ACBSA will be asked to address in the future by either the Secretary or the Assistant Secretary since the current administration will be changing in the next five months.

The Charter directs the functioning of the ACBSA and it is safe to say that the Advisory Committee will be asked questions involving transfusion and transplantation safety as it is influenced by economics, ethics, social, and legal issues to affect public health. Over the last few years, the Advisory Committee has put forth a strategic plan for the future and the shaping of that strategic plan must be aligned to the Office of Public Health and Science's strategic plan and also that of the Secretary. It is clear that strategic planning for transfusion and transplantation safety must be integrated into the Healthy People 2020 initiative in order to measure long-term outcomes.

Biovigilance, which is the diligent surveillance of adverse events of biological products, will be of major concern over the years to come. These biological products are not just whole blood-derived components, but also plasma fractionated components as well as organs and tissues. Anything that potentially could cause adverse events in those patients who rely on these products needs to be in the cross hairs of the HHS. We have learned much from the HIV and HCV tragedies of the last century and we need to be vigilant in the future.

Many patient advocacy groups would probably like the Advisory Committee to address more reimbursement issues, but this is the responsibility of the Centers for Medicare and Medicaid Services (CMS). While the Assistant Secretary for Health can weigh in on availability of products, the CMS Administrator is responsible under the Medicare Modernization Act to calculate reimbursement in prescribed methodologies. The ASH and the Office of Public Health and Science will continue to provide advice to CMS as requested in understanding issues affecting availability and safety.

How do you perceive the value of consumer input into and participation on the Advisory Committee?

The patient communities are the most important people we serve. They are the Americans that need the voice the most and their safety is the reason we strive to reduce the risk so that they can enjoy the benefit. Other consumers such as providers and insurers are also of great value to the ACBSA in order to obtain the product and provide benefit to the patient; however, the patient-focused, evidence-based decisions are the primary objectives. While the ACBSA does have patient groups and consumer representatives, the scientific members need to hear from the user community in order to hear a different perspective and see a face with the policy being discussed ●

JULIE A. BIRKOFER is PPTA's vice president, North America

HEREDITARY ANGIOEDEMA

RARE GENETIC DISORDER GAINS NOTICE

BY MARY GUSTAFSON

HEREDITARY ANGIOEDEMA (HAE) is a rare disease that affects one in 10,000 to 50,000 people. It is inherited in an autosomal dominant manner, meaning that one-half of the offspring of an affected person will have some form of the disease. People with HAE generally begin having symptoms of the disease in adolescence. The disease is disfiguring, debilitating and life-threatening. It is characterized by severe swelling of the extremities, face, trunk, bowel wall and upper airway. There are two types of the inherited disease. In the first, HAE type I (which occurs in up to 85 percent of patients), there is a deficiency or an abnormally low amount of a plasma protein called C1 inhibitor. In the second type, HAE type II, the circulating C1 inhibitor amount is normal or even high, but it does not function as the normal protein. It is important that a person has enough of the normal protein, which is made in the liver, because this protein works to regulate certain biochemical processes in the body.

Without the normal C1 inhibitor, a sequence of events occurs within the body that results in leakage of fluid from blood vessels. This leakage of fluids results

Abdominal attacks can mimic other conditions and undiagnosed patients may undergo unnecessary abdominal surgeries. Alternatively, diagnosed patients may have necessary surgeries, such as appendectomies, delayed because the pain and swelling may be attributed to the HAE.

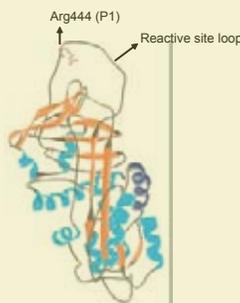
C1 inhibitor is a plasma protein that can be harvested from donated human plasma. A therapy made in some countries from human plasma has been available in Europe for more than 35 years and is the standard of care. The concentrated plasma protein therapy is used to provide normal C1 inhibitor to a patient that either lacks the plasma protein or has an abnormal plasma protein. There are numerous reports in literature describing the value of giving C1 inhibitor to patients having acute attacks and also in providing short-term prophylactic or preventative treatment. To date, this specific therapy has not been available for the 3,500 diagnosed patients in the U.S., except for investigational use. Other less specific treatments are used but with limited results, and some cannot be used on certain patients because of undesirable side effects. Some of those treatments include giving antihistamines during an acute attack, although these are of limited benefit. Treatment can also be given using attenuated androgens, which are derivatives of normal sex hormones, although these hormones are poorly tolerated in women and cannot be used in children. In addition, another treatment is short-term prophylaxis with Fresh Frozen Plasma (FFP), which is human plasma that contains other proteins and excessive fluid

Plasma protein companies are testing specific C1 inhibitor concentrates in the U.S. in order to license a therapy for use in the U.S. One such therapy was discussed at the U.S. Food and Drug Administration's (FDA) Blood Products Advisory Committee (BPAC) meeting in June 2008. At that meeting, several people with HAE provided testimony on their experiences living with the disease, their current treatment options and the need for the specific plasma protein concentrate therapy. The BPAC overwhelmingly recommended that the therapy be licensed in order to be available for patients in the U.S. While the FDA is not compelled to accept the recommendation of its advisory committees, an advisory committee's endorsement usually is accepted by the FDA. ●

MARY GUSTAFSON is PPTA's vice president, Global Regulatory Policy

C1 Esterase Inhibitor

- Serine protease inhibitor (i.e. Serpin)
- Plasma concentration (~180 µg/ml)
- 478 aa, 105 kD (SDS-PAGE)
- ~30-50% glycosylated
- Serpin domain contains a reactive site loop (RSL), 3 β-sheets, and 9 α-helices



Bos I.G.A et al, Immunobiology (2002)

in massive local uncontrolled swelling. If left untreated, HAE attacks can last up to a week or more and can be life threatening. Specifically, severe upper airway attacks lead to airway obstruction and death by asphyxiation.

It is not always known what triggers an attack. Trauma, including surgery and dental procedures, sickness, anxiety and stress have been shown to be associated with attacks.

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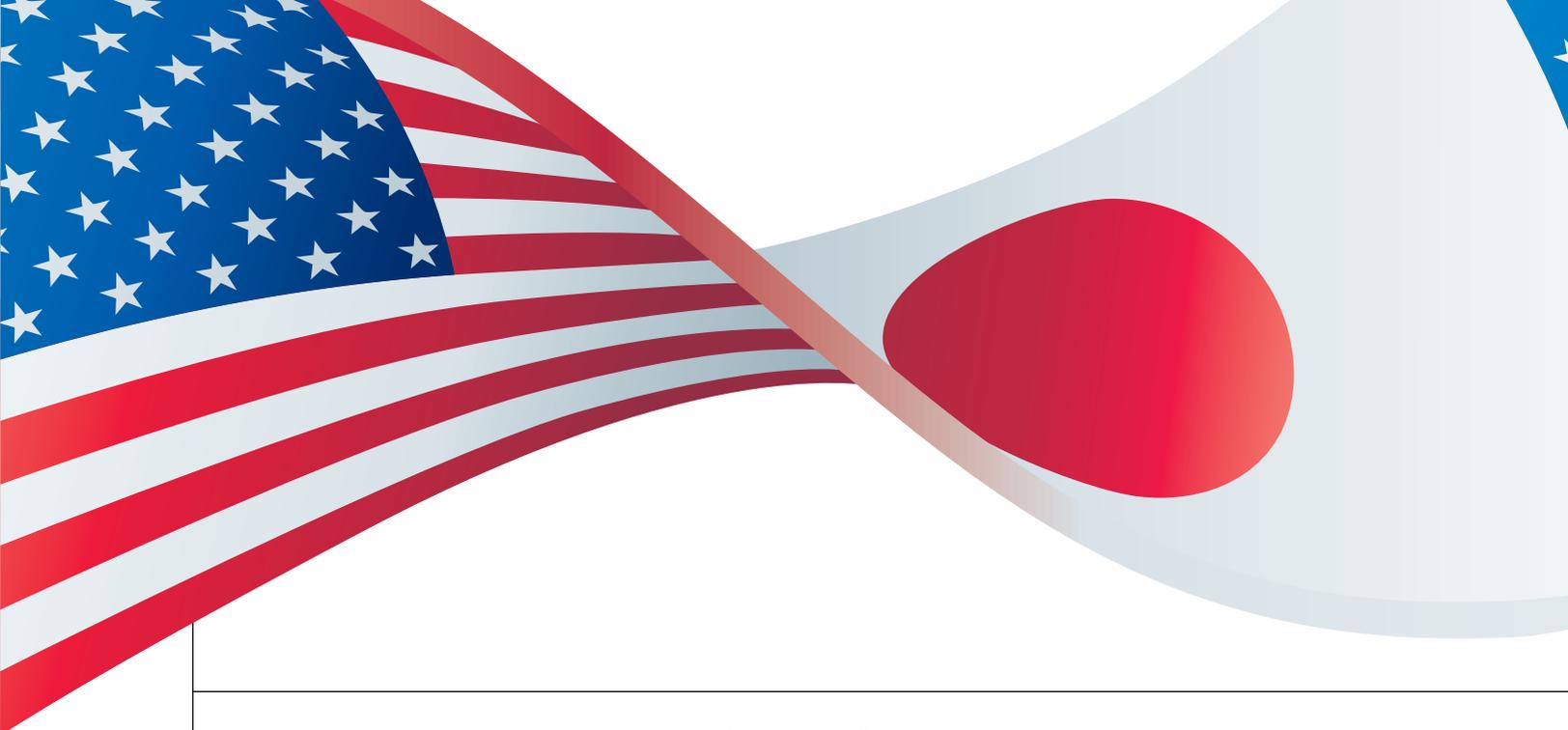
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BY JOSHUA PENROD

PPTA SOURCE UPDATE

JAPAN

AT THE PLASMA PROTEIN FORUM, a U.S. Department of Commerce representative outlined several important points with regard to access to the Japanese markets for plasma protein therapies. The policies of the government of Japan and the dynamics of the society make for complex negotiations.

First, there is recognition that the population of Japan is aging and decreasing. It is expected that in a few years, one quarter of the Japanese population will be older than 65, which increases health care costs, but, with less people in the workforce, there is reduced tax revenue. Combined with this are several trade-restrictive measures for blood and plasma products: a policy of self-sufficiency, a reimbursement system that does not recognize the unique nature of plasma therapies, and requirements for discriminatory labeling.

PPTA is working with trade authorities in both the United States and Europe on these issues. For example, the U.S. Department of Commerce, through a number of its organizational divisions, has engaged the Japanese authorities through a variety of means, including sector-specific negotiations and the U.S.-Japan Regulatory Reform Initiative. The U.S. government continues to issue current recommendations for increased trade liberalization for plasma products, culminating in its annual report to the leaders. The U.S. Department of Commerce routinely contacts PPTA to provide input on the next phase of negotiations. PPTA will work with the U.S. Department of Commerce to expand its range and scope of requests by the industry to the Japanese authorities.

JOSHUA PENROD is PPTA's vice president of Source.



ON JAPAN AND CHINA

CHINA

PPTA IS ALSO WORKING WITH SEVERAL DIFFERENT PARTIES to acquire better market access in China.

The main difficulty with the Chinese importation structure is Article 49 of the pharmaceutical law, which bans products made from plasma collected outside of China, with the exception of albumin.

There is growing recognition that China is experiencing a number of difficulties with its policy. First, China has significant public health issues associated with infectious diseases. Given the new era in China of more freedom of movement, largely from rural to urban areas, it has grown increasingly difficult for public health authorities to maintain control over the spread of infectious disease. Secondly, with the increasing prosperity and openness of information in Chinese society, Chinese patients are expecting more and better choices of products for treatment.

PPTA is planning a workshop in China in November, to be held in Beijing. Planned discussions include several regulatory, technical, standards, and manufacturing issues that demonstrate PPTA member companies' commitment to product quality and patient safety. In addition to this, PPTA is working with other entities, such as the Safe Blood for China Foundation, to ensure a broad and diverse range of policy directions for purposes of the upcoming workshop.

The U.S. Department of Commerce and U.S. Trade Representative have also had recent discussions with Chinese authorities. The discussions included the disclosure of the U.S. government's grave concern with the continuation of Article 49, and possible routes forward to the creation of a more trade-friendly environment for non-Chinese plasma products. It is expected that these negotiations will continue, on a parallel track with the development of the PPTA workshop in November. ●

DR. SHIGEAKI NONOYAMA

WORKING TO CURE PIDD AND IMPROVE QUALITY OF LIFE FOR PATIENTS

BY KARA FLYNN

DR. SHIGEAKI NONOYAMA OF THE DEPARTMENT OF PEDIATRICS at the National Defense Medical College in Saitama, Japan, recognized his calling fairly early when he was a resident in hematology at the Tokyo Medical and Dental University. During that time, he saw many patients and became interested in how the immune system is reconstituted following stem cell transplantation. This led him to his life's work, conducting critical clinical research in the treatment of patients with primary immunodeficiency disease (PIDD), which he has conducted for the past 23 years.

Although the focus of Dr. Nonoyama's current work is to train the next generation of medical students in a number of medical disciplines in the area of pediatrics, of great importance to him is teaching his students about PIDD, so that when they are practicing physicians they will recognize the warning signs of this disease and be able to better diagnose patients with this disease. "I have an outpatient clinic and I bring medical students there so that they can see how patients with PIDD are treated," he says. "Although PIDD is explained briefly in their textbooks, it gives them a better understanding if they can see the patients with their own eyes."

Dr. Nonoyama says this is critical as many physicians in Japan are still not aware of PIDD, and very few people are diagnosed with the disease. "We now have a PIDD database in Japan," he said. "Through this database, we now have a good network between scientists and physicians, where both of these groups who are critical in the treatment of patients with PIDD can talk to each other and have a place to communicate and share information. Traditionally, there have been many barriers between these two groups, but now these barriers are breaking down for the good of the patients we are treating."

Dr. Nonoyama is expanding this database beyond Japan and into other parts of Asia, and eventually hopes that he will be able to extend it to other parts of the world, so that everyone ultimately will be able to learn from each other. "One of our primary goals is to educate physicians in Japan about PIDD, therefore, we have created a Japanese version of the 10 warning signs that indicate that someone may have the disease as originally created by the Jeffrey Modell Foundation in the U.S.," he said. "This greatly assists with early diagnosis and increased public awareness of PIDD."

One of the most profound pieces of research that Dr. Nonoyama has conducted on behalf of patients with PIDD, is the identification of the genes responsible for hyper immunoglobulin M (IgM) syndrome, a family of genetic disorders in which the level of IgM antibodies is relatively high. The disorder causes immunodeficiencies, and leads to a higher than normal susceptibility to various types of infections. With this development, he is able to better understand his patients' prognosis and has performed stem cell transplants based on this information. "The patients I have treated come to my outpatient clinic from all over Japan," he says. "They are cured, but they often come to meet and chat with me. To me, this is the happiest time that I experience in my clinic and it gives me a sense of satisfaction, knowing that I've helped them."

There are approximately 1,300 patients diagnosed with PIDD disease in Japan, however, Dr. Nonoyama cautions that he believes there are many more people living in that country with the disease. "In my view, there are probably 10,000 people in Japan living with this disease who have not yet been diagnosed," he says.

One positive change for people with PIDD in Japan that occurred earlier this year in January, was the development of the Jeffrey Modell Diagnostic and Research Center for Primary Immunodeficiencies at the Riken Research Center for Allergy and Immunology (RCAI), in Yokohama, Japan with the collaboration of Kazusa DNA Research Institute and 13 medical colleges. (For more information on this center, please see article in *The Source*, Spring 2008 edition) "The new center will make a huge impact, as we can analyze the genetics of patients with PIDD and can now sequence DNA to uncover the underlying causes

"I want PIDD patients to live and to have more fun," he says. "To me, this would be the culmination of my life's work."

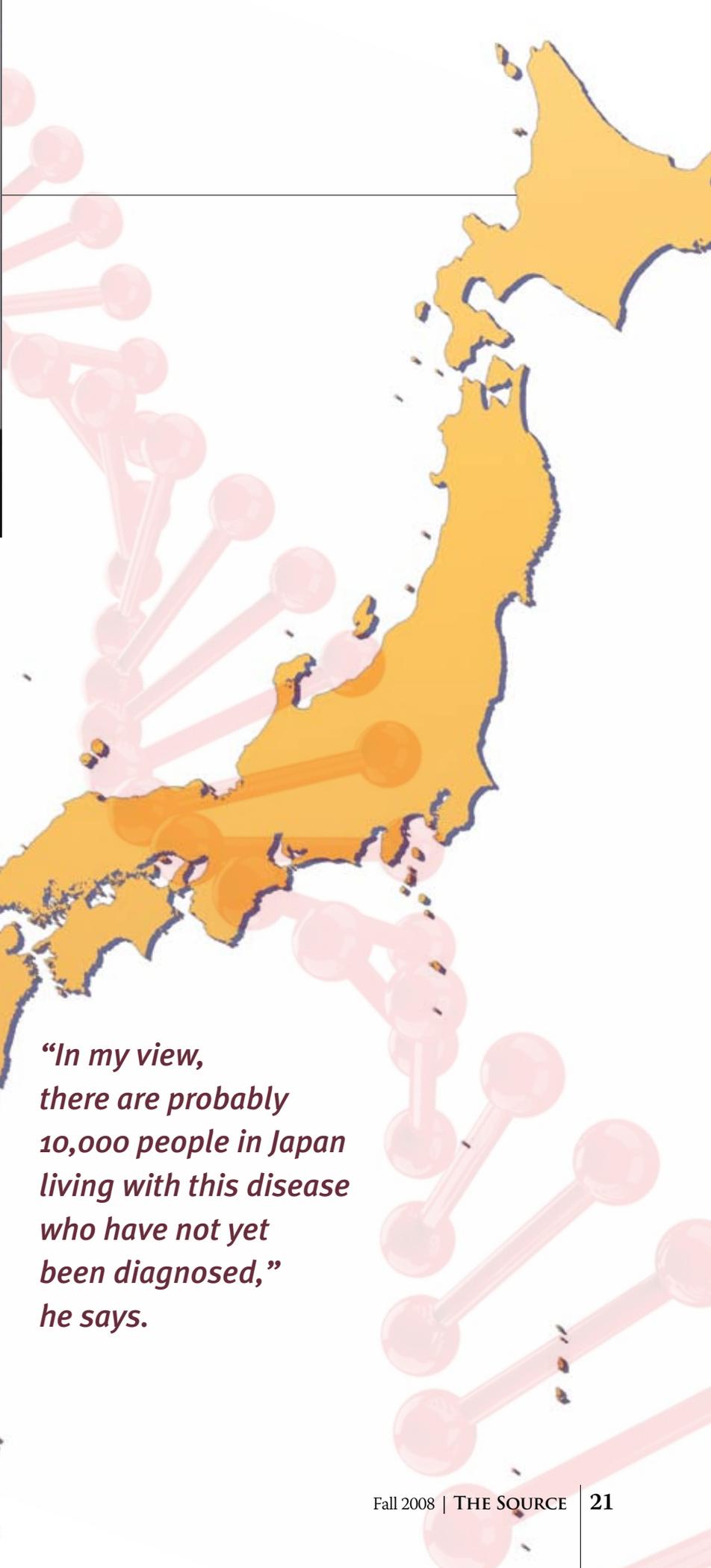


of these disorders and how we can better treat people with this disease,” said Dr. Nonoyama.

Although IVIG therapies used to treat PIDD are covered by government insurance, there are two problems, according to Dr. Nonoyama. The government limits the doses, it provides to patients (of immunoglobulin) and patients are not provided with enough therapies for treatment. “Once a patient becomes an adult, they increase their body weight and as a result, they require more of the therapy than they did when they were children,” he says. “As a council member of the Japanese Pediatric Society, and a committee member of the International Union of Immunological Societies’ (IUIS) PIDD research group, I am trying to educate the Ministry of Health, Labour and Welfare, regarding the appropriate dosage of intravenous immune globulin (IVIG) for adult and young adolescent patients, and have been stressing that it must not be limited. The dosage must be determined on a medical basis, and not by the economics.”

For Dr. Nonoyama, the ultimate goal is to cure all PIDD patients and improve their quality of life. “I want PIDD patients to live and to have more fun,” he says. “To me, this would be the culmination of my life’s work.” ●

KARA FLYNN is PPTA’s director of Global Communications.



“In my view, there are probably 10,000 people in Japan living with this disease who have not yet been diagnosed,” he says.

PETER TURNER HONORED WITH REILLY AWARD

BY KYM KILBOURNE

RECOGNIZING 40 YEARS OF WORK IN THE INDUSTRY, CSL Behring President Peter Turner was honored with the Robert W. Reilly Leadership Award at the 2008 Plasma Protein Forum in Washington, D.C.

Mr. Turner has been a leader in driving efforts to ensure patient access to care, collaborating with industry partners and patient organizations to help ensure a sustainable plasma protein sector. He has provided innovative leadership within CSL for research and development to produce new therapies and continued improvement in manufacturing processes, and has constantly promoted action that can benefit both the patients and industry.

He has had a strong commitment to the plasma products industry throughout his long career with the CSL group. Prior to becoming president in 2004, he led CSL in Australia and Switzerland, after heading the development of the Australian Plasma Products Facility. He has earned Bachelor of Science and Master of Business Administration degrees.

Mr. Turner completed his four-year chairmanship of the PPTA Global Board of Directors in 2007. His leadership was recognized by his peers on the Board of Directors who on two occasions asked that he extend his tenure beyond the normal two-year term. During his chairmanship, he helped guide the industry with clarity and commitment through a period of tumultuous change with significant rationalization and restructuring, followed by a time of consolidation and growth. Throughout, he maintained a strong commitment to the patient communities that we serve. He continues to actively serve on the Global PPTA Board as he has since 2001, and has also served as its treasurer.

The Robert W. Reilly Leadership Award was initiated in 1998 to annually recognize an individual who best exemplifies the leadership qualities of Robert W. Reilly, a leader of the plasma therapeutics industry association. As Executive Director and President of The American Blood Resources Association or ABRA (now PPTA Source), 1978 to 1992, and President of the International Plasma Products Industry Association (now PPTA) from 1992 to 1998, Robert W.

Reilly played a significant role in the development and acceptance of industry voluntary standards for quality plasma programs throughout the United States and was a leader in advancing relationships and open communication with regulatory authorities and consumer groups. In addition, Mr. Reilly developed the first education programs and industry symposia focusing on challenges in the plasma collection facility and fractionation and plasma therapeutics issues worldwide. ●

KYM KILBOURNE is PPTA's Manager of Communications



PREVIOUS HONOREES

- 2007 – **Jean-Marie Vlassembrouck**, *Baxter BioScience*
- 2006 – **David J. Gury**, *formerly of Nabi Biopharmaceuticals*
- 2005 – **Joseph Rosen**, *Baxter Bioscience/BioLife Plasma Services*
- 2004 – **Dr. George Schreiber**, *Westat Inc.*
- 2003 – **S. Tyrone Foster**, *formerly of Aventis Bio-Services*
- 2002 – **Richard Thomas**, *formerly of Bayer Corporation*
- 2001 – **Victor Grifols Lucas**, *Chairman of the Board, Grifols*
- 2000 – **Sammuel Penninger, Jr.**, *Serologicals Corporation*
- 1999 – **Jack Ryan**, *formerly of Bayer Corporation*
- 1998 – **John Bacich**, *formerly of Baxter Healthcare Corporation*



Peter Turner, president of CSL Behring, accepted the Robert W. Reilly Leadership Award at this year's Plasma Protein Forum in Washington, D.C. Pictured left to right are PPTA President Jan M. Bult, Peter Turner, and Larry Guiheen, chairman of the Global Board of Directors and president of BioPharmaceuticals for Baxter BioScience.

MR. LIVER TRANSPLANT

The enormous progress made in liver transplantation over the past two decades has resulted in survival rates approaching 90 percent at 12 months. The success of the procedure is hope for patients with end-stage liver disease or acute organ failure.

BY ROSE NOYES

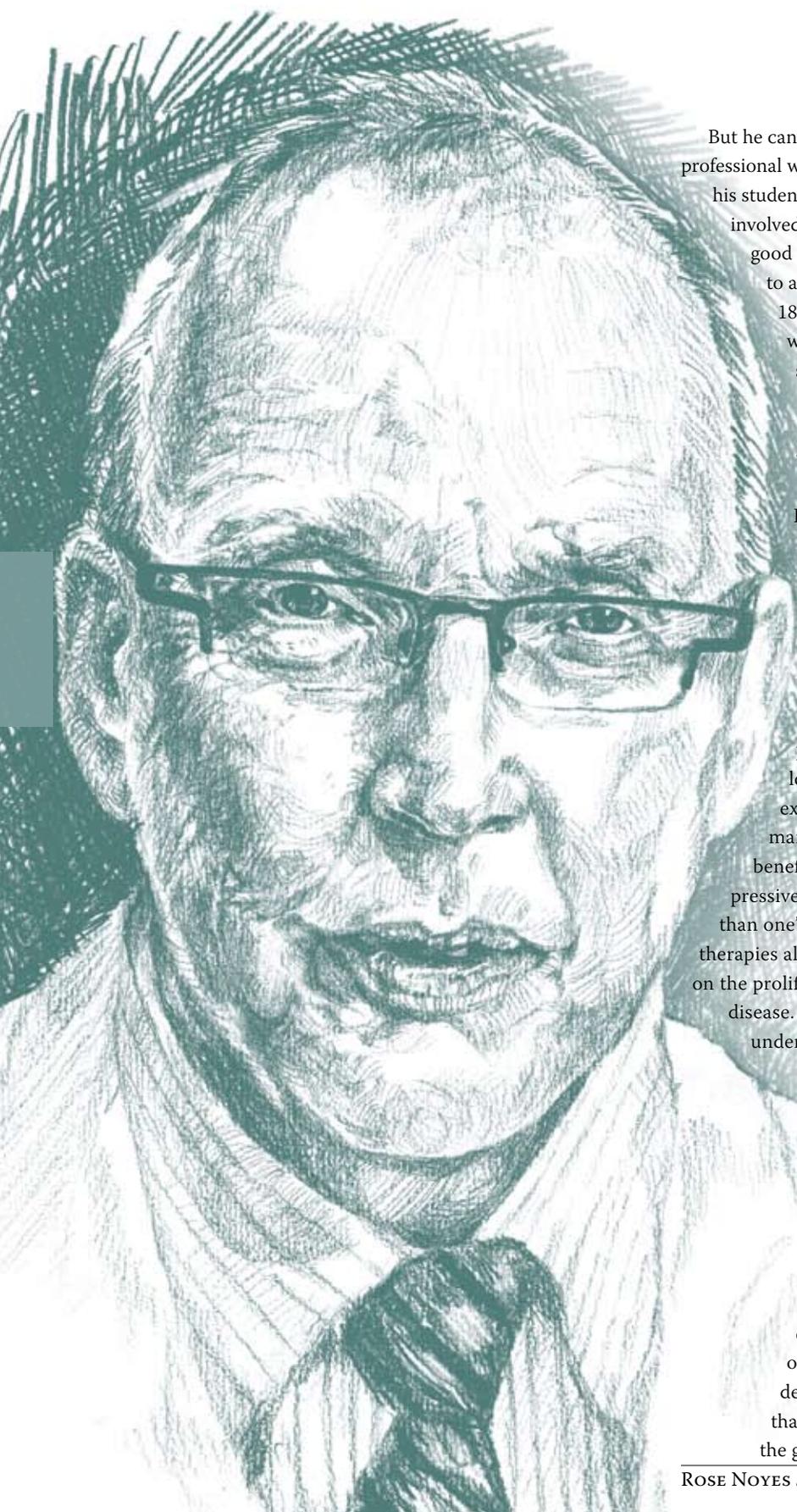
PROFESSOR HEROLD METSELAAR, MD

DR. HEROLD METSELAAR shakes the outstretched hand of the smiling man standing at the head of a long queue of similarly happy people waiting for their moment with him. Dr. Metselaar has just finished his acceptance speech for appointment as Prof. of Liver Failure and Transplantation at Erasmus University Hospital in Rotterdam, The Netherlands. It is April 11, 2008 and over 600 guests crowd the reception area to congratulate the man who dedicated so much of his medical career to renal and liver transplant success. Among the people waiting patiently to greet him are his former patients...in total over 80 percent of all his transplant recipients are here to honor him.

Prof. Metselaar's achievements in the transplant medicine arena are the culmination of years of experience and research. He was born in 1955 in a farming community in the northern part of The Netherlands. He doesn't remember any particular catalyst to study medicine in his early school years, he simply felt it was the right choice. After a lot of concentration and hard work to pass his exams, he received his degree in 1979. He became a staff member of the Department of Hepatogastroenterology of Erasmus Medical Center in 1988. He started as a resident of internal medicine in 1990, where he met Willem Weimar during his second year. Together they conducted a clinical study with anti-cytomegalovirus immunoglobulin (IG). Dr. Metselaar's nickname became "Mr. Metsotect" after the specific hyperimmunoglobulin used in his studies. Cytomega-

lovirus, or CMV, is a herpes virus that infects over 50 percent of the adult population worldwide and normally causes flu-like symptoms in healthy individuals. In post operative, immunosuppressed patients the virus can be deadly and resulted in the deaths of several transplant patients due to pneumonitis in the early 1990's. As a resident, Dr. Metselaar developed a rapid diagnostic tool for CMV infection. He was awarded his Ph.D in Medicine in 1990 for his research on the diagnosis and treatment of CMV infection in renal transplant patients. He was appointed medical director of the Rotterdam liver transplant program in 1995. His paper on the prophylactic effects of high titer immunoglobulins in transplant patients proved to be a defining point in his career. With Professor Hugo Tilanus he began research on immunosuppressive therapy and viral recurrence. Two years later he joined the liver transplant group of Erasmus University Hospital. This is when his nickname changed to "Mr. Liver Transplant".

How does someone with such a hectic schedule cope with the stress at work? Herold Metselaar thrives in a chaotic environment. Crisis management is his forte. At home he dabbles in cooking as a pastime and while his lovely wife looks after the horses on their farm in The Netherlands he prepares dinner. Their two daughters enjoy his expertly prepared stew and Italian risottos. His brownies were customer favorites at the local teahouse.



But he can be a grumpy old curmudgeon... and a humble professional who admits he has made mistakes. He warns his students to keep their emotions in check; don't get involved. But sometimes altruism demands that a good person should act. Dr. Metselaar was called to a Dutch jail earlier in his career to examine an 18 year-old girl who collapsed in her cell. She was an illegal immigrant and suffering from end stage liver disease. She died the next day. He was the only person to attend her funeral and would not end his search to find her parents until locating them in Morocco.

On hyperimmunoglobulin therapy, Dr. Metselaar states, "Anti-HB immunoglobulin (HBIG) was a major breakthrough in the treatment of patients with liver failure due to hepatitis B virus. Liver transplantation was not a real option due to the high recurrence rate [of infection] with a high incidence of graft failure within five years after transplantation. Therefore, hepatitis HBIG prevented recurrence of HBV and now the long-term survival rate after transplantation is excellent. Immunoglobulins saved the lives of many patients with HBV liver failure." Another benefit Dr. Metselaar noticed is the infection suppressive ability of immunoglobulins—more effective than one's own immune system. Immunoglobulin therapies also seem to have an immuno-regulatory effect on the proliferation of lymphocytes in graft-versus-host disease. These last observations have not been proven under controlled clinical trials, but the unfortunate truth is that even without trial outcomes supporting IVIG use for liver transplantation, there is not enough immunoglobulin for every transplant patient.

Sometimes it is a knotty conundrum that a successful person is the victim of their own success. In Dr. Herold Metselaar's case, his successful work with liver transplantation means more patients waiting for donors in a world where the finite availability of transplantable organs falls far short of the demand. Someday, he hopes to formulate a plan that will be approved by the politicians to close the gap. He hopes that day is soon. ●

ROSE NOYES is a guest writer for The Source.

NEWS

PLASMA PROTEIN NEWS FROM AROUND THE GLOBE

EUROPE

➤ PPTA staff participated in a **European Parliament working breakfast** organized by the European Health Forum Gastein (EHFG) and the Small and Medium Enterprises' Union of the European People's Party (EPP) on "The Cross-Border Healthcare Directive—Chances and Challenges for Patients and Providers." For more information on the new Commission initiative on cross-border healthcare please go to: http://ec.europa.eu/health/ph_overview/co_operation/healthcare/proposal_directive_en.htm

➤ PPTA staff participated in the **European Hemophilia Consortium's (EHC) Round Table of Stakeholders**, which was dedicated to the topic, "Is there a need for bleeding disorders centers of excellence in Europe?" It was agreed that establishing such a network would allow for better dissemination of information, expertise and guidelines and would contribute to a greater "knowledge mobility" in the field. In addition, it was agreed that the EHC in cooperation with the European Association of Hemophilia and Allied Disorders (EAHAD) should **define concrete objectives** for such a network and identify opportunities for funding within the European Commission's Public Health Program, which regularly calls for proposals on rare diseases related initiatives such as the creation of centers of expertise and patient registries. Lastly, participants were informed that the EHC is planning to organize an event at the European Parliament on "EU Principles of Hemophilia Care" in January 2009.

➤ PPTA's European Health Policy Steering Committee recently held a series of **"fly-in" meetings with Members of the European Parliament (MEP)** at the European Parliament in Brussels. Several key EU health policy topics were addressed with the MEPs. As a result of the successful meetings, several actions that aim to improve patient access to plasma protein therapies and educate stakeholders on key priorities for the plasma protein community were agreed upon with MEP Jorgo Chatzimarkakis (Liberals, Germany), MEP Miroslav Mikolasik (Christian Democrats, Slovak Republic), MEP Frédérique Ries (Liberals, Belgium),

MEP Adamos Adamou (European United Left, Cyprus) and MEP Thomas Ulmer (Christian Democrats, Germany).

➤ Over the past several years, PPTA, together with other associations representing manufacturers of biological products, has strongly objected to the almost universal classification of changes in the manufacturing process of biological products as Type II variations. The European Member States have approved the **new Commission Regulation on variations**, which will replace the existing Regulations (EC) No 1084/2003 and 1085/2003. Under the new regulation, only changes related to modifications in the manufacturing process or sites of the active substance for a biological product will have to be filed as Type II variations. All other changes will be classified based on their potential impact on the safety and efficacy of the final product, i.e. primarily notifications or Type I variations. The new rules will apply one year after entry into force, i.e. most likely around Q4 2009.

➤ Several Members of the Parliament (MPs) in France have submitted **parliamentary questions to the French Health Minister** regarding last year's infamous "Pellet" report, which recommended that France's current marketing authorization regime that discriminates against plasma protein therapies

produced from compensated plasma donations should be maintained for ethical reasons. The MPs expressed concern that so far the report has been kept "secret" by the authorities and has not been published, despite containing conclusions that could lead to a dramatic change in the way plasma protein therapies are licensed in France. Although the report supports the current regime for "ethical" reasons, it stresses that from an EU legal standpoint France cannot really defend it. No response from the Ministry of Health has been released yet. PPTA's French group, AMDSA, currently is lobbying key MPs on the need for compensated plasma donations and on the differences between blood and plasma donations.



The European Parliament

USA

› In July, as part of its annual rulemaking process, the Centers for Medicare and Medicaid Services (CMS) proposed to **reduce reimbursement for drugs and biologicals** with non-pass-through status dispensed or administered in the hospital outpatient department from average sales price (ASP) plus 5 percent to ASP plus 4 percent. If this proposal is finalized this fall, it would represent a **33 percent cut in the payment level** for such drugs since 2007, when reimbursement had been ASP plus 6 percent. CMS also proposed to eliminate reimbursement for intravenous immunoglobulin (IVIG) preadministration-related services (Healthcare Common Procedure Coding System code G0332) under both the hospital outpatient prospective payment system and physician fee schedule. After discussing the IVIG issue at length with PPTA over the last several months, Senator John Ensign (R-NV), who is a champion on many health care issues and a Member of the Senate Committee on Finance, responded to this agency proposal by sending a letter to CMS expressing his concern that cutting G0332 could exacerbate existing access issues for those patients requiring IVIG.



› President **George W. Bush signed H.R. 6331 into law** on July 15, 2008. The Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110-275) makes a number of **significant changes to Medicare law**, including the prevention of a scheduled 10.6 percent payment cut for physician services that was to go into effect on July 1, 2008, and an additional

5.4 percent cut beginning on January 1, 2009. Physicians will instead receive a **1.1 percent pay increase for physician services in 2009**. Unfortunately, this bill did not adopt language from S. 2990 or H.R. 2914, the Medicare IVIG Access Act, which would have helped ameliorate the IVIG access difficulties for many Medicare beneficiaries.

› The California Budget Conference Committee **adopted trailer bill language pertaining to blood factor products** on July 27. The language includes new authority for the Department of Health Care Services (“the Department”) to enter into contracts for the distribution of specialty drugs. The language does not include exclusive (or sole source) type con-

tracts that were contained in the original trailer bill language from May 16, 2008, which is a clear victory for the community. The language also establishes a mechanism for the collection of additional rebates for the sales of blood clotting factor that will be determined through negotiations between the Department and individual manufacturers. The patient community received assurances from the state that access to therapies would be maintained under this new structure. It should be noted that this language will not become law until the final adoption of the California budget.

› The U.S. Food and Drug Administration (FDA) published a **Federal Register (FR) notice** titled “Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; and Requirements for Donor Testing, Donor Notification, and Lookback.” The FR notice solicits comments on the information collections

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requirements relating to CGMPs and related regulations for blood and blood components. More information can be found at <http://www.fda.gov/cber/rules/bldgmpcom.pdf>.

➤ PPTA attended the **Hemophilia of North Carolina's Patient Advocacy Day in Raleigh, North Carolina** and was assigned to a group of five that included two patients and two parents. The group met with Senators and Representatives to discuss the concerns of the patient community including the July 1, 2009, sunset of a Medicaid statute that exempts clotting factor from the Medicaid prior authorization process. As a result of the group's efforts, **Senator Malone offered to sponsor a bill** that will eliminate the sunset and make permanent the clotting factor exemption. He stated the bill would be the first one he files in January of 2009.

JAPAN

➤ **PPTA staff met with the Licensing and Evaluation Division staff** of the Ministry of Health, Labor and Welfare (MHLW) to request swifter approval of partial change applications for plasma protein therapeutics. PPTA pointed out that **since 2004 application processing has taken in excess of 20 months** for most of the cases, which primarily pertained to changes in manufacturing methods. Currently, it takes one year or more from the date of filing to have the first inquiry meeting regarding the application. PPTA staff also met with the U.S. Embassy staff to inform them of the content of the request to MHLW. This issue will be involved in the report of Market-Oriented Sector Selective (MOSS) Talks between the U.S. Government and Government of Japan this autumn. ●

MEET THE PPTA STAFF



BY JAN M. BULT

PPTA ENHANCES its skilled team in September with the arrival of **Prof. Albert Farrugia**. Albert will focus on improving global access to care worldwide for patients in need of life-saving plasma protein therapies. Albert Farrugia is well known by regulators, patients and industry. He recently left the Australian Therapeutic Goods Administration (TGA) after many years of service.

Albert graduated in biology and chemistry in Malta and started to work as an analyst in a hospital laboratory service in the blood transfusion department. He observed that in the preparation of packed red cells, plasma was separated and then discarded. His department head was Dr. Jiri Rondiak who was distressed at the wasted plasma because plasma derivatives needed to be imported for the hospital at the same time. This event triggered Albert's interest in diseases treated with human plasma derivatives and especially clotting factors. As he says: "I got the bug."

After obtaining his doctorate, he headed the Malta blood service before immigrating to Australia in 1981. There he gained extensive experience in a series of jobs in plasma fractionation, blood service component production and also worked in hospital



Professor Albert Farrugia

transfusion laboratories. In 1994, he then joined the TGA in Canberra.

Albert is a man of various interests. He is personally interested in the well being of the patients that are in need of plasma protein therapies. Because of his sometimes intense work ethic, Albert balances his professional life with leisure activities. He is an avid philatelist, with awards for his stamp collections, which span several centuries. Albert is also a gifted and prolific artist, working in acrylics and watercolors. He has a charming wife who is a pharmacist, one son who has a Ph.D in sociology and another who is a teacher.

Albert's career goal is to increase access to therapies for patients. Albert knows that a lot of work lays ahead to challenge regulatory hurdles, remove trade barriers and improve the reimbursement environment.

Of the many issues that Albert feels strongly about is that self-sufficiency for finished products is a concept that is misleading and has unfortunate consequences for the availability of therapies in many regions.

PPTA is excited because of the expertise and personal commitment Albert Farrugia brings to the association in pursuit of its various, worldwide initiatives. ●

JAN M. BULT is PPTA's President.

EVENTS

UPCOMING CONFERENCES & SYMPOSIUMS

2008

September 12–14 European Haemophilia Consortium (EHC) Annual Meeting
Dublin, Ireland

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

October 1–2 Advisory Committee on Blood Safety and Availability (ACBSA) Meeting
Rockville, U.S.A.

October 4–7 AABB Annual Meeting and EXPO
Montreal, Canada

October 5 PPTA Source Business Forum
Montreal, Canada
PPTA members only

October 7–11 11th International Conference in Thalassaemia and Haemoglobinopathies
Singapore

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

October 19 - 23 The 32nd World Congress of the International Society of Hematology (ISH)
Bangkok, Thailand

November 12–14 World Health Organization Collaboration for Blood Safety
Geneva, Switzerland

December 3 Quality Assurance for Plasma Protein Therapies Workshop
3rd Qualified Person Forum 2008
Munich, Germany

December 4 - 5 3rd Qualified Person Forum 2008
Munich, Germany

2009

March 3–4 International Plasma Protein Congress
Paris, France

May 18 - 22 VIII Latin American Meeting in Hematology, Immunology and Transfusion Medicine
Havana, Cuba

March 23–25 21st Annual EuroMeeting of the Drug Information Association
Berlin, Germany

May 28–30 57th Annual Congress of the Japan Society of Transfusion Medicine and Cell Therapy
Saitama, Japan

June 2–3 PPTA Plasma Protein Forum 2009
Washington, D.C., USA

June 4–7 14th Congress of the European Hematology Association
Berlin, Germany

September 15 - 18 42nd Annual Meeting of the German Society for Transfusion Medicine and Immunehaematology (DGTI)
Rostock, Germany

October 24–27 AABB Annual Meeting
New Orleans, USA

October 25 PPTA Source Business Forum
New Orleans, USA
PPTA members only

2010

June 15–16 PPTA Plasma Protein Forum 2010
Reston, VA, USA

June 26–July 1 XXXIst International Congress of the ISBT
Berlin, Germany

October 7–10 XIVth Meeting of the European Society for Immunodeficiencies
Istanbul, Turkey

October 9–10 AABB Annual Meeting
Orlando, USA

October 10 PPTA Source Business Forum
Orlando, USA
PPTA members only



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