



Leaders Gather in Reston, Virginia for the

PLASMA PROTEIN FORUM 2011

BY KARA FLYNN

THE WASHINGTON, D.C. SUBURBAN CENTER OF RESTON, VIRGINIA

served as the backdrop for a series of lively discussions on a wide array of topics that took place during PPTA's Plasma Protein Forum held on June 14-15.

Highlights of the event on June 14 featured a keynote address headlined by Prof. Dr. Herold J. Metselaar, a professor of liver failure and transplantation at Erasmus University Hospital in Rotterdam, The Netherlands. Dr. Metselaar discussed the immunomodulating effects of intravenous immune globulin and new insights in mechanisms of action. A panel on clinical experiences with albumin and new developments featured perspectives from Prof. Albert

Farrugia, vice president of Global Access, PPTA discussing albumin's increased relevance to critical care, and Prof. Vincente Arroyo of the Hospital Clinic in Barcelona, Spain, who shared views on fluid therapy and the role of albumin in a range of medical indications. A second panel featured a lively discussion on the Orphan Drug Act and rare disease populations with Kay Holcombe, Genzyme Corp.; Patricia Knight, Knight Capitol Consultants; Jason Money, Generic Pharmaceuti-

cal Association; and Mark W. Skinner, World Federation of Hemophilia, discussing whether the current incentives under the Orphan Drug Act are sufficient to continue to spur the development of new drugs and biological for rare disease populations.

A panel that took place on the second day of the conference featured a noteworthy discussion on PPTA's voluntary standards programs, consisting of the International Quality Plasma Program (IQPP) and the Quality



Plasma Protein Forum attendees listen to presentations



SHARON S. BOYD / SHUTTERSTOCK



Prof. Dr. Herold J. Metselaar of Erasmus University Hospital, Netherlands (above) and Dr. Mark Weinstein of FDA (below)



Standards for Excellence, Assurance and Leadership (QSEAL). Joseph Rosen, Baxter BioLife; Tommaso Paoli, Kedrion SpA; and Miriam O'Day, Alpha-1 Foundation/Alpha-1 Association, explored the structure, purpose, relevance and future of the programs through stakeholder relations, importance to the industry and the program's relationship with regulatory authorities.

The full conference program featured sessions including topics addressing medically appropriate treatment regimes for patients using plasma protein therapies, milestones from the point of view of manufacturing and patient care and a panel where regulators from both the U.S. Food and Drug Administration and European Medicines Agency shared their perspectives on regulators' interactions and hurdles to true regulatory harmonization.

Please join us next year for Plasma Protein Forum 2012 on June 21-22 in Washington, D.C.

KARA FLYNN is PPTA's Director, Global Communications



Longtime Industry Veteran Reflects on PPTA's Mission

Dr. Don Baker, the recipient of PPTA's Robert W. Reilly award (see article on page 6) participated in a special session at the 2011 Plasma

Protein Forum reflecting on the mission of PPTA and its significant accomplishments over the years. Dr. Baker, a distinguished industry veteran with more than 30 years in the business, stated in his remarks that over the last 20 years, PPTA and its member companies have improved plasma protein therapies and have been particularly effective in developing and promoting standards to enhance the quality and safety of therapies. Dr. Baker said, however, that there is still more left to accomplish, including opportunities in quality assurance, and that PPTA must continue to work to educate and support, provide a forum for consensus building and promulgate standards as appropriate. He concluded his remarks by stating that there is an opportunity for PPTA to be an advocate for special licensure mechanisms for plasma-derived therapies. He said a risk-based approach, which takes advantage of the unique attributes of these therapies, is ideal.



Prof. Albert Farrugia of PPTA and Prof. Vicente Arroyo of Hospital Clinic in Barcelona, Spain (left)

Speakers on the panel "Orphan Drug Act and Rare Disease Populations" take questions from the audience (below)

