

INSIDE PPTA

PPTA NEWS FROM
AROUND THE GLOBE



PPTA'S NEW BROCHURE "INDUSTRY VOLUNTARY STANDARDS: The Value of the IQPP and QSEAL Designation" is now available

This new publication discussing global standards programs administered by the Association, including the International Quality Plasma Program (IQPP) and Quality Standards of Excellence, Assurance and Leadership (QSEAL), contains useful information about the hallmarks of the program and features quotes from representatives of a number of patient organizations highlighting the importance of the industry's active

commitment to the safety and quality of source plasma and finished plasma protein therapies. The brochure was created as part of PPTA's Source Industry Image and Credibility Campaign, which was developed to promote the source plasma collection industry through positive recognition of plasma donors and lifesaving plasma-derived therapies. To obtain a copy of PPTA's new brochure, please contact Diana Krueger at dkrueger@pptaglobal.org.

PLASMA PROTEIN THERAPIES MONTH ►

will be recognized in September 2011 in California and Florida, helping to raise awareness for the rare, genetic diseases treated with plasma protein therapies and to value the contributions of voluntary plasma donors in the states. Californians and Floridians will be recognized for their outstanding contributions to these lifesaving therapies that treat critically ill individuals and for their donations of plasma that make the creation of these unique therapies possible.



▼ PPTA COLLABORATED WITH THE NETHERLANDS MINISTRY OF HEALTH, WELFARE AND SPORT

and the patient community to host a discussion forum in The Hague that focused on blood and plasma products in the Netherlands now and in the future. The informative presentations provided participants, which included Members of Parliament, government representatives, physicians, patients and industry, with an insightful view of the current situation and developments concerning blood and plasma products in the Netherlands and entertained an interactive session on the various stakeholder views that were voiced.



PPTA SUBMITTED COMMENTS TO THE INTERNAL REVENUE SERVICE ►

regarding Notice 2011-9, Proposed Guidance Implementing the Annual Pharmaceutical Fee on Branded Prescription Drug Sales. The Association's comments focused on the agency's interpretation of the orphan drug exclusion and its proposed methodology for calculating Medicare Part B sales, and are consistent with the advocacy strategy regarding the fee and overarching goals to protect patient access to all brands of plasma protein therapies. The letter is posted on PPTA's global website, www.pptaglobal.org.



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◀ PPTA'S ANNUAL CAPITOL HILL FLY-IN

on Wednesday, May 11 brought together patients, patient representatives, members and staff for an unprecedented 108 meetings. The Association, with the support of patient organizations and members, advocated for policies that would continue to encourage the development of therapies for rare diseases by excluding all drugs and therapies that are only indicated by U.S. Food and Drug Administration (FDA) for a rare disease or condition from the annual pharmaceutical fee, which is part of the new health reform law. H.R. 2672 and S. 1423 were introduced in July and, if passed, would address this issue.

▼ WITH U.S. FOOD AND DRUG ADMINISTRATION (FDA)

and Department of Health and Human Services (HHS), PPTA co-sponsored a public workshop, Risk Mitigation Strategies to Address Potential Procoagulant Activity in Immune Globulin Products, on May 17-18, 2011. Association staff and members participated in the workshop as session co-chairs, speakers, and panelists. The workshop examined the pathogenesis of events in recipients; studies of products/processes for procoagulant activity and removal; and assay methods and validation feasibility. Among outcomes were increased awareness of the complexity of events, including role of procoagulants and host factors; understanding of fractionation processes with respect to procoagulant presence and removal; and status of assay development, feasibility for validation and use in a manufacturing environment.

▼ **IN JUNE**, the U.S. Department of Health and Human Services (HHS) appointed PPTA industry expert Mary Gustafson to serve for a two-year term on its Advisory Committee on Blood Safety and Availability (ACBSA). The Committee is a Federal advisory committee used by HHS. Ms. Gustafson is currently the Vice President of Global Regulatory Policy at PPTA and has 20 years of experience at the U.S. Food and Drug Administration (FDA). Prior to joining the Association, Ms. Gustafson served as the Senior Director of Regulatory Affairs at Nabi Biopharmaceuticals in Boca Raton, Fla. Julie Birkofer, Senior Vice President, North America, PPTA, had represented the industry on the ACBSA for the previous five years.



PPTA STATE AFFAIRS STAFF ATTENDED ALABAMA MEDICAID'S MEETING ON HEMOPHILIA STANDARDS OF CARE

hosted by the state's Medicaid pharmacy director, a national leader in Medicaid pharmacy policy. PPTA took the opportunity to discuss the Association's initiative, the State Patient Access Coalition, and the need for access to all FDA-approved clotting factors with the pharmacy director.



PPTA, WORKING IN COALITION WITH PATIENT ORGANIZATIONS AND OTHERS,

achieved a successfully carved out clotting factor from mandatory managed care in a statewide proposal that will create a managed care program in Florida (HB 7107). Florida is a trend-setter in Medicaid nationwide and therefore this is a model for access to all clotting factors for patients in Medicaid programs.