

# Stakeholder Report

On April 30, Stakeholders met in Rockville, Maryland in connection with the Advisory Committee on Blood, Safety and Availability (ACBSA) meeting to discuss issues that may impact patient access to plasma protein therapies, particularly the safety of therapies in the wake of recent concern in the patient community over variant Creutzfeldt-Jakob disease (vCJD). Representatives from national consumer organizations, the Department of Health and Human Services (DHHS) and PPTA member companies participated in the meeting.

Introductory remarks by PPTA included mention of recent communications projects. On April 28, the excellent work of Stakeholders and PPTA resulted in an advertorial that appeared in *Politico* newspaper and featured content from several national consumer groups. This eight-page special advertising supplement is a high quality work product read by many Capitol Hill offices. Reprints of the *Politico* advertorial are available to all Stakeholders. In addition, PPTA needs your feedback – please use the web-based “Tell Us What You Think” mechanism at [www.politico.com/ppta/contact.html](http://www.politico.com/ppta/contact.html) or send an email to Kym Kilbourne, [kkilbourne@pptaglobal.org](mailto:kkilbourne@pptaglobal.org). You also can visit the content online at [www.politico.com/preservepatientaccess](http://www.politico.com/preservepatientaccess).

Spring continues to be a busy time for all of us! A successful webinar program was held on April 24 with the Hemophilia Federation of America’s staff, leadership

and chapter executive directors. This was the first ever webinar held by PPTA with Stakeholders. The webinar advocacy series is geared entirely to providing the grassroots with information about the unique nature of plasma-derived and recombinant analog therapies (collectively, “plasma protein therapies”) so that if the community needs to become active in the states or in Congress, the basic foundation is in place for people to feel comfortable expressing their views to policymakers. The content of the webinar series is 100 percent focused on creating awareness in the community and providing accurate information. Each webinar is individually customized to the appropriate messages for a community. PPTA worked closely with HFA’s executive director to make sure that the content met the needs of HFA’s community, and we will proceed similarly in future webinars. PPTA staff also noted that the goal of the webinars is to disseminate information and energize a grassroots base.

Dr. Jerry Holmberg with the DHHS and who chairs the ACBSA, said a few words about the Department’s focus. Dr. Holmberg discussed again a topic raised at the December committee meeting regarding the public health role of plasma collection centers, recognizing that to all people who depend on plasma protein therapies recognize the importance of donor health. Dr. Holmberg acknowledged the significant progress made in terms of safety over the years, stating that the final products are very safe and thanked the

consumer groups for their role in helping the government and industry with issues regarding safety.

Featured speaker, Doug Lee, Ph.D., Senior Director of Pathogen Safety with Talecris Biotherapeutics, then spoke about the safety of plasma protein therapies from his perspective as a scientist who has been working in this field for many years and who currently serves on PPTA's Pathogen Safety Steering Committee (see attached presentation). Further, Dr. Lee recently has been selected to serve as the industry non-voting representative on the FDA's Transmissible Spongiform Encephalopathies Advisory Committee (TSEAC). The informative discussion, which centered on safety of final therapies, also provided a significant amount of details regarding vCJD and how this risk of transmission through plasma products is mitigated. Dr. Lee focused his discussion on the use of Source plasma. Stakeholders questioned the use of recovered plasma by some PPTA member companies, focusing on the fact that recovered plasma is not covered under the PPTA standards program. PPTA stated that while there is no inventory hold for recovered plasma, there is "lookback" capability for recovered plasma. PPTA also informed Stakeholders that as part of the continuing work under the Quality Standards of Excellence, Assurance and Leadership (QSEAL) voluntary standards program, PPTA is reaching out to the blood community and is considering the implementation of acceptance criteria for recovered plasma as a part of QSEAL. This update was well-received by the Stakeholder community attending the meeting.

Dr. Lee had an open discussion with the meeting attendees, emphasizing the collaborative effort with regulators,

patients, consumer groups, and industry all having contributed to safety. His presentation highlighted the evolution of pathogen safety over the past 20 years. Dr. Lee discussed in detail the numerous layers of pathogen safety methods used by manufactures. Dr. Lee concluded that the industry is vigilant regarding pathogen safety, and that manufacturers are constantly innovating new safety techniques based on the latest science. The plasma protein therapeutics industry continually strives for safety and welcomes an open dialogue with Stakeholders.

Before adjourning for the evening, the upcoming May 20 Fly-In was briefly discussed. Stakeholders requested a brief list of topics that PPTA is proposing for discussion (see attached.) As always, Stakeholders participating in the Fly-In are encouraged to raise issues at the forefront of their legislative agendas' as well. If anyone has any questions or would like to discuss specific legislative issues prior to the Fly-In, please contact Jon McKnight at [jmcknight@pptaglobal.org](mailto:jmcknight@pptaglobal.org). We look forward to your participation on the 20<sup>th</sup>!

Attachments:

1. Powerpoint Presentation: April 30<sup>th</sup>
2. Legislative Issues: Fly-in May 20<sup>th</sup>