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STAKEHOLDER REPORT

On June 15, 2015, PPTA held a stakeholder meeting in Washington, D.C.

Representaives from the following patient groups participated in the meeting, along with PPTA members and staff:

- Alpha-1 Foundation/AlphaNet
- Health & Medicine Counsel of Washington on behalf of GBS/CIDP Foundation and Hereditary Angioedema Association
- Cavarocchi-Ruscio-Dennis Associates on behalf of Jeffrey Modell Foundation and National Hemophilia Foundation
- Immune Deficiency Foundation

PPTA's Vice President, Legal Affairs, provided guidance on antitrust compliance and also requested that any meeting attendee who is a "covered recipient" under the Sunshine Act disclose that fact to PPTA staff.

A-PLUS ADVOCACY UPDATE

The A-PLUS representative shared the group's activities, including work on HR 1600, the "Patient Access to Treatments Act," co-sponsored by Rep. David McKinley (R-WV) and Rep. Lois Capps (D-CA). The bill addresses specialty tiers and cost sharing. A-PLUS is also focused on implementation of the Affordable Care Act (ACA); especially implementation of network adequacy rules. It was discussed that outreach to the National Association of Insurance Commissioners (NAIC) may be beneficial.

The FDA draft guidance entitled, "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products," was also discussed. Comments are due by July 14. The draft guidance, when finalized, will implement a policy change to the blood donor deferral period for MSM, from indefinite deferral to a one-year deferral. Hemovigilance is a top priority for the A-PLUS, through

the Transfusion Transmissible Infectious Monitoring System (TTIMS). Securing TTIMS funding for five years is a focus of A-PLUS.

PPTA shared that there will be a global impact from the new policy, particularly on the collection side in certain regions. A chart is attached which depicts various deferral periods by country. PPTA Regulatory Policy staff will be submitting comments on the guidance and will coordinate with A-PLUS as information becomes available.

FEDERAL PATIENT ACCESS

During the Federal Patient Access discussion, PPTA Director, Government Relations, gave a presentation on Durable Medical Equipment (DME) Competitive Bidding of infusion pumps. HHS Office of Inspector General has been a driver of the policy. This was a topic of the recent PPTA Fly-In, held May 14. The key messages were that patients need access to all brands and that these medicines are unique and not interchangeable. The group representatives all expressed concerns regarding patient access if competitive bidding is implemented.

PATIENT NOTIFICATION SYSTEM

The Patient Notification System continues to grow. PPTA will present at four patient group meetings this year. Registration numbers have increased by 500 this year.

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