

Stakeholder Report

PPTA held a Stakeholder Meeting on May 28 in Washington D.C. to discuss key advocacy initiatives of the association and consumer organizations. After welcoming participants from the Immune Deficiency Foundation, Guillain-Barré Syndrome Syndrome/Chronic Inflammatory Demyelinating Polyneuropathy Foundation International, the Committee of Ten Thousand, the National Hemophilia Foundation and the Hemophilia Federation of America and several industry representatives, Julie Birkofer, PPTA Vice President, North America, described the positive achievements of working together on federal and state legislative issues that affect patient access to plasma protein therapies.

PPTA staff presented an update of communications and media outreach conducted in support of advocacy, providing an overview of the role of communications in the states and specific examples of collaborative efforts in Florida and Minnesota that have yielded results. In Florida, PPTA worked with a primary immunodeficiency (PIDD) patient Jenny Gardner to facilitate sharing her personal story as an opinion-editorial in the *Tallahassee Democrat*, which ran prior to the patient legislative day in the state. This success demonstrates the power of working jointly to increase awareness of quality of care and patient access initiatives on a state-level. While similar efforts to

disseminate messages to the press in Minnesota with individuals with PIDD, hemophilia and alpha-1 antitrypsin deficiency have not yet earned press coverage, the groundwork that was made with patient advocates remains significant and, with some adjustments to the messaging to reflect the current timing, PPTA will again work with those individuals in an effort to earn media coverage on this important topic.

Communications staff also presented the new industry DVD aimed at informing policymakers about the high-value of plasma protein therapies and providing context from several perspectives including patients, donors and physicians, as well as donor center and manufacturing quality and safety and complexity. This DVD was given to meeting attendees and is available to consumer groups who wish to use it in connection with awareness and education in which they are currently engaged.

A beta of the website www.donatingplasma.org debuted, and the group provided valuable feedback in terms of its content and presentation. This website currently in development aims to offer a one-stop credible resource about plasma donation and its use to manufacture final therapies. It features donor and patient stories, locations of source plasma collection centers in the U.S., links to consumer organizations and details regarding the

plasma donation process. Additionally, the website will include selected video content from the PPTA DVD. Attendees also discussed the various ways to promote the new website including links with consumer organizations and PPTA member companies, marketing postcards, media relations and advertising.

In general, consumer group representatives and industry members were pleased with the direction and utility of these new communications products and offered helpful insights and commentary on their content. While it is challenging to reach consensus with all groups when producing new products, it was recognized that keeping open lines of communication in the spirit of collaboratively addressing patient access needs is essential.

PPTA federal affairs staff presented the latest information regarding recent legislation, including the Genetic Non-Discrimination Act, which President Bush signed into law on May 21. This new law prohibits discrimination by all insurance providers and by employers with regard to a person's genetic information. A speculative discussion of the election year politics, trending in pivotal states and its potential effects on federal and state health care policy yielded discussion on how priorities may shift in 2009 with respect to advocacy. A resounding "thank you" went out to all consumer group representatives and members who participating in PPTA's Capitol Hill day on May 14. Teams held 66 quality meetings with members of Congress, including one-fourth of the Senate and influential members of the Senate Finance Committee. Prior to individual meetings, participants heard

from three legislators, Rep. Steve Buyer (R-IN), Rep. Kevin Brady (R-TX) and Rep. Jay Inslee (D-WA) on legislation that they have introduced – drug pedigree, IVIG access, and follow-on biologics respectively – that is essential for patient access to safe and effective plasma protein therapies.

Staff discussed legislative issues including the 2008 Medicare legislation, the upcoming Health Reform Summit in mid-June hosted by the Senate Finance Committee, and several issues on hold until the 111th Congress such as health insurance reform, follow-on biologics, 340B Drug Pricing Program expansion and patent reform. Additionally, staff mentioned that final guidance from the Health Resources and Services Administration (HRSA) on some 340B Program proposals could be forthcoming and that the proposed rules from the Centers for Medicare and Medicaid Services on the Physician Fee Schedule and the Hospital Outpatient Prospective Payment System, which could possibly include a further reimbursement reduction from ASP +5% to ASP +3% for drugs dispensed in the hospital outpatient department as well as eliminate the preadministration code for IVIG in that site of service.

Following the federal legislative discussion, consumers reported on federal and state advocacy activities. Ed Gdula with the GBS/CIDP Foundation discussed his new role as a consultant with the organization. He provided several highlights of the May Awareness Month talks about the Miracle Mile Walks that took place in May in several cities to raise funds and awareness for individuals with GBS.

Marcia Boyle with IDF provided a brief history of the foundation and its involvement in advocacy, which she explained began in the late 1990s. Now the association has action alerts on its website with regard to legislation, volunteer advocates across the country and celebrates PIDD Awareness Month in April. The organization has led advocacy efforts on IVIG patient access legislation and recently spearheaded the introduction of the Kerry bill.

Glenn Mones with NHF announced the foundation's new CEO, Val Bias and discussed his background and experience with hemophilia and advocacy. Glenn described NHF's Washington Days in March as the largest they've held, with a record 250 participants. Specifically, the group advocated for a House bill similar to the Senate version on lifetime insurance caps. Glenn also shared that the MASAC comments on recombinant and plasma-derived therapies has been modified more recently to reflect the importance of open access to all therapies for individuals based on their particular needs. He commended PPTA and manufacturers for getting the important message out regarding the safety of plasma-derived therapies saying that, "we've come remarkably far considering the history," and that one size does not fit all when it comes to individual treatment plans.

Dave Cavanaugh with COTT discussed problems with accessing factor in six states under the 340B program at the WellPoint designated pharmacy located at the Indianapolis airport. Explained that this problem may grow to include all 14 states where WellPoint provides health insurance. He also discussed

concerns with changes to the Genetically Handicapped Persons Program in California that will affect people with hemophilia in the state. The group discussed the need for more on-the-ground work in the short-term given the compressed timeframes at work in California. Additional discussion to secure cosponsors for the Medigap bill ensued. PPTA pledged to work to secure two cosponsors and everyone around the table expressed strong support.

Kisa Carter with the Hemophilia Federation of America praised the PPTA Capitol Hill Fly-in and expressed that she was glad to participate as a part of the community. She mentioned that she is exploring hosting a symposium in Washington, D.C. in connection with the upcoming 15th anniversary of HFA next year and her plans to organize a small fly-in in connection with the anniversary as well. HFA also is searching for a new executive director, and may also look to move its offices from Rockville to Washington, D.C. once the new staff leader is on board. HFA has supported advocacy days in the Nebraska and Tennessee for example, and is considering developing a tool kit to assist other local advocates with establishing similar programs. Kisa discussed the Ryan Dant Healthcare Act (H.R. 5748) introduced by Rep. Kenny Marchant (R-TX) on April 9, which would amend title XIX of the Social Security Act to permit States to exclude earned income in determining eligibility for medical assistance for individuals with extremely high prescription drug costs.

The meeting concluded with an open discussion of support from consumer groups for PPTA's involvement in

working together on federal and state advocacy initiatives. There was consensus among the group that additional focus on grassroots advocacy is essential and message alignment essential to patient-led advocacy.

In closing, PPTA offered thanks all of the consumer organization representatives and members who were able to participate in the meeting.

Attachments:

1. Powerpoint Presentations:
Stakeholder Meeting May 28
2. 340B Issue Brief
3. Talking Points: Gas
4. Copy: Reimbursement Primer
5. Copy: H.R. 5478
6. Copy: H.R. 5478 Dear Colleague letter