

Stakeholder Report

The first Stakeholder Meeting of 2009 was well attended. On February 10 Stakeholders met in Washington, D.C. to discuss issues that may impact patient access to plasma protein therapies at the federal and state levels and strategies to mitigate their impact. Representatives from national consumer organizations, the U.S. Food and Drug Administration (FDA), and PPTA member companies participated in the meeting. Consumer representatives opened the meeting with a discussion on their organization's top federal advocacy objectives. Among those objectives discussed were: lifetime caps on private health insurance policies; reintroducing Medigap legislation in the 111th Congress; IVIG access; early diagnosis and treatment; follow-on biologics; ensuring that patients with rare, chronic diseases are protected in any health care reform legislation; and comparative effectiveness. Mark Weinstein with the FDA stated that priority areas for his office include follow-on biologics, FDAAA implementation, risk management, focusing on rare diseases and preparing for the eventual nomination and confirmation of a new commissioner.

Two guest speakers participated in the meeting. The first, Jeff Allen, Ph.D. represented the newly formed Partnership to Improve Patient Care (PIPC) in which PPTA is a member. Dr. Allen discussed comparative

effectiveness and its role in improving patient care, presenting research developed in his role as the Executive Director of the Friends of Cancer Research that applies to the debate on comparative effectiveness research given that a significant number of cancers fall into the category of rare diseases. He outlined the principles of the PIPC, which can be found on (<http://dev.improvepatientcare.org>). His presentation spurred discussion of the breakdown in allocation of funds in the government stimulus bill to fund research projects in this area with funds going to the American Red Cross, National Institutes of Health, the Department of Health and Human Services for research projects already assigned, health IT, and to form an advisory committee. Dr. Allen, by way of highlighting examples from abroad, indicated the very real threat that the information could be used for cost-containment initiatives that may not be in the best interests of providing quality patient care.

Joining the meeting for a lively discussion of federal policies that limit patient access, specifically restrictive formularies, was guest presenter Deborah Williams, Director of U.S. Government Affairs, Baxter Healthcare Corporation. Ms. Williams outlined the very real threats for restrictive formularies and shared her insights on the issue from her experience working on Capitol Hill and as an economist.

She discussed how federal funds may be used, and highlighted the pros and cons of comparative effectiveness research, including ensuring that patient input is considered. She concluded by saying that comparative effectiveness research nor QALYs (quality adjusted life years) are not appropriate to preserve care for patients with rare diseases and severe life-threatening disorders.

Timing of the Politico advertorial was discussed and will now appear on Tuesday, April 28 in order to be positioned closer to the May 20 legislative “Fly-In” day, and to give issues affecting the users of plasma protein therapies and the industry more time to mature. Consumer groups are making important contributions to the content of the piece, which is an 8-page insert in the Politico newspaper with an accompanying microsite on www.Politico.com that will present the same copy. Delaying the advertorial also will allow consumer groups to target their messages more specifically to legislation that may be introduced this spring, such as lifetime caps, Medigap and IVIG access legislation. The goals of the project are to inform legislators, their staff and members of the Administration about the industry, the patients with rare diseases that the therapies treat and positions related to legislation on follow-on biologics, comparative effectiveness, and others as appropriate.

In order to support state advocacy initiatives, everyone is putting resources behind generating media awareness in Minnesota for the Quality of Care bill introduced in late January. National consumer groups and state patient

advocates are working hard to deliver the message about why the legislation is critical. The focus is to generate op-eds in key legislators Districts and to generate an interest among influential reporters covering health care issues in St. Paul. The Association is in a supporting role and is able to assist when appropriate with media outreach. In order to maximize these efforts, a local agency is on board to advance the legislation and establish contacts with key reporters and influential news outlets. The Association hopes to replicate portions of this effort in other targeted states this year as activity warrants and opportunities arise.

The group discussed progress on the development of a Webinar program this year that aims to provide information and create awareness among a grassroots consumer audience about plasma protein therapies, how they are manufactured, their cost structure, their uniqueness, and the health policy issues that policy makers are considering that could impact patient access to therapies. Stakeholders provided valuable feedback, particularly with regard to the balance of content in the first slide deck, the outline of which was presented at the meeting. Consumer representatives felt that information from or about PPTA or the industry as a whole (for example, information about standards programs) should be threaded through the presentation as appropriate and indicated that placing information up front that energizes consumers who are attending, letting them know “why they are attending” and that helps them tell their “rare disease” story would resonate with the grassroots. The Webinar I slide deck will be sent to each consumer group contact

for additional feedback, to discuss customizing the program to their specific audience and to schedule presentation of the program in the manner in which the consumer group requests.

It was reinforced that this is a partnership with the consumer groups, and PPTA will rely on them to provide their members with information about the program and the opportunity to participate. Promoting the Webinar's to the grassroots constituency of each consumer organization is the key to a successful outcome. It was acknowledged that this is a new grassroots outreach initiative and that we are trying something new given the mounting threats to sustaining patient access, both federal and state.

It was further acknowledged that many organizations are already working effectively to engage the grassroots on legislative issues through such tools as Cap Wiz and issuing action alerts. These tactics are excellent and the Webinar program would complement those initiatives.

PPTA's newly hired manager of State Affairs was introduced. Various reports on state advocacy initiatives were discussed including the progress of the patient group coalition that is working on the Quality of Care legislation in Minnesota. This coalition includes the primary immunodeficiency, alpha-1 and von Willebrand disorder patient populations. The bill must be heard by either the House or the Senate committee by March 27. It was announced that a "plasma collection center day" is being organized at the Minnesota capitol to help legislators learn more about plasma collection and

its benefits to their constituencies. An advocacy timeline is under development and the coalition is meeting regularly by conference call.

Additional threats to patient access in the states were reported on as well, including a grim U.S. map illustrating that just four U.S. states are not reporting serious budget deficits. This will impact patient access as state budgets are being squeezed and the Medicaid spends will be analyzed for cost-cutting measures. It was reported that states with the worst budget shortfalls include California, New York, Florida and Louisiana. A number of direct and indirect threats to patient access in the states was discussed and California and Florida more in depth. In California, where state employees are taking furloughs, PPTA is monitoring rebate implementation for restrictive formularies and budget and legislation for threats to access. The importance of Stakeholders meeting on a regular basis with decision-makers to educate them on the need for patients to have access to their medically appropriate therapy was discussed. Issues in Florida were discussed. Currently there is a pressing need to lobby to maintain Medicaid eligibility for individuals in the Medically Needy as well as the MEDS/AD program, which collectively impact 33 hemophilia patients. The conversation about state issues concluded with a discussion of how Stakeholders can best work together on advocacy issues and direct threats to access. It was suggested that when an issue arises, PPTA should act as an "information clearinghouse" and inform Stakeholders. The importance of coordinating actions such as, drafting letters, discussing

advocacy strategies and engaging the grassroots was discussed.

Other issues that were raised included a report from one consumer group that it is seeing more calls from consumers who have private health insurance and cannot afford their month payment and/or their 20 percent co-pay for their therapies. It was noted that cost shifting to the patients is increasing and patients are being asked to pay for a larger share of their treatment and are left with “nowhere to turn.” It was agreed that this was an important issue that should be given further consideration.

The meeting concluded with a thank you to everyone who was able to participate in the meeting and the hope to see everyone at the next Stakeholder Meeting on April 30, which will be a dinner held in conjunction with the ACBSA meeting.

Attachments:

1. Powerpoint Presentations:
Stakeholder Meeting February 10th