

Patient Advocacy Advisory Board

Saturday, June 23, 2018
Pennsylvania Convention Center

Minutes

Attendees: Rosemary Ciotti; Stephen Schwartz; Tricha Shivas; Theresa Wickerham; Dorothy McGrath; Jim Hendrix; Josh Mailman; Anita McGlothlin; Ramon Llamas; Jeri Francoeur; Giuseppe Esposito, MD; Linda Budzinski; Karin Brough; Wayne Powell

1. Commencement

Chair Stephen Schwartz called the meeting to order. A quorum was established. The minutes of the May 30, 2018, meeting were approved. The agenda was approved.

2. Legislative Update

W. Powell provided the Committee these updates on relevant legislative and regulatory issues:

- There has been no movement on the BCBS/Anthem coverage issue pertaining to coverage of DatScan, we are awaiting a final evidence summary.
- Legislation that seeks a carve out for payments for diagnostic radiopharmaceuticals costing more than \$500 has not yet been introduced.
- The federal budget that was signed into legislation earlier this year included a surprise amendment that allows all radiopharmaceuticals which would have gone off pass-through status in 2018 to remain on pass-through status for two extra years. It also mandated a GAO study of the coverage issue.
- SNMMI met with 15 CMS staff in April regarding the problems with bundling expensive RPs in with higher volume low volume RPs. CMS seemed to see the problem but didn't like the \$500 carve-out solution.
- SNMMI Health Policy and Regulatory Affairs staff are becoming more active on coverage decision legislation and will be scanning all carriers' websites for information regarding coverage decisions. W. Powell encouraged PAAB Members to share any information on which coverage policies are affecting them. He noted that when assessing coverage decisions, policies regulators are looking real scientific data; anecdotal evidence is not effective.
- SNMMI has submitted a letter to the FDA on the amino acids used in conjunction with Lutathera treatments because patients were having severe reactions to the available amino acids.

J. Mailman stated that he is aware that Progenics is seeking an update on the radiopharmaceutical issue.

R. Ciotti asked for an update on a reactor that was not on-line. W. Powell reported that it would be up in 1-2 weeks and the delay was due to supply issues in Chicago.

S. Schwartz asked if the new tariffs imposed by the Trump administration would have any negative effects on

pricing of medical supplies and machines. W. Powell responded that it would be contingent on the number of parts originating in China. He noted that all industry representatives are in opposition to the tariffs.

3. Review of Outreach Grid

L. Budzinski briefly reviewed the Outreach grid document, noting that for the Outreach Domain, the grid's first two objectives (increasing patient and physician awareness regarding nuclear medicine and molecular imaging) will always be the top priority. She noted that the domain has made a great deal of progress on the top three (I-immediate) priorities and that in the coming year, it would be time to also begin work on the next three (M- mid-term) priorities of increasing interaction with the imaging community, conducting outreach to hospital administrators, and increasing financial resources devoted to Outreach. The Board agreed to consider these objectives and discuss what if any role the PAAB might play in these over the coming months.

S. Schwartz expressed his desire as part of the first objective (patients) to have a representative of a group dedicated to Parkinson's disease on the PAAB. L. Budzinski noted that the Michael J. Fox Foundation and the Parkinson's Foundation have both declined to participate but that there are other groups the Board can approach.

4. Patient Education Day Preparation

L. Budzinski will print out the revised exhibit hall tour list and distribute it to PAAB members. J. Mailman noted that in addition to the companies on the list, members should stop by the Department of Energy booth as well as the VeinLite booth.

Members commented that the online PED registration process was improved over last year.

J. Mailman reviewed the lunch program and the pre-event survey he distributed. He stated that the survey examines who owns the patient relationship—i.e., the follow-up, therapy and who you would discuss PRRT with—the nuclear medicine physician or the oncologist. Results suggest that there is a 50/50 split between the NM doctor and the oncologist.

The PAAB members agreed to meet at 9:30am in the general session room to begin preparations for the 10:30 am start time.

Action Items

- **Legislative Update** W. Powell encouraged PAAB Members to share any information on which coverage policies affecting them.
- **Review of Outreach Grid** The Board agreed to consider the Domain's mid-term objectives (interaction with imaging community, outreach to hospital administrators and increasing financial resources devoted to Outreach) and discuss what if any role the PAAB might play in these objectives over the coming months.

The Meeting adjourned at 8:30 pm