

PQRI Board of Directors Meeting

Friday, June 1, 2007
9:00 am – 12:00 pm

Face to Face Meeting
Drinker, Biddle & Reath LLP
1301 K Street NW
Washington, DC 2005

MINUTES

The meeting convened at 9:05 a.m. with the Chair presiding. A quorum was not reached with only three Board members in attendance. Electronic voting on matters requiring Board action will be taken following the conclusion of this meeting.

Reading of the Admonition Statement

Read an admonition statement relative to anti-trust issues:

“Our discussions today are subject to the anti-trust guidance applicable in the U.S. Nothing discussed at this meeting is intended to restrict the individual decision-making of any member company or to represent an agreement to coordinate marketing or sales conduct. Those participating in this meeting are advised to avoid discussion of competitively sensitive subjects, including, confidential marketing, sales, and pricing information.”

Review and Approval of the Agenda

The agenda was presented and agreed upon, with the addition of a discussion of the Budget for FY08.

Approval of Minutes

The full representation of the December 11, 2006 meeting minutes were approved by the three members present, as presented.

The summary minutes of the December 11, 2006 minutes were approved by the three members present, as presented for posting on the PQRI web site.

Forward approved minutes onto AAPS for the EC to review. Action item accomplished.

Treasurer's Report

- Review of April financials discussed and accepted as presented. Board did request that statements in the future reflect the research funding commitments that are upcoming. (i.e., the \$330,000 commitment for the BCS III WG, Stability Shelf Life WG, and the Sulfonate Esters WG)

Steering Committee Report

- discussed the restructuring of the TCs on the SC as well as the new 'focused workshops' proposal. Nominations for TCs will come to the SC through the primary member organization representative. The SC has the responsibility for populating the new TC as well as selecting the new TC Chair. **SC Chair to draft the copy of the policy for handling selections for both TCs and WGs so that it can be added to the minutes to clarify the SCs position on the issue. Action item accomplished. send the corrected copy of the letter and website posting addressing the restructuring to authors for their final okay and copy Board members on the documents. Action item accomplished.**
- review process for handling of members on TCs who belong with organizations that have withdrawn from PQRI. Member will need to be removed from the TC, and where appropriate, make seek vetting/sponsorship through another PQRI member organization.
- Adhoc committee of four SC members will review and update the bylaws and policies and procedures based on what was voted on last February 2006. There is some confusion about which version of the bylaws is the correct version, and which should then be posted on the web. **Send copies of the various documents to the committee members for their review. Action item accomplished.**
- SC addressed the WG member selection process and cautioned that we need to be very careful in how we couch our rejection of nominations for WGs. When a letter is sent to the volunteer, we need to make sure that we are positive in our outlook thanking them for their offer of service and perhaps suggest other venues that PQRI could benefit from their assistance. A good example given was perhaps utilizing folks as reviewers of final paper/products of the work group to get them engaged in some manner in the business of the Institute.
- Discussed the SCs new proposal for focused workshops and in particular the proposal by the AAPS Inhalation Therapy Focus Group. The Focus Group was asked to readdress the scope of their discussions to make sure they include PhRMA as well as generic issues in order to solicit PhRMA's support of the workshop. **SC will work with the ITFG to help them reframe their workshop.**
- presentation to PhRMA TLC in April went very well and was received favorably by PhRMA. Two concerns raised include 1) those groups which have recently left PQRI (ISPE and GPhA) and, 2) the number of members that will be on the new TC being formed.
- **Chairs of Board and SC to reconnect with FDA to confirm that FDA is actively engaged in PQRI projects in the early phases to ensure proper direction of the WGs.**

Old Business

- Health Canada was invited to participate as an observer at the May 31, 2007 SC meeting. Two Health Canada reps were present via teleconference. An email was received following the teleconference with questions regarding membership and participation on the various committees. *PQRI to draft email back to Health Canada advising them of the process and directing them to the PQRI website for details regarding PQRI bylaws. Action item accomplished immediately following Board meeting.*
- Board discussed the Member Assessments for FY08 and a motion was made and seconded to continue to assess member organizations at the 50% rate. That would be 50% of their original agreed upon amount. This would bring in a total revenue of \$75,000 for FY08. *PQRI to solicit and email vote from other Board members in reference to this action. An electronic email vote was taken with other Board members which obtained an approval of 5/5 of the Board members to the motion. PQRI to draft letter to member organizations from Chair as well as an invoice. Letter will outline the active spending of research funding on the various projects ongoing at PQRI. PQRI to send email to member org. reps to give them a heads up of upcoming assessment notice. All action items were accomplished by June 11, 2007.*
- Board reviewed the budget sheets from FY07 and made some projections and requests for the FY08 budget process. *PQRI to send email to TCs asking them to ask their WG Chairs for budget information for any projected extraordinary expenses for inclusion in the FY08 budget. PQRI to ask AAPS accounting if they can include a section in the Operating Budget which shows the total costs for Meeting Expenses. This will include the committee as well as work group meetings expenses. Just add a separate category to show these expense totals. The breakdown detail information from the budget is available through Journyx for Board review when necessary. Action items accomplished as the account manager has set up the requested category for board review. PQI secretary also created FY08 worksheet and added in her cost projections and sent to Treasurer for his input and review on June 6, 2007. Information needed prior to the end of June for Board review and approval prior to submitting budget to AAPS for their handling.*

New Business

- Board reviewed and discussed the Academic Reimbursement Guidelines. The decision was made to adjust the nightly hotel rate to a maximum of \$250 and the daily food rate to \$75. *PQRI to acquire electronic vote from other Board members to approve this action item. Action item accomplished with a 5/5 Board vote to approve the increase in reimbursement costs.*
- Board discussed the AAPS request for consideration of purchasing website insurance. AAPS had forwarded some literature on the issue and a projected cost of \$2,000-\$3,000 per year (which comes out to 10% of the AAPS premium). Board felt that if in fact PQRI is covered under AAPS' umbrella policy, they would like to see the breakdown of what the actual incremental costs are to insure PQRI. Board felt that 10% of AAPS' costs were a bit high for PQRI to absorb as our website is minuscule in comparison to AAPS' site needs. *PQRI to request additional information from AAPS for the Board's consideration. Action item accomplished. Additional information was requested via email on June 1, 2007.*

Board Meetings for 2007

It was agreed that Board meetings would be scheduled in conjunction and adjacent with SC meetings. Therefore, the next Board meeting will be a teleconference scheduled for August 17, 2007 from 1:00 pm – 2:00 pm. The next face to face meeting will be held on December 6, 2007 immediately following the Steering committee meeting in DC.

There being no further business of the Board, a motion was made to adjourn the meeting at 12:05 p.m.