November 6, 2014

Joe V. Selby, MD, MPH  
Executive Director  
Patient-Centered Outcomes Research Institute  
1701 Pennsylvania Ave., NW, Suite 300  
Washington, DC 20006

Dear Dr. Selby:

The Advanced Medical Technology Association (“AdvaMed”) appreciates this opportunity to comment on the Patient-Centered Outcomes Research Institute’s (“PCORI”) draft Proposal for Peer Review of Primary Research and Public Release of Research Findings (the Proposal).

AdvaMed’s member companies produce the life-saving and life-enhancing medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

We offer the following comments below for PCORI’s consideration. In addition, we look forward to continuing our engagement with PCORI on issues that could significantly affect medical device manufacturers.

Proposal for Peer Review
AdvaMed agrees with PCORI that a strong peer review process can add to the credibility and trustworthiness of PCORI-funded research findings. AdvaMed also agrees that any peer review process conducted by PCORI should not interfere with an investigator’s or research institution’s ability to publish research results in peer-reviewed journals.

Manufacturer Participation on Review Team
Our main comment relates to the review team. PCORI suggests in its proposal that methodological and scientific review will be performed by methodologists and scientific content experts in the appropriate fields who must disclose their conflicts of interest.

Since PCORI’s inception, AdvaMed has appreciated and supported PCORI’s efforts to be open and transparent in its processes. We have been especially pleased with PCORI’s outreach to the medical device industry for input on proposals and participation in meetings, webinars and other
public forums. We therefore find it notable that the Proposal did not include any discussion regarding industry input.

As we have commented many times in the past, AdvaMed’s member companies have on staff clinical and scientific experts who are committed to developing innovative devices, diagnostics and other advanced medical technologies and whose valuable clinical experience can enhance the quality of the PCORI research during all phases.

**AdvaMed recommends that the Proposal be amended to clarify that clinical, scientific and technical experts from device manufacturers may be among those chosen as methodologists or content experts as appropriate to participate on review teams as part of the peer review process for particular studies.** AdvaMed can be helpful in facilitating this process by reaching out to our member companies to recommend such experts.

*Public Release of Research Findings*

Regarding the public release of research findings, we understand the time constraints placed on PCORI by the authorizing legislation. PCORI is proposing to post to its website, within 90 days of PCORI’s acceptance of a final report, a 500-word summary or abstract, along with results table and ancillary information for patients and the general public with readability at an 8th-grade level. PCORI further proposes to make the final report of each study publicly available on its website not later than 12 months after the final report is accepted for publication by a journal.

We note that the final report published in a peer-reviewed journal may differ to some degree from the report that was accepted by PCORI. Such changes may be editorial or more substantial, but either way could render the final published report inconsistent with the final report accepted by PCORI. One solution may be to provide a link from PCORI’s website to the journal publication, noting the potential for such changes. However, inconsistent information could create concern by some parties – e.g., physicians, patients and caregivers – that the information itself is inaccurate. PCORI could also consider accepting the final journal article as the final PCORI report. PCORI will need to develop a systematic way to address such inconsistencies.

We are concerned about the posting of ambiguous, inconclusive or incomplete research results. Such findings must be very carefully managed. While there may be some benefit to patients in posting such research findings, these can also be confusing and difficult to understand, particularly if data is interpreted differently in a final journal publication.

**AdvaMed recommends that PCORI develop approaches for dealing with such research findings, particularly as such research may relate to specific medical technologies.** Again, we are happy to work with PCORI to discuss and develop potential approaches.

Finally, it is important to remember that PCORI-funded research is intended to be patient-centered. The research findings that will be posted to the PCORI website will be used by real patients, and their caregivers, to help them understand and digest important information so they can make critical health care decisions for their own unique situations and preferences.
It is critical that the research abstracts and ancillary information be summarized in such a way that it is clear and accurate, yet understandable to the general public.

AdvaMed greatly appreciates the PCORI’s efforts thus far to operate in an open and transparent manner, and to incorporate stakeholder input along the way. We have stated in our policies that openness and transparency in all aspects of research – from determining priorities to establishing research methodologies to providing opportunities for meaningful feedback at various stages in the research process – will enhance the credibility and strength of the ultimate conclusions of that research.

We believe AdvaMed’s engagement in these activities can be particularly meaningful. We would be pleased to answer any questions regarding these comments. Please contact Chandra Branham, JD, Vice President, Payment and Health Care Delivery Policy, at (202) 434-7219 or cbranham@AdvaMed.org if we can be of further assistance.

Sincerely,

Donald May
Executive Vice President, Payment and Health Care Delivery Policy