March 15, 2012

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 respond to the Patient-Centered Outcomes Research Institute’s ("PCORI") request for public comments on its draft National Priorities for Research and Research Agenda, issued on January 23, 2012.

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.

AdvaMed has closely monitoring the activities of the PCORI since its inception, and has provided feedback on a number of occasions, including making a public statement during the recent PCORI National Patient and Stakeholder Dialogue session on February 27, 2012, in Washington, DC. We look forward to continuing to engage with the PCORI an ongoing discussion with Medicare coverage policy staff regarding possible revisions to this important document.

As we stated in our comments at the public session last month, we appreciate PCORI’s efforts to be open and transparent in its process of developing national priorities for patient-centered research and a national agenda to advance those priorities. In addition, we support PCORI’s mission to provide patients, caregivers and clinicians with evidence-based information that can help them make better-informed healthcare decisions.

Upon reviewing the draft priorities and research agenda, we do want to raise three key areas of concern to PCORI’s attention:
1) The broad scope of the draft National Priorities and Research Agenda does not lend itself to meaningful public comment;
2) It remains essential for PCORI to focus on clinical comparative effectiveness research; and
3) PCORI should provide stakeholders the continued opportunity to give meaningful feedback at each stage in the process.

1) **First, the scope of the draft National Priorities and Research Agenda is very broad and does not lend itself to meaningful public comment.**

The draft priorities and research agenda are extremely broad. We understand that PCORI has attempted to provide a framework for identifying broad questions that can be addressed through evidence-based research to improve the patient experience of care and enable better, more informed medical decision-making. We also agree that the five areas that PCORI has identified as priority areas (addressing assessment of prevention, diagnosis and treatment options; improving healthcare systems; improving communication and dissemination of patient-centered information; addressing disparities; and accelerating patient-centered and methodological research) are undoubtedly important areas where comparative clinical effectiveness research could be beneficial to patients and physicians.

However, these five areas identified by the PCORI, while important, are so broad that it is difficult to provide detailed comments at this time. Therefore, we emphasize the importance of providing additional opportunities for meaningful comments as the research agenda becomes more detailed with respect to specific research topics. For example, PCORI should include opportunities to provide input when specific research topics are identified in the future, as well as opportunities to comment on preliminary research findings.

2) **Second, it is essential for PCORI to focus on clinical comparative effectiveness research.**

AdvaMed has long supported the use of comparative effectiveness research to inform medical decision making, not to replace medical judgment or interfere with the doctor-patient relationship. The objective of CER should be to provide better evidence for patients and their physicians to use in making individual clinical decisions.

Therefore, we want to reiterate that the research the PCORI ultimately funds should be patient-centered clinical effectiveness research – focusing on clinical outcomes, effectiveness, risk and benefits. Research that emphasizes comparative clinical outcomes and effectiveness ultimately will improve quality of care and will have a positive impact on overall improvements and efficiencies in the health care system.

3) **Finally, PCORI should provide stakeholders the continued opportunity to give meaningful feedback at each stage in the process.**

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
oppeness 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.

At the recent PCORI Board of Governors’ meeting held on March 5, 2012, in Baltimore, MD, the Board stated that PCORI intends to analyze and incorporate the public comments received on the draft priorities and research agenda into a revised version and to adopt the revised version in advance of releasing broad PCORI Funding Announcements in May of 2012 for the first four priority areas discussed above. Again, we would argue that until there is greater detail available regarding specific research topics, it is difficult to provide meaningful comment or clinical input that would be helpful to the PCORI.

The PCORI has stated many times that the development of its priorities and research agenda will be an ongoing process, with continuous opportunities to refine the documents and to specify potential areas of research. Therefore, AdvaMed looks forward to ongoing opportunities to engage in these discussions.

We believe our engagement can be particularly meaningful once PCORI begins to identify specific research areas and topics. The clinical experts who are devoted to developing and manufacturing innovative devices, diagnostics, and other advanced medical technologies have valuable clinical experience and expertise that will enhance the quality of the PCORI research.

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,

Ann-Marie Lynch
Executive Vice President, Payment and Health Care Delivery Policy