



805 15<sup>th</sup> Street NW, Suite 650 | Washington, DC 20005 | (202) 466-8700  
[www.CriticalCareRoundtable.org](http://www.CriticalCareRoundtable.org)

*The Critical Care News Summary is an update from the Roundtable on Critical Care Policy. For further information on the Roundtable, please visit our website at [www.CriticalCareRoundtable.org](http://www.CriticalCareRoundtable.org).*

## Roundtable News

# Please Save the Date!

### Congressional Outreach Day

**When:** Wednesday, October 5, 2011  
8:30a.m. – 2:30p.m

**Where:** Capitol Hill  
Washington, D.C.

**Additional details and a formal invitation to follow shortly.**

## Federal Activity

### Patient-Centered Outcomes Research Institute

On Tuesday, the Roundtable submitted public feedback to the Patient-Centered Outcomes Research Institute (PCORI) in response to their request for input on eight initial topics for a series of “Tier 1” pilot projects. The eight areas of interest for projects identified by PCORI are intended to assist PCORI in establishing national priorities for research; support the development of novel methods or the collection of preliminary data that can be used to advance the field of patient-centered outcomes research (PCOR); and inform the development of a future PCORI research agenda.

One of the Roundtable’s priorities has been to advocate for research that will improve the quality and safety of care delivered to the critically ill and injured. As such, the Roundtable has recommended that future PCORI research topics and priorities support the production and promotion of evidence-based research that seeks to improve outcomes for the critically ill and injured, stating, “Given the current lack of comparative effectiveness data coupled with the considerable volume of resources used by critical care medicine, the prioritization of critical care within PCORI’s research topics could greatly accelerate improvements in quality and safety for the critically ill and injured. Doing so would not only lead to improvements patient experience and outcomes, but would also result in the delivery of more efficient care.”

To view the Roundtable’s submission, please click [here](#).

Similarly, the American Medical Association also submitted feedback to PCORI regarding the type of research that should be conducted by PCORI, urging the institute not to give short shrift to underdeveloped research areas, including critical care: “Focusing PCOR on areas where there is the most clear effectiveness data is an attractive and logical decision since the more data that is available, the easier it is to generate the research. However, this approach could underemphasize critically important areas where the body of research is much less or newer as is the case with pulmonary, critical care and sleep medicine. It is important that PCOR efforts consider this issue in assigning priorities.”

PCORI will issue a request for applications (RFA) for pilot project grants in late September, which will focus on methods and approaches appropriate to PCOR, including observational methodologies, systematic reviews, mixed methods and qualitative methodologies, simulations, small pragmatic pilot trials and survey methods.

Additionally, yesterday, PCORI issued a Request for Proposals (RFP) for two landscape reviews on eliciting the patient’s perspective in patient-centered outcomes research. The deadline to provide notice of intent to respond to either of these solicitations is September 15, 2011, and proposals are due October 6, 2011.

Direct links to each RFP are provided below, and the RFPs can be downloaded here from the PCORI website under the “Funding Opportunities” tab.

- [Review and Synthesis of Evidence for Eliciting the Patient's Perspective in Patient-Centered Outcomes Research \(Literature Review\)](#)
- [Expert Stakeholder Interviews to Identify Evidence for Eliciting the Patient's Perspective in Patient-Centered Outcomes Research \(Interviews\)](#)

## **The White House**

President Obama has issued a Presidential Proclamation declaring this September “National Preparedness Month” in honor of the 10<sup>th</sup> anniversary of the September 11<sup>th</sup> attacks, and in response to the hurricane that devastated the Midwest and the South throughout the Spring and the effects of the recent hurricane.

States the President in his Proclamation, “Whenever our Nation has been challenged, the American people have responded with faith, courage, and strength. This year, natural disasters have tested our response ability across all levels of government....Preparedness is a shared responsibility, and my Administration is dedicated to implementing a ‘whole community’ approach to disaster response. This requires collaboration at all levels of government, and with America's private and nonprofit sectors. Individuals also play a vital role in securing our country. The National Preparedness Month Coalition gives everyone the chance to join together and share information across the United States.” To view the full Proclamation, please click here.

When our nation is faced with a health emergency such as a natural disaster or a terrorist attack, the critical care delivery system is an integral component of our nation’s medical response, and since the Roundtable’s inception one of our top priorities has been identifying the challenges and needs to optimizing the delivery of high quality critical care services in the event of a major public health crisis. The Roundtable will be working to highlight the importance of national preparedness throughout the

month, including with the upcoming vote in the House of the bipartisan Pandemic and All-Hazards Preparedness Reauthorization Act of 2011.

The Roundtable applauds the President for his efforts to encourage Americans to recognize the importance of preparedness and working together to enhance our national security, resilience, and readiness, and salutes the professionals and organizations dedicated to providing medical care of the critically ill and injured during a major public health crisis.

## News and Reports

**“FDA agrees to speed reviews in exchange for drugmakers continuing to pay millions in user fees,”**  
***The Washington Post*, September 1<sup>st</sup>, 2011**

On Thursday the Food and Drug Administration unveiled a draft agency-industry negotiated agreement to reauthorize the Prescription Drug User Fee Act, with performance goals, dispute resolution procedures, drug safety enhancements and regulatory science improvements constituting the core tenets of the pact, which will now undergo public scrutiny before being officially transmitted to Capitol Hill. The deal comes after months of closed-door meetings between FDA and drug industry officials working to extend a two-decade old program that supplements the agency’s budget with company funding.