March 15, 2012

Dr. Gene Washington  
Chairman  
Patient-Centered Outcomes Research Institute Public Comments  
1701 Pennsylvania Avenue, N.W., #300  
Washington, DC 20006

Re: NAMI Comments on PCORI’s Draft Research Priorities and Research Agenda

Dear Dr. Washington:

On behalf of the National Alliance on Mental Illness (NAMI), I am pleased to submit the following comments to the Patient Centered Outcomes Research Institute’s (PCORI) draft research priorities and research agenda. NAMI is the nation’s largest organization representing people living with serious mental illness and their families. Through our 1,100 affiliates in all 50 states, NAMI is engaged in education, support and advocacy designed to improve the lives of individuals living with serious mental illnesses such as schizophrenia, bipolar disorder, schizoaffective disorder, borderline personality disorder, major depression and severe anxiety disorders such as PTSD.

As a patient and disease advocacy organization, NAMI strongly supports the PCORI Board’s commitment to aggressive outreach to patients and their family caregivers as central to your mission. We are extremely encouraged by the progress you are making on your efforts to reach out to, and meaningfully engage, patients. In addition, NAMI also supports the PCORI’s critical mission to conduct comparative clinical effectiveness research using an open, transparent process that includes opportunities for broad stakeholder input. We believe that a sound, patient-centered CER program is an important element of high-quality, effective health care in the years ahead.

NAMI was pleased to participate in the very productive February 27 forum on the draft research priorities and research agenda held at the National Press Club in Washington. We are hopeful that PCORI can hold similar events – both in Washington, DC and across the country – to ensure maximum opportunities for input from all stakeholders, most especially patients.

NAMI would like to make the following specific comments regarding PCORI’s draft priorities and research agenda:

**PCORI should set national research priorities based on the specific conditions, interventions and health outcomes that matter most to patients, providers, and caregivers.**

NAMI is concerned that PCORI’s current draft research priorities and research agenda lack sufficient specificity about the types of research priorities and the “national research project agenda” required by the statute that the institute intends to fund. For example, the draft research priorities and agenda are currently very broad subject areas that essentially provide a more
detailed description of PCORI’s authorizing statute. In NAMI’s view, this approach appears to be inconsistent with statute, and will not allow patients in a particular disease area to provide meaningful input about the interventions or outcomes that matter to them. Instead, these decisions are likely to be pushed into a closed, nonpublic, grant-making process.

It is important to note here that the draft priorities articulated by PCORI are an accurate restatement of the priorities set forth in its authorizing statute and prior research prioritization efforts. As noted by in the PCORI in its overview, the statute points out a set of criteria (the “PCORI Criteria”) to be considered in formulating the Priorities and Agenda:

“...identify national priorities for research, taking into account factors of disease incidence, prevalence, and burden in the United States (with emphasis on chronic conditions), gaps in evidence in terms of clinical outcomes, practice variations and health disparities in terms of delivery and outcomes of care, the potential for new evidence to improve patient health, well-being, and the quality of care, the effect on national expenditures associated with a health care treatment, strategy, or health conditions, as well as patient needs, outcomes, and preferences, the relevance to patients and clinicians in making informed health decisions, and priorities in the National Strategy for quality care established under section 399H of the Public Health Service Act that are consistent with this section.” (42 USC 1320e(d)(1)(A))

In NAMI’s view, the statute envisioned a process by which PCORI would take its statutory guidance, along with outside input from entities such as the IOM, to develop a specific set of priorities. The statute articulates first developing a set of priorities that is specific enough to subsequently establish a research agenda that takes “into consideration the types of research that might address each priority and the relative value (determined based on the cost of conducting research compared to the potential usefulness of the information produced by research) associated with the different types of research, and such other factors as the Institute determines appropriate.” 42 USC 1320e(d)(1)(B) Unfortunately, the non-specific priorities articulated by PCORI simply reflect broad themes of agreement, and not real research priorities.

The research agenda was envisioned by the statute to be guided by the draft priorities, with additional insight provided by expert advisory panels. The statute states, “The Institute may appoint permanent or ad hoc expert advisory panels as determined appropriate to assist in identifying research priorities and establishing the research project agenda under paragraph (1) and for other purposes.” 42 USC 1320e(d)(4)(A)(i) The statute also provides for resources to ensure the effective participation of patient and consumer representatives on the Board. 42 USC 1320e(d)(5) It is important to note that the statute recognizes the significance of setting the research priorities and research agenda, by explicitly stating that the activities related to establishing research priorities and a research agenda are non-delegable by the Board (per 42 USC 1320e(e)(2)), and does not ever envision an investigator-initiated research agenda.

PCORI’s national research priorities should focus on comparative clinical effectiveness research, not cost.
In comments last year on PCORI’s draft definition of “patient-centered outcomes research,” many organizations representing patients and other stakeholders urged the Institute to delete language in the draft definition that included cost as a factor in PCORI’s research. Many commenters expressed concern that this language went beyond PCORI’s statutory mandate to conduct comparative clinical effectiveness research. However, PCORI has chosen not to respond to this input and modify the “patient-centered outcomes research” definition based on these recommendations.

NAMI has consistently argued against inclusion of cost analysis in any new national program for comparative clinical effectiveness research; the Affordable Care Act’s clear focus on clinical and patient health outcomes was one of the reasons we strongly supported it. We remain deeply concerned that PCORI now has decided, in its first major policy decisions, to explicitly add cost to its agenda. For example, in describing its draft research agenda, PCORI says comparisons of tests and treatment options should focus on “clinical, social, economic, and geographic factors that may affect patient outcomes.”

It is well-recognized that a wide range of cost and economic factors can influence patient outcomes. However, inclusion of these factors in comparative assessments of value also is very controversial, complex and subjective. While we appreciate that PCORI may intend to focus on cost analyses other than strict cost-effectiveness, we believe this ultimately will be a distinction without a difference from the standpoint of advancing a patient-centered research agenda. While costs can impact patient care, the expansion of PCORI’s mandate to include cost will lead to an agenda that ultimately is payer-centric and cost-based. Instead, PCORI should align its agenda with patient-centered research as defined in statute and delete the references to cost.

In order to achieve a research agenda that is truly patient-centered, PCORI should employ a clear, transparent process that responds to public input.

Without an open, public process for gaining comments and input from patients, providers and clinical experts on specific research topics and questions, PCORI will not be able to define a cohesive agenda for answering the research questions that matter most to patients. NAMI is concerned that the process articulated by PCORI is never envisioned by the statute, and involves delegating authority to the health research community to establish the research agenda and the specific conditions and diseases to be researched.

PCORI has taken some important steps to provide for public input and transparency in its decision-making on research priorities. However, additional improvements are needed to give patients, providers and the public full opportunity for input, and to give them assurance that their input will be fully considered, including:

1) Moving forward, PCORI needs to identify specific research priorities in the coming months, it should encourage meaningful public input on both the research priorities and research agenda by allowing separate, sequential comment periods as envisioned by statute. PCORI should not rely on this singular comment period as sufficient input before moving forward with finalizing the priorities and agenda in mid-April as planned.
2) Extending the time period for PCORI consideration of comments. NAMI is concerned that the current process is extremely compressed. The timetable described by PCORI only provides 45 days at most between the end of the comment period and the time the PCORI Board is planning to finalize the priorities. This compressed timetable conveys an impression that public input will not be taken seriously, and should be extended.

3) Defining a formal mechanism for responding to public input in finalizing the research priorities and agenda.

4) Finalizing PCORI’s conflict of interest policy, including real conflicts of interest as defined in the statute, before issuing funding announcements based on the research agenda. The statute clearly states that contracts for the management of funding and conduct of research must “abide by the transparency and conflicts of interest requirements under subsection (h) that apply to the Institute with respect to the research managed or conducted under such contract.” At the March PCORI Board meeting, three people were nominated for PCORI’s Standing Committee on Conflict of Interest. NAMI looks forward to learning more about the Committee’s findings.

NAMI is grateful for the opportunity to offer comments on the draft research priorities and research agenda. We look forward to future opportunities to offer input into the work of the PCORI and the future of comparative effectiveness research.

Sincerely,

Michael J. Fitzpatrick, MSW
Executive Director