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Washington, DC 20006

Dr. Joe Selby  
Executive Director  
PCORI  
1701 Pennsylvania Ave. NW, Suite 300  
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Dear Dr. Washington and Dr. Selby:

I am pleased to be writing to you on behalf of the Partnership to Improve Patient Care. As you know, PIPC and our member organizations strongly supported the legislation creating the Patient-Centered Outcomes Research Institute, and we appreciate your considerable efforts and progress in establishing PCORI. We believe that a sound, patient-centered CER program is an important element of high-quality, effective health care in the years ahead.

As PCORI now begins the important process of defining comparative clinical effectiveness research priorities and a research agenda, we urge you to do so through procedures that are fully open and transparent and provide adequate opportunities and sufficient time for meaningful input from the patient and provider communities. I believe the single most important outcome PCORI can achieve in the year ahead is to establish decision-making and operating procedures that build buy-in and trust from the patient and provider communities and the public at large.

From day one, the issue of research priority-setting has been of central importance to us. As I noted in an October 2010 article in *Health Affairs*, transparency and public input will help ensure “that all who wish to participate in the institute’s projects or observe its processes are able to do so,” and are essential to building broad public trust and support. PIPC expanded on these concepts in two recent White Papers, which we sent to the PCORI Board in March of this year.

Our first White Paper outlined the framework of the health reform law creating PCORI, and the key elements of stakeholder involvement, transparency, public participation, and open decision-making that are included in the law. Our second White Paper published in March 2011 identified important elements of priority-setting processes for comparative effectiveness research (CER) based on a survey of the literature and statements of various stakeholders. The white paper highlighted five key elements of a patient-centered priority setting process including transparency and openness, broad stakeholder participation, a range of input opportunities, clinical input and guidance, and systematic input by decision-makers of information received. The elements described in both of

these White Papers will be particularly useful for PCORI to consider as it begins the process of setting the institute's research priorities and agenda in a manner that is both consistent with its authorizing statute and that builds credibility among stakeholders.

Citing prior work at the Institute of Medicine, for example, PIPC's White Paper on priority setting noted that a sound procedure "must present the logic of the process clearly and carefully to others," and "should be explicit, so that people can trace backwards from results to inputs and so satisfy themselves that the process was fair." The paper also explained why "clinical expertise is vital to the priority-setting process." PCORI is now at the point where these critically important procedures are being established. As you work to finalize these procedures, we ask you to consider including the following elements:

- **PIPC strongly recommends that PCORI provide separate, sequential public comment periods on the CER research priorities and CER research agenda.** We are concerned that PCORI appears to be planning on providing a single comment period on both priorities and the research agenda, and believe this would have the effect of eliminating an opportunity for comment on research priorities. The statute appears to envision sequential development of priorities and projects (for example, in stating that the research project agenda should take "into consideration the types of research that might address each priority"), and thus would require separate comment periods. PCORI should allow for separate 60 day-comment periods (the maximum allowed by statute), beginning with the national priorities and once those are finalized, moving to the establishment of a research agenda. We also encourage PCORI to develop draft priorities that are at a sufficient level of specificity to allow for meaningful input; the specific research priorities within broad categories are far more important to patients and providers than the broad categories themselves. PIPC believes that separate comment periods would benefit PCORI by helping to facilitate commentary from patient organizations that can be extremely limited in time and staff (having a concurrent comment period may lead to organizations only submitting one set of comments to PCORI or being unable to devote time to fully comment on two such broad proposals).
- In addition, as PCORI develops draft research priorities and a research project agenda, we ask you to **provide adequate opportunity for broad input from patients, physicians and other providers with relevant clinical expertise.** This is essential to defining a patient-centered CER research agenda. As noted by PIPC Steering Committee member Kathleen Teixeira in a statement at PCORI's Board meeting in July, "Defining a patient-centered research program will require strong, ongoing involvement from physicians and other care providers. The statute requires PCORI to communicate research findings in ways that are 'comprehensible and useful to patients and providers in making health care decisions.' This cannot happen unless physicians and providers are involved early and often in the research process, particularly in identifying research priorities and defining research questions. If a study is not asking a question that is relevant to the needs of patients and providers, no amount of effort will enable you to communicate the results in a way that is useful to providers." Achieving meaningful input will require mechanisms beyond a single 60-day

comment period. The statute itself recognized this, calling for the Board to take additional steps to support patient advocates, and to create ad hoc experts of clinical experts and others with relevant expertise.

- **PCORI should describe a systematic process for describing how input it receives will be considered and incorporated (for example, input from focus groups and written public comments).** To the extent PCORI can demonstrate to stakeholders that their input is valued and considered, stakeholders are more likely to remain engaged in PCORI's work, and the research the Institute produces will be viewed as credible. As the priorities and research agenda are being drafted and finalized, stakeholder input should be sought prior to and after a first revision. PCORI should make clear from the outset the process for updating the priorities and research agenda, including the timing and scope of the activity. It may also be worthwhile for PCORI to make available all public comments that are submitted; this could help organizations find others with similar priorities as well as demonstrate full transparency and consideration of public input.

PIPC recognizes that PCORI's task of identifying and implementing an agenda for patient-centered CER is not an easy one. PIPC commends PCORI for working towards your first formal public comment period on the national priorities for research; we further recognize that the task of defining an agenda for patient-centered CER is not simple. We believe the steps we have identified are basic elements of an effective, efficient decision-making process to help achieve this goal. Please call on me at any time to discuss PIPC's recommendations. Thank you for your hard work and dedication.

Sincerely,

A handwritten signature in black ink, consisting of a stylized initial 'T' followed by the name 'Coelho' in a cursive script.

Tony Coelho

cc: PCORI Board Members