

Partnership to Improve Patient Care (PIPC)
Comments by Kathleen Teixeira to the Patient-Centered Outcomes
Research Institute
July 18, 2011

My name is Kathleen Teixeira and I am here to speak on behalf of the Partnership to Improve Patient Care (PIPC) and as the Senior Director of Government Affairs for the American Gastroenterological Association, which has 17,000 members from around the globe. The AGA is a Steering member of PIPC for our shared interest in supporting comparative effectiveness research that strengthens physician and patient decision making, improves health care quality, and supports continued medical progress.

PIPC supports PCORI's work to define and build a program for patient-centered outcomes research, and PIPC commends the PCORI Board for taking steps to create a new research program that is patient-centered. We appreciate the Board's recognition that the Affordable Care Act is unique in its focus on the needs of patients and their caregivers, and bold in defining a patient-centered framework for comparative effectiveness research.

I would like to make two points in my time today:

- 1) Physicians and care providers must play a vital role in advancing patient-centered outcomes research.
- 2) PCORI's definition of patient-centered outcomes research should focus more explicitly on patients and their caregivers.

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. The law also gives the Institute the option of creating additional expert advisory panels to assist "in identifying research priorities and establishing the research project agenda." We recommend that PCORI consider creation of such panels as a means of obtaining the needed clinical expertise into its decision-making.

The physician community would welcome the opportunity to participate in advisory panels not only to identify research priorities but also throughout the research process to ensure that the right questions are asked, that the research methodology answers the questions in a meaningful way, and that the outcomes are disseminated in a manner that is easily incorporated into practice for patients.

Second, PCORI's work to finalize a definition of "patient-centered outcomes research" will be a very important process. PIPC is very supportive of language in the working definition that emphasizes the need for research to focus on questions that matter to patients and their physicians. We also are pleased that it recognizes the importance of considering individual preferences, autonomy and needs, and a wide variety of settings and diversity of participants.

At the same time, PIPC urges PCORI to consider several changes to the definition. First, clearly state a focus on needs of patients, their caregivers and providers. Patient-centered outcomes research should be defined as research that is "intended to help patients make informed healthcare decisions" and is "responsive to the expressed needs and preferences of patients and their care providers."

The definition should align with the research definitions included in the health care reform law by stipulating that research is intended to provide information comparing the clinical effectiveness and health outcomes of different health interventions. Third, the definition should consistently focus on patients and providers as the primary end-users of the research, and on clinical and health outcomes as the research endpoints. Language that broadens the definition to other stakeholders and questions of resource allocation should be deleted. While these dimensions of research are important, they go beyond the scope of patient-centered outcomes research.

In addition, we recommend that PCORI include open, transparent procedures as a characteristic of patient-centered outcomes research. Strong provisions on openness and transparency are a hallmark of the health reform law's provisions creating PCORI, and are essential to achieving a patient-centered program.

To that end, we commend PCORI for proactively soliciting public input on its draft definition of patient-centered outcomes research, and providing a clear deadline for comments. We hope this establishes a precedent for other policy and program decisions facing the Institute, such as conflict of interest policies. Open, transparent procedures and broad stakeholder input also will be essential as the Institute begins the process of setting research priorities. In addition to soliciting public input, the Institute also should describe how it considers public comments in its final policy decisions.

In closing, I am pleased to be here and look forward to the potential of PCORI to create a distinct and truly patient-centered CER program. We believe that with sufficient, meaningful input from the patient and provider communities, PCORI will achieve the goal of a sustained, national program for patient-centered outcomes research.