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March 14, 2012

Joseph V. Selby, MD, MPH
Executive Director
Patient-Centered Outcomes Research Institute
Public Comments
1701 Pennsylvania Avenue, NW
Suite 300
Washington, DC 20006

Dear Dr. Selby:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments as part of the Patient-Centered Outcomes Research Institute's (PCORI) draft National Priorities for Research and Research Agenda. The AMA supports the investment in comparative effectiveness research (CER) as an important activity to expand the evidence base of medicine and produce improved patient outcomes.

As a threshold matter, the AMA applauds the PCORI's efforts to solicit input on the draft priorities and research agenda. We support the creation of an established PCORI mechanism that facilitates ongoing input from individual physicians, state medical associations, and national medical specialty societies concerning national priorities as well as physician participation in other components of the CER enterprise, including research, dissemination, and uptake. The PCORI's success hinges on partnering and leveraging relationships with organizations that are trusted sources to physicians in their practice management and medical decision-making. We urge you to identify and implement additional strategies and initiatives to expand the CER enterprise to physician practices outside of academic medical centers and into small-and medium-size physician practices.

National Priorities and Research Agenda

The initial priority areas of CER should focus on high volume, high cost delivery models, modalities, and other health services which evidence significant variation in practice. Related to the foregoing, the national CER priorities should, at a minimum, address the prevention, management, and treatment of preventable disease which collectively represent a major cost-driver in today's health care system. Areas in need of further study and research

include cardiovascular, endocrinology and metabolic disorders (including diabetes), and nutrition (including obesity). For example, in the area of wellness, prevention, nutrition, and obesity there is a paucity of CER findings. It is an area with a wide range of available interventions with little clarity about which is most effective.

The AMA urges the PCORI to strategically target support for CER where it will significantly improve health care value by enhancing physician clinical judgment, fostering the delivery of patient-centered care, and producing substantial benefit to the health care system as a whole. This requires an initial focus on conducting actual CER. While we support initiatives and efforts that are designed to increase and expand on shared decision-making, there is a profound need to produce comparative clinical information in the first instance. The AMA urges PCORI to fund specific scientific research studies comparing treatments and therapies.

We also strongly urge PCORI to prioritize support for two powerful infrastructure mechanisms, clinical registries and clinical data networks. This infrastructure will not only produce research findings, but play a key role in priority-setting as well as uptake and adoption of findings in a rapid cycle. Clinical data registries allow health care stakeholders to observe patterns of care and the effectiveness of various interventions over time. Randomized controlled studies, although ideal, are not always feasible to obtain, especially for surgical procedures and rare diseases.

Individual Variation and Rare and Understudied Conditions

There is broad agreement that PCORI must ensure that CER is designed, communicated, and used in ways that recognize variation in individual patients' needs, circumstances, preferences, and responses to particular therapies, rather than encouraging one-size-fits-all solutions based on population averages. Because prevalence rates and the most effective interventions for many diseases vary greatly by race, ethnicity, gender, age, geography, and economic status, we support the inclusion of racial and ethnic health disparities—and health disparities more generally—as a CER priority area. Similarly, the PCORI should support personalized medicine and the ability of physicians to tailor treatments to the needs of individual patients based on genetic information and other factors. The foregoing is achieved, in part, by focusing on adopting PCORI priorities and policies that reward applicants that utilize methodologies, research practices, and data collection techniques that power research findings generally as well as more granular findings in the context of health disparities and personalized medicine.

Future CER Priorities and PCORI Strategies

CER usually considers technology and pharmaceuticals, but behavioral interventions potentially could have the greatest impact for individual patients and system-wide as PCORI assess future needs. Prioritizing interventions designed to change physician behavior and to effect behavioral change in patients is necessary, as are other clinical interventions, technologies, and pharmaceutical remedies.

Joseph V. Selby, MD, MPH

March 15, 2012

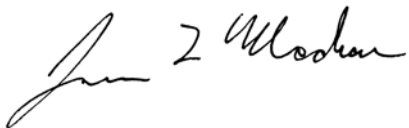
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PCORI Priorities and Research Agenda Area and the Patient Voice

A strong patient-physician relationship will result in higher quality health care. The same holds true for appropriately and meaningfully communicating and using CER at the point of care. Opportunities to strengthen the patient voice in the CER enterprise will occur when there is actual CER available to digest, communicate, and disseminate for use. Many important activities are underway today related to medical decision-making. The AMA has been involved in this work for a long time, and specifically recognizes three core elements in helping patients become active partners in their health care. These include: 1) clinical information about health conditions, treatment options, and potential outcomes; 2) tools to help patients identify and articulate their values and priorities when choosing medical treatment options; and 3) structured guidance to help patients integrate clinical and values information to make an informed treatment choice. To help patients play a more active role in their medical decision-making, we need more comparative clinical effectiveness research. The foregoing is at the heart of what health care stakeholders and Congress intended to achieve with the passage of the ACA and the establishment of the PCORI. Armed with this scientific information we can develop more targeted and effective tools for improving patient engagement in their health care decisions.

The AMA appreciates this opportunity to provide input to the PCORI and welcomes the opportunity to continue working together to increase the quality and rigor of information available to physicians at the point of care in order to drive improved patient outcomes.

Sincerely,

A handwritten signature in cursive script, appearing to read "Jim L Madara".

James L. Madara, MD