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March 15, 2012

[By e-mail submission to comments@pcori.org]

Joseph V. Selby, MD, MPH

Executive Director

Patient-Centered Outcomes Research Institute

5185 MacArthur Blvd. NW Suite 632

Washington, DC 20016

Re: Patient-Centered Outcomes Research Institute Draft National Priorities for Research and Research Agenda, Version 1

Dear Dr. Selby:

The Infectious Diseases Society of America (IDSAs) is pleased to have this opportunity to comment on the Patient-Centered Outcomes Research Institute's (PCORI) Draft National Priorities for Research and Research Agenda, Version 1.

IDSAs represents nearly 10,000 infectious diseases physicians and scientists devoted to patient care, prevention, public health, education, and research in the area of infectious diseases (ID). The Society's members focus on the epidemiology, diagnosis, investigation, prevention and treatment of infectious diseases in the United States and abroad. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, hepatitis, surgical infections, other life-threatening infections caused by unusual or drug-resistant microorganisms, and new and emerging infections, such as severe acute respiratory syndrome (SARS) and pandemic H1N1 influenza.

The Patient Protection and Affordable Care Act (ACA) provided for the creation of PCORI as an independent, non-profit health research organization to direct the conduct of patient-centered outcomes research, with the goal of helping people make informed health care decisions and improve health care delivery. PCORI aims to improve the development, conduct and dissemination of patient-centered outcomes research, defined essentially as "comparative clinical effectiveness" research with the patient at its center. IDSAs applauds PCORI for developing and soliciting public comments on the first Draft National Priorities for Research and Research Agenda that will serve as the framework for building this emerging area of research.

By statutory requirement, PCORI has identified five "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.” The five priorities are:

- Comparative Assessment of Options for Prevention, Diagnosis, and Treatment
- Improving Healthcare Systems
- Communication and Dissemination Research
- Addressing Disparities
- Accelerating Patient-Centered Outcomes Research and Methodological Research

The draft research agenda identifies research areas within each priority.

IDSA recognizes that the initial draft research agenda is broad and open-ended to allow for researchers, patients and other stakeholders to contribute to the shaping of the research agenda. We understand that PCORI plans to refine the research agenda over time and develop targeted funding opportunity announcements in the future. IDSA urges PCORI to consider infectious disease areas that align significantly with PCORI’s national priorities for research and where there are gaps in the current evidence base that would benefit from patient-centered outcomes research.

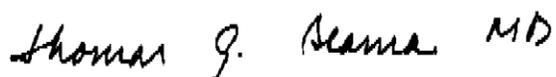
Some emphasis on chronic conditions is inherent in PCORI’s priorities, and many patients live with chronic infectious diseases such as AIDS and viral hepatitis. Until recently, patients with hepatitis C virus (HCV) infection were often not treated because treatments had low cure rates (25-45%) and significant side effects. The approval in 2011 of the first HCV-specific protease inhibitors resulted in new combination therapy that significantly improves cure rates to 70%, changing the treatment decision parameters for patients and physicians. While higher cure rates make it more likely that patients will choose to be treated, identifying asymptomatic HCV carriers is challenging. It has been estimated that 50-75% of individuals with HCV are unaware of their status, and morbidity and mortality are increasing as undiagnosed patients grow older and develop complications. Proposed ideas for identifying undiagnosed patients include screening by birth cohort, an identification method prompted by the data that infection is most prevalent among those born between 1945 and 1965. Assessment of diagnosis and treatment options for hepatitis C easily fits with PCORI’s first priority. Recent advances in research have brought new options in diagnosis and treatment of hepatitis C, and now there is the need to translate advances into better health care for patients.

The rise of antimicrobial resistance is a growing and urgent public health crisis, and there are several ways that patient-centered outcomes research can help address this crisis. Many drug-resistant bacterial infections result from patients’ stays in hospitals and other health care facilities. Infectious diseases physicians work in collaboration with other health care personnel to develop and implement evidence-based practices to prevent and control these health care-associated infections (HAIs). Within the priority on “improving healthcare systems,” research can address how to change physician behavior and change processes within healthcare systems that contribute to HAIs. The development and assessment of antimicrobial stewardship programs is a closely related topic that can also be addressed with patient-centered outcomes research. Antimicrobial stewardship involves coordinated interventions designed to improve and measure the appropriate use of antimicrobials by promoting the selection of the optimal antimicrobial drug regimen (if needed), dose, duration of therapy, and route of administration. Inappropriate use of

antibiotics contributes to the development of resistant infections, and implementation of antimicrobial stewardship programs can lead to better outcomes for patients, as well as preserving the precious resource of antibiotics for future use.

Although infectious diseases have not to date been cited in discussions of PCORI's research agenda, IDSA believes that there is significant alignment with PCORI's priorities for several critical areas in infectious diseases. Patient-centered outcomes research in these areas of ID can contribute to building the evidence base, improving health care delivery, and improving the ability of patients and their clinicians to make informed health care decisions. Should you have any questions about these comments, please contact Audrey Jackson, PhD, IDSA's senior program officer for science and research, at ajackson@idsociety.org or 703-299-1216.

Sincerely,

A handwritten signature in black ink that reads "Thomas G. Slama MD". The signature is written in a cursive style.

Thomas G. Slama, MD, FIDSA
President