

October 30, 2014

Dr. Joe Selby  
Executive Director  
Patient-Centered Outcomes Research Institute  
1828 L Street NW  
Washington, DC 20006

Dear Dr. Selby:

We applaud the Patient-Centered Outcomes Research Institute (PCORI) for convening a multi-stakeholder workshop to identify and prioritize potential research questions related to hepatitis C. This type of prioritization effort is reflective of the statute's guidance for soliciting and engaging an expert advisory panel in the development of priority topics and a research agenda.

The PCORI workshop underscored for us how the questions that matter to patients can be very different from those of payers or academic researchers, and therefore the critical importance of having patients fully engaged in an explicit, transparent process for developing patient-centered research priorities. It was clearly articulated by patients and providers at the workshop that the most important patient-centered outcome in the case of hepatitis C is a cure for every patient diagnosed with this infectious disease. To be truly patient-centered, we feel strongly that PCORI's prioritization process should capture the research questions that are best suited to help patients achieve this outcome - a cure for all patients.

In an effort to develop potential patient-centered research topics for PCORI, the Partnership to Improve Patient Care (PIPC) convened stakeholders representing hepatitis B and C patients and providers on May 8, 2014 to discuss dissemination and implementation strategies for hepatitis that would more effectively ensure patients are diagnosed and treated. As a result of the roundtable, we provided PCORI with specific recommendations for research related to screening and health delivery system improvements.

We are pleased that PCORI took the next step to convene a first of its kind, expert advisory panel on October 17, 2014 to determine whether clinical comparative effectiveness research (CER) could help answer questions that matter to patients about hepatitis C. PCORI solicited research questions from stakeholders, evaluated the submitted topics, and provided rationale and topic briefs to the meeting participants. We now urge PCORI to continue to advance a prioritization process that captures the research questions that most reflect patient needs, outcomes and preferences by following the roadmap for prioritization proposed by PIPC in November, 2013, as follows:

1. Priority-setting should begin with a public solicitation for potential research topics from a broad range of stakeholders, and PCORI should feed this into a structured process for refining draft priorities.
2. PCORI staff should perform the initial evaluation and culling of suggested research topics. The initial, vetted lists compiled by PCORI staff should be prepared with accompanying rationale and topic briefs.
3. The topic list should be ranked by expert Advisory Panels.
4. Each Advisory Panel should further develop a recommended priority list of topics.
5. Advisory Panel priority lists should be reviewed by PCORI staff, to be submitted for public comment.
6. The draft priority list should be presented to the PCORI Board of Governors for approval.
7. PCORI should assure openness and transparency throughout the priority-setting process.

Consistent with this roadmap, we would like to recommend the following next steps in PCORI's prioritization process for clinical CER related to hepatitis C:

- **Ranking Topic List by Expert Advisory Panel and Further Development of Priority List of Topics:** Patient-centered outcomes research by definition seeks to address questions that matter to patients. Therefore, to accomplish the ranking and development of a priority list of topics by experts, we urge PCORI to review the final votes of those participating in the October 17 meeting and prioritize the questions that mattered most to patients (i.e. questions that received the most votes from patient representatives). For questions that were not prioritized by patients, we urge PCORI to consider whether they have potential to be patient-centered outcomes research questions, and if so, to continue to engage the patient community in re-framing the questions for future consideration.
- **Public Comment:** Once PCORI staff has reviewed and identified the priorities mattered most to patients, PCORI should allow the public to comment on the draft priorities per the statute's guidance on priority-setting.
- **Board Approval:** Once public comments have been considered, the PCORI Board of Governors should consider a final list of specific research priorities.
- **Transparency:** PCORI must continue to be open and transparent throughout the research prioritization process. The Institute should publicly post questions being considered for prioritization on its website, including PCORI's analysis of those questions.
- **Continued Engagement of Experts:** We urge PCORI to engage an expert advisory panel on hepatitis C, including patients and providers, every year to ensure that the research priorities and the research agenda related to hepatitis C is continuously updated, and that experts remain engaged throughout the research process, including the research design, dissemination and implementation of the research.

In closing, we want to thank PCORI for recognizing the great potential for improving health outcomes of patients with hepatitis C by prioritizing patient-centered outcomes research questions. As was so eloquently stated in the final moments of the October 17, 2014 meeting, "Every hepatitis C patient deserves a cure." Truly *patient-centered* outcomes research must advance that objective, and we look forward to working with PCORI to do so.

Sincerely,



Tony Coelho

**Signing Organizations:**

Ms. Lorren Sandt, Caring Ambassadors Program, Inc.

Dr. Brian Edlin, Senior Principal Investigator, Institute for Infectious Disease Research, National Development and Research Institutes, New York, NY and Associate Professor of Medicine, Weill Cornell Medical College, New York, NY

Ms. Robin Lord Smith, Hepatitis C Association

Mr. Ryan Clary and Dr. Cami Graham, National Viral Hepatitis Roundtable

Ms. Ivonne Perlaza Fuller, Hepatitis Foundation International

Ms. Ronni Marks, The Hepatitis C Mentor & Support Group, Inc.