

February 14, 2012

Carolyn M. Clancy, M.D., Director
U.S. Department of Health & Human Services
Agency for Healthcare Research and Quality
Effective Health Care Program
VIA ELECTRONIC SUBMISSION

RE: Comments on Effectiveness and Safety of Antiepileptic Medications in Patients With Epilepsy

Dear Dr. Clancy:

The Epilepsy Foundation, American Epilepsy Society, American Academy of Neurology, Finding A Cure for Epilepsy and Seizures, National Association of Epilepsy Centers, and the North American Regional Commission of the International League Against Epilepsy are writing in response to the recently release AHRQ report on antiepileptic medications. As you may recall our organizations submitted comments on the draft report and original key questions. We are attaching both letters from 2011 and 2010 to this communication. The epilepsy community, our researchers, and health professionals have strong support for comparative effectiveness research that leads to improvements in the quality of care, provides a valuable decision-making resource, and increases efficiency in the delivery of healthcare. Unfortunately, we do not believe that this report offers valuable guidance to patients or medical professionals. We also wish to express disappointment regarding the lack of response or incorporation of our input into the final report.

Over the last almost two years, a list of concerns related to the formation and design of the CER initiative in epilepsy was presented to AHRQ. This represented the input and views not only of members of the organizations listed in this letter, but also many who are listed as key informants or reviewers of the report. It is greatly disappointing that the most prominent organizations serving people with epilepsy, and the professional organizations that pave the way for increased quality in epilepsy research and care, had such a minimal or nonexistent impact on a report from the Effective Health Care Program.

The attached letters demonstrate the concerns with the design, development, evaluation, and impact on epilepsy that the leadership of the Epilepsy Foundation, the American Epilepsy Society, and the American Academy of Neurology expressed to AHRQ and the report authors. We continue to believe that this report will create a negative impact on the care of patients with epilepsy or that healthcare professionals, realizing the major flaws in this research, will determine the AHRQ document to be irrelevant to practice. This is incredibly disappointing not only as an example of stakeholder input and review, but also of the importance of the Effective Healthcare Program overall.

Based upon on concerns we shared with AHRQ, we reiterate issues that were originally raised. We strongly believe that there is insufficient published data on all of the underlying pathologies for epilepsy to make accurate comparisons of various AEDs across a wide variety of seizure types. The total number of patients with epilepsy and the broad heterogeneity of the pathology of epilepsy mean that there are insufficient numbers of published studies looking at various types of epilepsy. Based upon a rapidly developing understanding of pathologies for epilepsy, we believe that comparisons of various AEDs are fraught with problems related to statistical power. From our reading of the report, these issues were never adequately addressed.

For all of the above reasons, the Epilepsy Foundation, American Epilepsy Society, American Academy of Neurology, and the North American Regional Commission of the International League Against Epilepsy strongly urge AHRQ and the Effective Health Care Program to pull the report from publication. Again, we urge the agency to bring these topics back to epilepsy experts and convene a working group that provides true input and collaboration in developing research questions and study protocols. We continue to encourage you and AHRQ leadership to provide not only an outlet for receiving research topics, but also take a leadership role in convening a collaborative dialogue with epilepsy experts to ensure that research protocols reflect an accurate understanding of epilepsy and its treatment, as well as the areas of critical need for research and how to best design that research.

Should this report and dissemination of its findings move forward, we urge you to include our organizations as points of contact for all outreach and communications that relate to publicizing, summarizing, or otherwise sharing this report with the public; as well as having representatives from our organizations on any focus or advisory groups that relate to this report and its distribution. **Our organizations would be interested in setting up a meeting, preferably on Wednesday, April 4, 2012 with you to further discuss epilepsy research projects that better reflect the current understanding of epilepsy and improve patient outcomes.** Please feel free to contact Angela Ostrom, Epilepsy Foundation Director Federal Relations at (301) 918-3766 or aostrom@efa.org.

Sincerely,



Brien Smith, M.D., F.A.A.N.
Chair, National Board of Directors
Epilepsy Foundation



Frances Jensen, M.D.
American Epilepsy Society President 2012



Bruce Sigsbee, MD, FAAN
President, American Academy of Neurology



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David Labiner, M.D., President
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Sheryl Haut, M.D.
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cc: Jean Slutsky, P.A., M.S.P.H., Director, Center for Outcomes and Evidence
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