

COMPARATIVE EFFECTIVENESS RESEARCH UPDATE

July 17, 2009

- **“Usefulness Guidance”** – AAFA and the National Health Council (NHC) are promoting the concept of “usefulness guidance” to promote a level of review that considers the usefulness of research at the point of patient care or within practice guidelines. We are proposing that any committees formed to advise on CER consider “usefulness guidance”, and we will offer language to support this to relevant House and Senate committees as part of health reform legislation.
- **CER Amendment to “Affordable Health Choices Act”?** We expect that the House Energy and Commerce Committee will consider an amendment to the *Affordable Health Choices Act* introduced this week that will incorporate provisions of the CER Act of 2009 bill introduced in May by Rep. Schrader (a “Blue Dog” Democrat). If this amendment is adopted next week, the current CER language in the *Affordable Health Choices Act* would be replaced by the language of the Schrader bill. That bill basically aligns with the CER principles adopted by AAFA and the National Health Council:
 - Creates a non-profit, non-governmental entity to oversee CER
 - Scope of research includes healthcare interventions, protocols for treatment, procedures, medical devices and diagnostic tools as well as pharmaceuticals.
 - Will not allow coverage or reimbursement decisions by the CER entityIn the Senate, we are looking at language that roughly conforms to the Baucus-Conrad Bill introduced earlier this year, but with modifications consistent with NHC principles on CER (See **letter on CER Principles** by NHC President Myrl Weinberg)
- **Stimulus Bill Milestones related to CER -**
 - **Two reports on CER issued** – On June 30th, the Federal Coordinating Council on Comparative Effectiveness Research (FCC-CER) and the Institute of Medicine (IOM) issued reports to Congress recommending -
 - FCC-CER: how to leverage existing CER work done by AHRQ and NIH (link to the full report: <http://www.hhs.gov/recovery/programs/cer/cerannualrpt.pdf>)
 - IOM: 100 research topics as research priorities. Click here for a brief of this report <http://www.iom.edu/Object.File/Master/71/032/Stand%20Alone%20List%20of%20100%20CER%20Priorities%20-%20for%20web.pdf>
 - **HHS, AHRQ and NIH** must meet a July 30 deadline to submit their FY 2009 operating plans for CER using Stimulus funding.
- **An Asthma and Allergy Perspective** – AAFA Board member and researcher Lawrence Schwartz, MD offered some helpful thoughts –

“Comparative Effectiveness Research should be supported and AAFA actively engaged, but CER should be managed properly to avoid unintended outcomes that do not support optimal patient care. Recommendations from CER to inappropriately restrict coverage should certainly be monitored and addressed.

An important limitation of many clinical trials, including CER trials, is that individual differences can get lost in the analysis of what works best for the majority of patients. For example, an inhaled steroid may work best in most asthmatics, but a leukotriene antagonist may work best in an important minority. As we learn how genetics influence the response of different individuals to different drugs, what is the best therapy for most people may not be so good for others because of how they respond to or metabolize a drug differently. Many clinical trials examine well-defined but small subpopulations of patients. Asthma trials typically exclude smokers, yet many adult asthmatics have smoked or continue to do so; and this population of asthmatics may respond differently than those who never inhaled tobacco smoke.”