

April 14, 2009

Delivered Via Electronic Mail

To: Federal Coordinating Council on Comparative Effectiveness Research

From: Alliance of Comparative Effectiveness Stakeholders

Dear Members of the Council:

The Alliance of Comparative Effectiveness Stakeholders (ACES) includes patients, providers, family caregivers and their partners in patient care who will serve as a leading voice for patients in the debate on comparative effectiveness research (CER) to ensure that their concerns are carefully and fully considered by policy-makers as CER initiatives are approved and implemented. Through education, information-sharing, and coordination with other CER coalitions and advocacy groups, ACES aims to preserve access to care, support formal stakeholder involvement in CER as well as assure data and methods used in CER include patient and provider perspectives.

The undersigned members of ACES appreciate the opportunity to share these comments as the Federal Coordinating Council on Comparative Effectiveness Research ("Council") works to provide input on priorities for the \$400 million fund made available by the American Recovery and Reinvestment Act ("Recovery Act") that the Secretary will allocate to advance comparative effectiveness research activities. ACES members have adopted a set of principles that we recommend for the Council's consideration as it works to identify priorities for CER:

An effective CER initiative will require that policy-makers act upon feedback provided via a continuing dialogue with stakeholders.

Transparency of decision-making and broad stakeholder participation and input must be ensured.

Cost containment cannot be the primary focus of CER.

CER must not limit patients' access to necessary treatments.

CER must not restrict the practice of medicine.

CER must recognize and encourage new innovations in patient care.

An effective CER initiative must be structured to meet the needs of an increasingly diverse patient population.

Given the enormous increase in funding to Federal Agencies for comparative effectiveness research, we respectfully urge the Council to ensure that its recommendations reflect the necessary data sources, analytical constructs, and methodological tools to conduct such broad-based research and produce meaningful results. The Recovery Act invested significant funding into this effort, and we believe a sound framework must be established to ensure those dollars are used effectively and appropriately.

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Similarly, we believe that an expanded CER initiative must include a formal structure to ensure broad public input and transparent decision-making as recommendations are determined, including direct participation by private-sector advocates for patients, family caregivers, providers, suppliers and manufacturers. Transparency is a critical component to "doing it right." There has been a strong push for transparency in the Obama Administration, and we hope that the Council will conduct its deliberations on CER activities in public, with an opportunity for stakeholders to participate fully in these important discussions.

We would also note that recommendations for CER should include populations where a lack of scientific data currently exists, including research on at-risk and under-served populations, individuals with disabilities and the chronically ill. Finally, we would again emphasize that CER must focus on the development of appropriate clinical evidence – not the development of payment and coverage policy recommendations that would restrict patient access and physician practice based on CER findings.

We thank you for considering our views.

Sincerely,

Alzheimer's Foundation of America
Eli Lilly & Company
Medical Device Manufacturers Association
Millennium Pharmaceuticals
National Council for Community Behavioral Healthcare
National Minority Quality Forum

American Medical Rehabilitation Providers Association
Amgen
Men's Health Network
National Alliance for Caregiving
National Hispanic Medical Association
Treatment Effectiveness Now Project

Co-signing Members of the Alliance of Comparative Effectiveness Stakeholders