

January 26, 2009

The Honorable Daniel Inouye, Chairman  
The Honorable Thad Cochran, Ranking Member  
Committee on Appropriations  
The Capitol, S-131  
Washington, DC 20510

The Honorable Tom Harkin, Chairman  
The Honorable Arlen Specter, Ranking Member  
Committee on Appropriations  
Subcommittee on Labor, Health and Human Services, Education, and Related Agencies  
131 Dirksen Senate Office Building  
Washington, DC 20510

Dear Chairman Inouye, Ranking Member Cochran, Chairman Harkin and Ranking Member Specter:

We are writing to urge you to ensure that any comparative effectiveness research (CER) included in the economic stimulus package establish a legislative framework that is strong and patient-centered. The goal of CER should be to arm individual patients and their doctors with the best available information to help assess the relative clinical outcomes of various treatment strategies and alternatives, recognizing that this will vary with circumstances. When used appropriately, comparative clinical effectiveness information can serve as a valuable tool that can contribute to improving health care delivery and outcomes by informing clinical decision making. By focusing on quality of patient care, such research also can help us achieve better health care value. However, we are very concerned that the House legislation and accompanying report language could have unintended and negative effects for patients, providers and medical innovators, leading to restrictions on patients' access to treatments and physicians' and other providers' ability to deliver care that best meets the needs of the individual patient. Rather, we believe any provisions related to comparative effectiveness should:

- **Focus CER on comparative clinical benefit, rather than cost-effectiveness.** Any legislation should state that funding will be used only to support clinical comparative effectiveness research, and define clinical comparative effectiveness as research evaluating and comparing the clinical effectiveness of two or more medical treatments, services, items and care processes and management. Additionally, CER should not encourage a generalized, "one-size fits all" approach. Rather, it is necessary to design studies and communicate results in ways that reflect variation in individual patient needs, that help patients and doctors make informed choices, and account for differences among patients including co-morbidities, sex, race and ethnicity. Recognizing these differences is important to allowing patients optimal treatment today and to encouraging the development of innovative targeted therapies which will advance personalized medicine.
- **Be conducted through an open and transparent process that allows for patients, providers and other stakeholders to participate equally in governance and input,**

**starting from the research planning stage.** There are many challenges in successfully conducting and communicating high-quality, patient-centered CER. Therefore, comparative effectiveness programs should include transparent decision-making procedures and broad stakeholder representation to enhance the credibility and usefulness of such studies.

- **Ensure that research supports providers in delivering the best possible care to their patients. To maintain a focus on patient and provider needs, the research entity should not engage in making policy recommendations or coverage decisions.** Patients may respond differently to the same intervention and the needs of the individual must be taken into consideration. Imposing rigid, federally-proscribed practice guidelines, which fail to recognize such variations, among patients can lead to poor patient outcomes and increased health care costs.

Comparative effectiveness information that reflects interactions among all of the various components of the health care system has the greatest potential to empower clinicians and patients to make more appropriate decisions. In addition to comparing scientific treatment interventions, research should also focus on how innovations in care delivery models, such as disease management programs, may produce better health outcomes.

We look forward to working with you to create a system that improves information about clinical outcomes, ensures that patients continue to have access to life-saving treatments and the tools necessary to advance a better quality of life for all Americans. Thank you for your consideration.

Sincerely,

AACSA Foundation  
The AIDS Institute  
Alliance for Aging Research  
Alliance for Better Medicine  
Alliance for Patient Access  
Alpha-1 Association  
Alpha-1 Foundation  
American Association for Cancer Research  
American Association for Respiratory Care  
American Association of Neurological Surgeons (AANS)  
American Association of Orthopaedic Surgeons  
American Association of People with Disabilities  
American Autoimmune Related Diseases Association  
American College of Obstetricians and Gynecologists  
American Institute for Medical and Biological Engineering (AIMBE)  
American Osteopathic Association  
Association of Clinical Research Organizations (ACRO)  
Association of Reproductive Health Professionals  
Asthma and Allergy Foundation of America  
Autism Society of America  
Breast Cancer Network of Strength

C3: Colorectal Cancer Coalition  
Californians for Cures  
Celiac Disease Center at Columbia University  
Children's Tumor Foundation  
Coalition of State Rheumatology Organizations  
Colon Cancer Alliance  
Congress of Neurological Surgeons (CNS)  
COPD Foundation  
Cure Arthritis Now  
Cutaneous Lymphoma Foundation  
Easter Seals  
FasterCures  
Foundation for Sarcoidosis Research  
Friends of Cancer Research  
GBS/CIDP Foundation International  
The Government Accountability Project  
Interamerican College of Physicians & Surgeons, Inc.  
Intercultural Cancer Council Caucus  
International Cancer Advocacy Network (ICAN)  
International Myeloma Foundation  
Kidney Cancer Association  
Lung Cancer Circle of Hope  
Malecare Cancer Support  
Men's Health Network  
Muscular Dystrophy Association  
National Alliance for Hispanic Health  
National Alliance on Mental Illness  
National Alopecia Areata Foundation  
National Foundation for Ectodermal Dysplasias  
National Hemophilia Foundation  
National Kidney Foundation  
National Spinal Cord Injury Association  
Ovarian Cancer National Alliance  
Plasma Protein Therapeutics Association  
Prostate Cancer International, Inc.  
Prostate Health Education Network, Inc. (PHEN)  
RetireSafe  
Society for Women's Health Research  
Tuberous Sclerosis Alliance  
United Spinal Association  
Us TOO International Prostate Cancer Education and Support Network  
VHL Family Alliance  
Virginia Prostate Cancer Coalition  
Vital Options International  
ZERO - The Project to End Prostate Cancer

cc: The Honorable Max Baucus  
The Honorable Kent Conrad  
The Honorable Charles Grassley  
The Honorable Edward Kennedy  
The Honorable Michael Enzi  
The Honorable Harry Reid  
The Honorable Mitch McConnell