

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

Alliance for Plasma Therapies

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)

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
The Government Accountability Project
Intercultural Cancer Council Caucus
International Cancer Advocacy Network (ICAN)
International Myeloma Foundation
International Prostate Cancer Education and Support Network
Kidney Cancer Association
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
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