



THE ALLIANCE FOR PATIENT ACCESS

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:

On behalf of the physician membership of the Alliance for Patient Access, I am writing to express concern regarding provisions of H.R. 598, *The American Recovery and Reinvestment Act of 2009*, respecting funding for a federally funded comparative effectiveness research program. While as physicians we appreciate the potential benefits of such an initiative, of concern to our membership is report language accompanying the legislation that seems to suggest the cost-benefit analysis might be a factor considered by researchers when making findings regarding clinical effectiveness. Specifically Chairman Obey's report language of concern reads:

“By knowing what works best and presenting this information more broadly to patients and healthcare professionals, those items, procedures, and interventions that are most effective to prevent, control, and treat health conditions will be utilized, while those that are found to be less effective and in some cases, more expensive, will no longer be prescribed.”

As physicians, the members of the Alliance for Patient Access are dedicated to ensuring that patients have access to approved therapies, diagnostic tests, and medical care. We urge that initiatives in the area of comparative effectiveness research proceed with caution to ensure that unintended initiatives do not limit patient access to the full range of approved healthcare options.

[www.AllianceforPatientAccess.org](http://www.AllianceforPatientAccess.org)

**Chairman**

David Charles, M.D.  
6509 Edinburgh Drive | Nashville, TN  
Tel: (615) 936-2596  
Email: pdavidcharles@gmail.com

Physicians certainly welcome research that will provide reliable data that the physician might utilize when prescribing medicines, ordering diagnostic tests, and directing patient care. However, if clinical effectiveness research is in fact cost effectiveness research, as implied by Chairman Obey's report language, then dangerous limits on healthcare options for all Americans could result.

Specifically, AfPA's concern is that the findings based on cost-effectiveness studies will be used by health plans and other payers to justify restricting diagnostic tests, hospitalization, or limiting formularies, effectively denying patient access to approved medical treatment options. While studies and their findings might apply to an entire population, each patient is an individual and might be the exception to the rule. Each patient deserves the opportunity to receive the treatment that is "just right" for his or her specific case. Certainly, that is what each of us would want for ourselves, or our loved ones, if we were the patient.

Comparative effectiveness research must recognize the value delivered to patients when their healthcare is directed by their physician, and not their health plan. Physicians take cost considerations into account, but they do so on a patient specific basis and not by relying on one-size-fits-all applications of healthcare.

The future of healthcare is more personalized medicine. Physicians must use all the data they have gathered about the patient's condition and medical history to design a personalized health management plan to manage chronic disease, and treat illness or injury.

Appropriate comparative effectiveness research will empower physicians as they enter the new era of personalized medicine. Cost effectiveness research will only serve to limit patient access to approved therapies and the best care. Please ensure that any new federally sponsored comparative effectiveness research initiative is structured to ensure cost considerations are not the basis of determining the relative merits of studied therapies.

Sincerely,

David Charles, M.D.  
Chairman, Alliance for Patient Access

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