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June 18, 2007

The Honorable Thomas Allen
U.S. House of Representatives
1127 Longworth House Office Building
Washington, D.C. 20515

Dear Congressman Allen,

On behalf of the 34,000 members of the American College of Cardiology (ACC), we offer the ACC's qualified support for your recently introduced legislation, the "Enhanced Health Care Value for All Act of 2007," H.R. 2184. We express thanks for being offered the opportunity by Ms. Susan Lexer of your staff to provide comment on the legislation prior to introduction, and appreciate your leadership on comparative effectiveness research.

We hope that as you advance this legislation you will consider the ACC's thoughts and suggested changes in an effort to strengthen the legislation and ensure that the emphasis is on improving the quality and cost of care through better informed decision-making between the physician and patient. We believe that the promise of comparative effectiveness research to improve health care in the U.S. will be compromised if it is allowed to become simply a novel means to restrict coverage and set arbitrary utilization targets.

Funding for outcomes research, including comparative effectiveness research, is needed in order to improve the quality of care and the systems that deliver it. We are pleased that your bill establishes a Health Care Comparative Effectiveness Research Trust Fund and authorizes the Agency for Healthcare Research and Quality (AHRQ) to spend \$3 billion over five years for comparative effectiveness activities. The ACC agrees that AHRQ—whose mission is to improve the quality, safety, efficiency, and effectiveness of health care for all Americans – is the appropriate home for conducting federal comparative effectiveness research, provided that it receives adequate funding for these purposes.

As you are aware, Section 1013 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 gave AHRQ the infrastructure necessary to house this research, but the funding levels appropriated to this effort have been inadequate. We understand the House Subcommittee on Labor-HHS-Education Appropriations recently passed its FY 2008 spending bill which doubles AHRQ's current comparative effectiveness budget, bringing total funding for the Effective Health Care Program to \$30 million. We strongly support this increased funding and hope that at a minimum it will be retained in the spending bill as it moves forward.



We recommend that the legislation strengthen the representation of scientific and medical experts on the Comparative Effectiveness Advisory Board and Council to promote the focus of comparative effectiveness research on determining optimal medical treatments vs. cost analyses. While we recognize that comparative effectiveness has and will continue to be used to make coverage decisions, it cannot be the sole, or the most important purpose.

It is important to note that while considerable emphasis has been placed on the potential for health care cost savings that comparative effectiveness research may yield, there has been little acknowledgement or discussion about the likelihood that, in any given study of comparative treatments, the most effective may also be the most expensive. To prevent such results from negatively influencing future research topics and study designs, the ACC believes it is critical that any “cost analysis” of comparable treatments be conducted separately from, and not be incorporated into, clinical comparative effectiveness research. Thus, we believe comparative effectiveness research should—as emphasized in your bill—focus on science, not costs, in the interest of promoting what is best for patients. To that end, we also recommend that the Advisory Board be charged with fostering innovative ways of disseminating the research results to physicians and patients to speed the process of adopting clinical advances.

Through the ACC’s past 23 years of developing clinical guidelines, performance measures and clinical appropriateness criteria, we have found that comparative effectiveness research has proven to be a vital tool that helps translate clinical research into more informed medical decision making. The ACC has developed the infrastructure over this time to encourage critical examination of the incremental value of diagnostic testing and medical and device therapy. Each time a guideline is issued, it spurs additional research to prove or disprove the conclusions reached in the guideline recommendations. Guidelines have also served as the basis for developing the ACC’s National Cardiovascular Data Registry™ (NCDR)—which, in turn, helps to answer questions on whether recommendations based on clinical trials apply in real world practice settings. Comparative effectiveness is only one step in the translation of research into practice, and should be considered in the broader context of basic research, clinical trials, guidelines, performance measures, registries and outcomes research.

To strengthen the proposition that clinical effectiveness research focus on science vs. costs, we recommend including a clear definition of comparative effectiveness and the context of its use in the legislation. The ACC asks for your assistance in educating fellow policy makers that comparative effectiveness research should serve the purpose of establishing the incremental value offered by an individual therapy when added to other current therapies, and not just to provide comparisons of individual therapies.

Comparative effectiveness research should go beyond traditional studies of treatment efficacy as determined in trial settings and attempt to define the effectiveness of alternative care protocols (i.e. not just drugs vs. other drugs, or devices vs. other devices, but also combinations of drug and device therapies). Once the comparative effectiveness has been defined for different approaches, it is still necessary for the health care system, physicians and patients to determine whether a treatment is appropriate both in general and for individual patients. This is especially important for those individual patients who because of age, genetics, co-morbidities or other factors (AKA “outliers”) do not respond to the treatment protocol shown to be generally more effective. The results of comparative effectiveness research will provide the data necessary to inform better decision making in the future. It will be up to physicians, patients and policy makers to use this information wisely once it is obtained.

An example of the potential impact of comparative effectiveness research on utilization—and the need to be careful in how it is defined, conducted and ultimately used—can be found in the effects of the COURAGE clinical trial, which sought to study two different ways to treat patients who suffered chronic chest pain: placement of arterial stents (PCI), or medical therapies (drugs). Although consensus has not been reached on the applicability of the trial's results to the general population, on May 17, 2007 the *Wall Street Journal* reported that the number of coronary stents implanted in U.S. patients dropped sharply in April, a month after the trial findings were released. This drop suggests a rapid response by physicians to the COURAGE study, notably without any payment incentives or other external mechanisms to influence their professional judgment.

It is as yet unknown how much of this drop is appropriate, and/or whether it reflects a delay in treatment while patients and physicians consider the implications of COURAGE for the management of an individual patient's disease. What COURAGE and the other comparative trials demonstrate is that the answers sought by this type of research are rarely black and white and remain far from static. Each trial was done for a specific patient population comparing two or more potential treatment strategies in the context of an ever present innovation. Different patient populations respond differently to various therapies. Advances in invasive procedures (both CABG and PCI) and medical therapy require ongoing updates to these comparisons. Even if the current trend delaying or avoiding PCI continues for patients who are appropriate candidates for medical therapy alone, the long term quality and cost implications remain unknown.

Over time, physicians and patients will have to integrate the most recent findings with individual risk profiles to determine the most appropriate course of treatment. The hope is that by funding the ongoing collection of high quality comparative effectiveness research such as that represented by COURAGE, the health care system can decrease unwarranted variations in care that result from a lack of data, variations in resource availability and physician case-based knowledge. The result will not be an elimination of variation in care but rather a redirection toward patient-centered variations in care based on high quality data, informed resource allocation over time, and patient preferences. Such change will help ensure that the funds Medicare currently spends annually on PCI will be high value for patients.

Should the Energy and Commerce Health Subcommittee decide to conduct a hearing this year on comparative effectiveness, I hope you will consider an ACC representative as a witness. We believe that the ACC has much to offer in this arena based on our experience and would be pleased to work with you to advance legislation this year that: 1. funds comparative effectiveness research; 2. affirms the AHRQ's role in coordinating comparative effectiveness research; and 3. establishes a process and infrastructure, through the creation of an Advisory Board and Council, by which discussion around the issues of research priority setting and the dissemination and use of research findings can occur. If you wish to speak further or have any questions, please do not hesitate to contact either of us at JDove@prairieheart.com or lambrc@mmc.org.

Sincerely,



James Dove, M.D., F.A.C.C.
President, ACC

Costas Lambrew, M.D., F.A.C.C.