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July 2, 2007

The Honorable Pete Stark
Chairman, House Ways and Means Health Subcommittee
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Stark,

On behalf of the over 34,000 members of the American College of Cardiology (ACC), I respectfully offer for your consideration the ACC's thoughts on the concept of comparative effectiveness in health care, and the prospects of expanding the federal government's role in promoting this important research. The ACC applauds your leadership on this important issue—most recently demonstrated by the June 12 hearing devoted to gathering information about, and developing strategies for increasing, comparative clinical effectiveness research.

In addition, I would also like to offer our organization's clinical and policy expertise to support your efforts—and those of your colleagues on the Ways & Means Health Subcommittee—in evaluating this concept, and developing potential implementation strategies through legislation. It is our sincere hope you will consider the ACC a useful resource for reference as the Subcommittee moves forward on future proposed legislation.

Defining Comparative Effectiveness:

As noted in Section 1013(a)(6) of the MMA, comparative effectiveness research should reflect the principle that physicians and patients should have the best available evidence upon which to make choices in health care items and services. The ACC believes comparative effectiveness research should therefore focus on science, not costs, in the interest of promoting what is best for patients. Moreover, the impact of using various treatments on costs will be different for providers and payers (varying even among public and private payers) such that cost analyses would be better performed by those whose costs are being affected rather than by those conducting or supervising the clinical research.

Any federally-sponsored comparative clinical effectiveness research that incorporates cost analyses within its methodology would be approached with severe skepticism among providers, who would likely perceive that such research exists solely for the purpose of saving Medicare money. As a result, the research will lose the credibility among physicians that will be so vital for its success in impacting clinical practice. Thus, the goal of comparative effectiveness research should be to provide the data necessary to better inform physician/patient decision-making in the future.

The mission of the American College of Cardiology is to advocate for quality cardiovascular care — through education, research promotion, development and application of standards and guidelines — and to influence health care policy

Towards that end, we believe that 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 various combinations of drug and device therapies). Once the comparative effectiveness of different treatment approaches have been defined, it remains necessary for the health care system, physicians, and patients to determine whether a treatment is appropriate both generally and for each individual case. This is especially important for those individual patients who, because of age, genetics, co-morbidities or other factors do not respond to the treatment protocol shown to be generally more effective. It is important to remember that research, no matter how well done, cannot account for all of the important variables that patients and physicians must consider when determining the best course of action for an individual with a specific set of clinical problems.

Physicians, patients and policymakers must use this information wisely once it is obtained, as the potential for misuse and abuse of such research is substantial—and can have significantly negative impacts on access to care for not only our most vulnerable populations, but potentially all stakeholders. The ACC strongly supports Ranking Member Dave Camp's statement, made at the hearing—with which you agreed—that comparative effectiveness research must not be used to set Medicare coverage or otherwise limit patient access to specific therapies.

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 of the likelihood that, in any given study, the most effective treatment 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.

Effect of Comparative Effectiveness Research in Cardiovascular Care:

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 (Percutaneous Coronary Interventions—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's 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 their management of an individual patient's disease. [One important fact for their consideration is that 93% of the patients were screened out of the COURAGE trial—that is, the trial represents results in only 7% of the study's population with stable cardiovascular disease.] Even if the current trend of delaying or avoiding PCI continues for patients who are appropriate candidates for medical therapy alone, the long-term quality and cost implications remain unknown. What the COURAGE experience does illustrate is that patients and physicians will evaluate and respond to the findings of good comparative effectiveness research, and further, that imposing utilization

management mechanisms—e.g. benefits changes and prior authorizations—are not always necessary to achieve the goal of rational use of medical care.

COURAGE and the other comparative trials also demonstrate 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—i.e. Coronary Artery Bypass Grafting (CABG), PCI—and medical therapy require ongoing updates to these comparisons. Similar considerations will need to be addressed for other comparative effectiveness studies, regardless of the treatments to be evaluated.

The Federal Role in Comparative Effectiveness:

The ACC believes that the Agency for Healthcare Research and Quality (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 sufficient funding for these purposes.

While Section 1013 of the MMA gave AHRQ the infrastructure necessary to house this research, the funding levels appropriated to this effort—\$15 million in 2006 and 2007—have been inadequate for purposes of promoting greater numbers of comprehensive comparative effectiveness studies. It is our understanding that the House Subcommittee on Labor-HHS-Education Appropriations recently passed its FY 2008 spending bill, which doubles AHRQ’s current comparative effectiveness budget to \$30 million. We strongly support this increase in funding, and hope that at a minimum it will be retained in the spending bill as it moves forward.

The Enhanced Health Care Value for All Act of 2007:

The ACC recently offered its qualified support for the “Enhanced Health Care for All Act of 2007” (H.R. 2184), as introduced by Rep. Tom Allen, and believes the approach to comparative effectiveness research promoted in the bill is a step in the right direction. To strengthen the legislation, the ACC suggested that attention must also be given to finding innovative ways of disseminating the research results to physicians and patients so as to speed the process of adopting clinical advances. In addition, we recommended that the legislation enhance 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.

Conclusion:

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.

One concern we have surrounding some discussions of potential comparative effectiveness proposals has been the notion that the federal agency to be established or assigned to oversee such research efforts should also use that information to create clinical guidelines. We strongly believe that guideline development is best done by medical specialty societies—like ACC, where the clinical expertise resides—to synthesize the information from multiple sources in ways that are actionable and where there is greater credibility among patients and providers.

As you consider legislative proposals that bolster the federal comparative effectiveness research effort, the ACC urges you to ensure that the emphasis of any initiative is to improve the quality of care through better informed decision-making between the physician and patient.

Again, I offer the ACC as a resource on this topic and would be happy to speak with you at any time. Thank you for your ongoing commitment to making the Medicare program sustainable over the long-term, while working with physicians to ensure that Medicare beneficiaries receive the highest quality of care.

Sincerely,

A handwritten signature in cursive script that reads "James T. Dove, M.D.".

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

cc: Jack Lewin, C.E.O.