

ORAL TESTIMONY

Presented by

Jack Lewin, M.D.
Chief Executive Officer
American College of Cardiology

Presented to the

UNITED STATES HOUSE OF REPRESENTATIVES
APPROPRIATIONS COMMITTEE
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND
RELATED AGENCIES

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Mr. Chairman and members of the subcommittee, I am Dr. Jack Lewin, Chief Executive Officer of the American College of Cardiology (ACC), a 37,000 member, non-profit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care — through education, research promotion, development and application of standards and guidelines — and to influence health care policy.

Heart disease is the leading cause of death for both women and men in the United States and is projected to cost the country \$475 billion in health care services, medications, and lost productivity in 2009. Nearly 2,400 Americans die of cardiovascular disease each day — an average of 1 death every 37 seconds. In 2009, an estimated 785,000 Americans will have a new coronary attack, and about 470,000 will have a recurrent attack. It is estimated that an additional 195,000 silent first myocardial infarctions occur each year. About every 25 seconds, an American will have a coronary event, and about every minute someone will die from one.

Fortunately, the death rates for cardiovascular disease have declined and Americans due to advances in science through new drug and device therapies, surgical innovations, enhanced emphasis on prevention, and innovative public educational programs--all made possible through NHLBI-funded research. In fact, since 2000 we have seen a 29 percent reduction in morbidity and mortality rates; nonetheless additional improvement is needed, including reducing variation, uneven quality, reducing disparities of race and gender. Our citizens-many of them potential cardiac patients-do not want us to become complacent as we celebrate the many advances in the prevention, diagnosis, and treatment of cardiovascular disease that have resulted from our nation's pioneering research and educational programs.

ACC encourages Congress to provide a strong federal investment in research and prevention programs that address cardiovascular disease. Federal research is providing for breakthrough advances that fundamentally change our understanding of the prevention and treatment of cardiovascular disease, leading to better outcomes, decreased costs, and increased quality of life for patients.

ACC Funding Recommendations for FY2010

ACC urges the Subcommittee to consider the following FY 2010 funding recommendations when determining appropriations for programs within the Department of Health and Human Services:

National Institutes of Health (NIH): The College supports a 7 percent increase in NIH funding for FY 2010, for a total of \$3.227 billion. Research conducted through the NIH has resulted in better diagnosis and treatment of cardiovascular disease, thereby improving the quality of life for those living with the disease and lowering the number of deaths attributable to it. Adequate funding through the NIH is necessary for basic, clinical, and translational research that facilitates the delivery of new discoveries to the bedside.

National Heart, Lung, and Blood Institute (NHLBI): ACC supports an FY 2010 budget of \$3.227 billion to help the NHLBI continue its critical research into the causes, diagnosis, and treatment of heart, blood vessel, lung and blood diseases. This investment will allow NHLBI to continue fulfilling the goals laid out in its strategic plan, “Shaping the Future of Research: A Strategic Plan for the National Heart, Lung, and Blood Institute.”

Agency for Healthcare Research and Quality (AHRQ): The College recommends an FY 2010 base funding level of \$405 million for AHRQ, an increase of \$32 million. We support the recent increases in funding for AHRQ’s comparative effectiveness research program. We recommend that increased funds for AHRQ in 2010 be dedicated to bolstering these other important research topics to balance the recent investments in comparative effectiveness research. Comparative effectiveness research alone will not solve our health system challenges; the full spectrum of health services research on health care costs, quality, and access should be supported.

CDC Heart Disease and Stroke Prevention Program: ACC recommends \$74 million, a \$20 million increase, for the Centers for Disease Control and Prevention (CDC) State Heart Disease and Stroke Prevention program. The CDC Division for Heart Disease and Stroke Prevention’s public education efforts are making strides in the prevention of and early intervention in treating cardiovascular disease – thereby potentially reducing future care costs significantly.

HRSA Rural and Community AED Program: The College recommends \$8.927 million for the Health Resources and Services Administration (HRSA) Community Access to Emergency Defibrillation program. This funding level would restore the program to its FY 2005 funding level when it provided grants to 47 states. This is an important initiative that saves lives by placing external defibrillators in public facilities.

Research Needs in Cardiovascular Care

ACC and the American Heart Association (AHA) have a long history in the development of clinical practice guidelines. The College strives to produce the preeminent medical specialty practice guidelines, with more than 18 guidelines on a range of cardiovascular topics. They are developed through a rigorous, evidence-based methodology employing multiple layers of review and expert interpretation of the evidence on an ongoing, regular basis. Many clinical research questions, however, remain unanswered or understudied. The guideline recommendations based on expert opinion rather than clinical data vary by cardiovascular topic from only 20 percent for coronary bypass surgery to more than 70 percent for valvular heart disease.

Through its clinical policy development process, the College has identified knowledge gaps for cardiovascular disease. If addressed, these currently unresolved issues have potential to positively impact patient outcomes, costs, and the efficiency of care delivery. An investment in answering the following scientific questions through the NIH, in particular the NHLBI, and through the Agency for Healthcare Research and Quality (AHRQ), will help to better narrow the target population who can benefit from treatment and therefore increase the efficacy and

efficiency of patient-centered care delivery:

1. What is the effect of common cardiovascular therapies on elderly populations whose metabolism and kidney function is lower and may not respond to medications in the same way as the younger patients typically included in clinical trials?
2. What is the effect of common cardiovascular therapies on patients with multiple other diseases/conditions?
3. What are the best approaches to increasing patient compliance with existing therapies?
4. What screening and risk models (existing or new) could further define who will benefit from various therapies?
5. What are the optimal management strategies for anticoagulation and antiplatelet agents in heart attack patients, patients with stents, and atrial fibrillation patients to maximize benefit and reduce bleeding risks?
6. What are the best approaches to managing complex but understudied cardiovascular topics such as congenital heart disease, valvular heart disease, and hypertrophic cardiomyopathy? These topics have become areas of higher research interest as techniques have developed to extend the lives of these patients.
7. What are the risks and benefits of common off-label uses of widely used therapies and procedures, such as drug eluting stents?
8. What are the best catheter-based techniques to increase treatment success and reduce complications for both coronary and cardiac rhythm procedures?

The above list of topics is not exhaustive but gives an overview of some of the themes of the evidence gaps that exist across the ACC/AHA guidelines.

In addition to specific clinical research topics, ACC recommends funding to help address structural issues that could help identify, prioritize, and interpret research findings over the long term.

1. The NIH should fund more trials of direct comparison between pharmacological and other therapies. Without these important trials, the current emphasis on promoting comparative effectiveness will be founded upon efficacy trials and not effectiveness.
2. The NHLBI should work with the clinical cardiology community to proactively design clinical trials to address unanswered clinical questions and identify methods that allow for greater comparability among studies. NHLBI should work with ACC and the AHA to

develop an evidence model that would drive future research initiatives based on current evidence gaps in the guidelines; and

3. NIH should fund the development of a robust informatics infrastructure across Institutes to process research evidence. Studies should be designed such that their results could be “fed” into a computer model that would provide additional insights for developers of clinical recommendations.
4. NIH should fund studies of patient preference and values.

The Role of Comparative Effectiveness Research

Through the ACC’s past 25 years of developing clinical guidelines, performance measures and clinical appropriate use 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. ACC supports an increased investment in federal comparative effectiveness research based on the principle that physicians and patients should have the best available evidence upon which to make choices in health care items and services. An important component in data collection comes through clinical registries. The College’s National Cardiovascular Data Registries (NCDR) can play a substantial role in this area.

The College strongly believes that keeping cost analyses independent of comparative clinical effectiveness research ensures that the clinical research achieves a high degree of credibility among all stakeholders. The entity responsible for supervising/conducting this research must not also make coverage and benefit decisions; such decisions should be independently made, based on the best available scientific evidence, and should take into consideration the need for flexibility based on the individual needs and complexities of the patient. In addition, ACC believes 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. Lastly, the College urges the concurrent development and implementation of strategies for the widespread dissemination and use of the results of comparative research by health care providers, through systematic programs of physician education and support from specialty societies such as ACC.

In conclusion, by continuing this nation's major investment in biomedical research in general, NIH, NHLBI, AHRQ, and CDC-sponsored research in particular, Congress will help literally thousands of investigators make discoveries and advance knowledge. As researchers open new paths to and through medical frontiers, it is exciting to contemplate the implications for the future health of our citizens. Already, as a result of a multitude of discoveries and innovations, thousands of highly-skilled cardiovascular specialists are performing procedures such as coronary angioplasty and prescribing medical treatments that were unimaginable just a few years

ago. But this is not just about treatment. Health care professionals are also promoting powerful prevention strategies that have been validated by HHS sponsored researchers.

The need to reduce the enormous social and economic costs of cardiovascular disease is a compelling reason to increase our cardiovascular disease research budget significantly. The need has never been greater. The United States must prepare itself, both scientifically and fiscally, for the inevitable increase in the incidence of cardiovascular disease that will accompany the graying of the so-called baby-boomer generation.

I hope the Subcommittee shares my optimism about the unique opportunities that our scientists and clinical investigators now have to achieve their long-standing goal of conquering this nation's number one killer. In summary, the American College of Cardiology would like to encourage you to generously fund government-sponsored cardiovascular research -- it is a wise investment in our nation's future.

Mr. Chairman, I appreciate having this opportunity to speak to the Subcommittee.

I have submitted a written statement for the record.

Thank you.