



September 15, 2006

**Association of  
American Medical Colleges**  
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The Honorable Joe Barton  
Chairman  
Committee on Energy and Commerce  
United States House of Representatives  
Washington, DC 20515

**Darrell G. Kirch, M.D.**  
President

Dear Mr. Chairman:

On behalf of the Association of American Medical Colleges (AAMC), I write to endorse the National Institutes of Health Reform Act of 2006. The AAMC represents all 125 accredited U.S. medical schools; nearly 400 major teaching hospitals and health systems, including 68 Department of Veterans Affairs medical centers; and 96 academic and scientific societies representing 109,000 faculty members. These institutions annually receive more than half of all extramural funds awarded by the National Institutes of Health (NIH).

We are indebted to you for your personal commitment to this legislation, to the NIH, and to the nation's medical research effort. I and the members of our committee valued the opportunity to meet with you personally in July to discuss your thoughts about the NIH and the bill, and we recognize and appreciate the real and significant changes that you have made in this proposal during the course of the past year.

This legislation proposes changes that we believe will enhance the effectiveness of the NIH at a time when our nation faces unprecedented scientific opportunities and health challenges. We applaud your call for additional funding to foster new initiatives while sustaining ongoing endeavors. In particular, we strongly endorse the bill's recognition of the vital importance of new investigators and investigator-initiated research to promote innovation and ingenuity and the continued success of the nation's medical research enterprise.

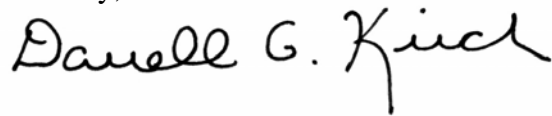
In January 2005, the AAMC established an *ad hoc* committee, co-chaired by Robert Kelch, M.D., Executive Vice President for Medical Affairs and CEO of the University of Michigan Health System, and Philip Pizzo, M.D., Dean of the Stanford University School of Medicine, to review and engage the issues that arose as this legislation progressed. Members of this committee had the opportunity to review the draft legislation earlier this week and were very pleased that many of the issues they had raised during the past year have been addressed. Our members do have some concerns with the current draft, which, if addressed, would strengthen the bill and build greater community support. We respectfully ask the Energy and Commerce Committee to consider the attached proposals,

either through technical refinements in the legislative text or in the report language accompanying the bill, when it takes up the legislation.

The AAMC commends Katherine Martin on the Energy and Commerce Committee staff and Cheryl Jaeger in the Majority Whip's Office for their exemplary work on this legislation. We are grateful to them for their tireless efforts to listen to our concerns, to develop alternative proposals, and to work in a collegial fashion with our members and staff to revise this legislation to address those issues.

We look forward to working with you and your colleagues in the House, as well as the Senate and the NIH, as this legislation moves forward.

Sincerely,

A handwritten signature in black ink that reads "Darrell G. Kirch". The signature is written in a cursive style with a large, prominent "K" and a long, sweeping underline.

Darrell G. Kirch, M.D.

attachment

**National Institutes of Health Reform Act of 2006**  
**Technical Refinements**

1. Maintaining adequate funding opportunities for first-time NIH R01 applicants, and establishing “academic homes for clinical and translational science” by fully funding the number of Clinical Transformation Science Awards (CTSA) projected in FY2007 and 2008 are very high trans-NIH priorities. To meet these priorities will be especially challenging for the Institutes and Centers if the NIH budget remains constrained in the next two or more fiscal years. Accordingly, we propose that the report language make explicitly clear that monies from the Common Fund should be used to support first-time NIH R01 applicants, perhaps on a matching basis with the individual Institutes and Centers, and to fully fund the number of CTSA awards required to meet the NIH’s previously projected target.
2. In the description of the activities to be identified by the Division of Program Coordination, Planning and Strategic Initiatives to be supported by the Common Fund, we propose the following additions to the legislative language:
  - a. On page 21, line 3, amend “identify research that represents” to “identify research and research resources that address”.
  - b. On page 21, line 8, after “additional research” insert “or to meet research resource needs”.

We believe these changes would facilitate our first recommendation and are consistent with the support currently provided by the NIH Roadmap for analytical tools such as innovative technologies, databases, and research networks, and for training translational and clinical researchers.

3. We wish to be certain that our understanding is correct that all research to be supported by the Common Fund will undergo the same rigorous peer review of scientific merit required under 42 USC 289a.
4. Under the evaluation of the Common Fund, we propose that, in addition to the recommendations to Congress on the size of the Fund (page 32, lines 2-5), the Director of the NIH should submit an evaluation of the Common Fund and the research and research resources supported by the Fund. We believe that a thorough assessment of the activities supported by the Fund, and its successes and shortcomings, is essential for the NIH, the Congress, and the stakeholders to make an informed judgment about the future size of and directions for the Fund.
5. For the demonstration projects authorized under section (beginning on page 48), we propose that the Director of NIH submit an evaluation of these programs to the Congress at the end of the third year of the programs, including an assessment of whether the awards made under the programs met the goals and priorities established by the Director. We believe this information is essential for the NIH, the Congress, and the stakeholders to make an informed judgment about the continuation of the programs. We further propose that as part of this evaluation,

consideration be made to supporting any continuation of the programs through the Common Fund.

6. We note that the Secretary “may select” the Director of NIH to chair the Scientific Management Review Board (page 13, lines 23-24). We believe this would undermine the appearance of independence of this Board and would place the Director in a very uncomfortable situation if he or she exercises the authority granted to object to the Board’s recommendations for major changes to existing Institutes and Centers (page 17, beginning at line 7). We propose eliminating the option for the Director of NIH to chair the Board. We support having the Director as a permanent member of the Board on an ex officio basis (page 12, lines 5-6). We also suggest that the presence of Institute and Center Directors on the Board could also raise questions about the Board’s independence. The “interests” of the Institutes and centers might be better represented by appointing senior, accomplished, long-term awardees, who could provide a more independent perspective on the relevant scientific opportunities and needs, as well as on the functioning of the Institute or Center with which they have had a long history of interactions.
7. The bill states the Director of the NIH “shall approve the establishment of all national centers of excellence recommended by the national research institutes, other than centers recognized under section 414;” (page 23, lines 8-11). The purpose and justification for this new authority are unclear, nor is it clear why the national cancer research and demonstration centers authorized under 42 USC 285a-3 are uniquely exempted. Centers of excellence created by the individual Institutes have gone through rigorous review processes of scientific merit and programmatic relevance, and should not, in our view, require further approval by the NIH Director. We propose removing this provision.