



Statement

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The National Institutes of Health Reform Act of 2006

Presented by

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Before the

Committee on Energy and Commerce
United States
House of Representatives

September 19, 2006

Statement of Darrell G. Kirch, M.D.
President, Association of American Medical Colleges
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We are indebted to the Chairman for his personal commitment to this legislation, to the NIH, and to the nation's medical research effort. Members of our *ad hoc* Working Committee on NIH Reauthorization have reviewed the current draft and are very pleased that many of the issues they have raised during the past year have been addressed. The AAMC endorses the legislation.

We strongly concur with NIH Director Zerhouni that research conducted and supported by the NIH has and will continue to transform the practice of medicine. The public's large investment in the NIH, and in our member institutions where much of the nation's medical research is carried out, comes with a series of responsibilities and obligations. The proposed legislation provides an appropriate vehicle to enhance the robust systems of accountability that currently exist at the NIH.

The AAMC supports the call for additional funding above the level of the Biomedical Research and Development Price Index (BRDPI) to foster new initiatives while sustaining ongoing endeavors. We strongly endorse the bill's recognition of the vital importance of new investigators and investigator-initiated research.

The AAMC supports the establishment of a formal strategic planning process to identify areas of trans-NIH research to take full advantage of emerging scientific opportunities and to address pressing public health challenges. We note that the proposed composition of the Council of Councils strikes an appropriate balance between the need for scientific input and the desire for broader representation of the various stakeholder communities, and concur that decisions regarding the research projects to be supported through the Common Fund should be based on scientific merit and not political decisions.

The AAMC endorses the creation of a comprehensive electronic reporting system across all of the NIH's institutes and centers, which will supply new insights into the value the public has derived from its sustained investment in basic and clinical research.

The AAMC fully supports the creation of a Common Fund to support trans-NIH initiatives and is pleased that the legislation provides a reasonable rate of growth for the Common Fund that is linked to the growth of the overall NIH budget. We propose that the Director of the NIH, in consultation with the Council of Councils, submit a thorough evaluation of the Common Fund and the research resources supported by the Fund prior to any decision about increasing the size of the Fund beyond 5 percent.

We have provided the committee with additional recommendations that we believe would strengthen the bill and build even greater community support. We respectfully ask the committee to consider these proposals, either through technical refinements in the legislative text or in the report language accompanying the bill.

My name is Darrell Kirch, M.D., and as President of the Association of American Medical Colleges (AAMC), I am pleased to have this opportunity to testify on behalf of the AAMC in support of 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).

Chairman Barton, 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 several members of the AAMC's *ad hoc* Working Committee on NIH Reauthorization had the opportunity to meet with you in July to discuss your thoughts about the future directions for NIH, the need for increased transparency and accountability, and the role this legislation would play in achieving these objectives.

We recognize and appreciate the significant changes that you have made in this proposal during the course of the past year. In January 2005, the AAMC established an ad hoc committee of academic medical center leaders, 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 developed. This committee reviewed earlier discussion drafts of this legislation that were released last year, and provided extensive comments that formed the basis for the statement the AAMC submitted to this committee last July. Our advisory committee has been fully apprised of the ongoing discussions between our respective staffs throughout the

summer and has provided advice on the Association's positions throughout this process.

Members of our committee have reviewed the current draft and are very pleased that many of the issues they have raised during the past year have been addressed.

The AAMC believes that the NIH is one of this nation's greatest achievements. The Federal Government's unwavering commitment to medical research, embodied in its investment in the NIH for nearly 70 years, has created a medical research enterprise that is the envy of the world and has contributed greatly to improving the health and well-being of all Americans, indeed of all humankind. We strongly concur with NIH Director Elias Zerhouni that the research conducted and supported by the NIH has and will continue to transform the practice of medicine.

We fully recognize that the public's large investment in the NIH, and in our member institutions where much of the nation's medical research is carried out, comes with a series of responsibilities and obligations. We recognize that we have been entrusted by the American people to be proper stewards of their funds, to conduct research in an unbiased manner, and to protect the safety and dignity of the thousands of individuals who volunteer to participate in research studies. We believe that the biomedical investigators and research staff both at the NIH and at our institutions work very hard to maintain the trust that has been placed in them by our fellow citizens. But given the vital importance of this area of the public trust, we must do better. We believe that the legislation you have proposed provides an appropriate vehicle to enhance the robust systems of accountability that currently exist at the NIH.

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 join with all members of the medical research community in applauding and supporting your call for additional funding above the level of the Biomedical Research and Development Price Index (BRDPI) 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 ongoing innovation and ingenuity and continued world leadership by the nation's medical research enterprise.

The AAMC supports the establishment of a formal strategic planning process to identify areas of trans-NIH research to take full advantage of emerging scientific opportunities and to address pressing public health challenges. We are pleased that the planning process outlined in the legislation mirrors the actions that the NIH has already undertaken through its Office of Portfolio Analysis and Strategic Initiatives. We also note that the proposed composition of the Council of Councils strikes an appropriate balance between the need for scientific input and the desire for broader representation of the various stakeholder communities. Mr. Chairman, we strongly agree with you that the decisions regarding the research projects to be supported should be based on scientific merit and not political decisions.

The AAMC also endorses the creation of a comprehensive electronic reporting system, which we agree will enhance the agency's accountability by providing increased transparency across all of the NIH's institutes and centers to all stakeholders. Scientists, patients, and policymakers all will

benefit from increased access to this information, which will supply new insights into the value the public has derived from its sustained investment in basic and clinical research.

The AAMC fully supports the creation of a dedicated source of funding, known as the Common Fund, to support the trans-NIH initiatives identified. Our community strongly believes that increases in this fund should not come at the expense of ongoing research programs, and we are pleased that the current legislation provides a reasonable rate of growth for the Common Fund that is linked to the growth of the overall NIH budget.

Once the Common Fund reaches 5 percent of the total NIH budget, the Director of the NIH, in consultation with the Council of Councils, is to submit recommendations to the Congress for further changes in the size of the Common Fund. We would propose modifying this provision by requiring the Director of the NIH, in consultation with the Council of Councils, to submit a thorough evaluation of the Common Fund and the research and research resources supported by the Fund prior to any decision about the size of the Fund. We believe that impartial 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 Common Fund.

Regarding the proposed uses of the Common Fund, we offer the following suggestions.

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.

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 legislative language be amended to permit the support of research resources as well as research. We believe this recommendation is 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.

We have provided the committee with these and some additional recommendations that we believe would strengthen the bill and build even greater community support. We respectfully ask the committee to consider these proposals, which I have attached to my testimony, either through technical refinements in the legislative text or in the report language accompanying the bill, when it takes up the legislation.

National Institutes of Health Reform Act of 2006
Technical Refinements
Submitted by the Association of American Medical Colleges
September 19, 2006

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 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.