



July 19, 2005

The Honorable Joe Barton
Chairman
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

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Jordan J. Cohen, M.D.
President

Dear Mr. Chairman:

The Association of American Medical Colleges (AAMC) appreciates the opportunity to comment on the draft legislative proposal to reauthorize the National Institutes of Health (NIH). The AAMC represents the nation's 125 accredited medical schools, more than 400 major teaching hospitals and health systems, and 94 medical and professional societies representing 109,000 faculty members. Our member institutions perform over half of all extramural research sponsored by the NIH and are at the forefront of biomedical and clinical research.

The AAMC is pleased the current draft is a clean proposal focused on the organization and function of the Office of the Director of NIH. The AAMC supports several of the objectives of the draft legislation, including:

- Enhancing the capacity of NIH to undertake trans-NIH strategic planning and coordination to identify new areas of emerging concern and assuring appropriate response;
- Strengthening the authority of the NIH Director to oversee and coordinate the nation's medical research portfolio; and
- Standardizing reporting requirements to promote greater accountability and stewardship of the funds invested in medical research.

In general, the AAMC would emphasize that the critical factors underlying the universally acclaimed success of the NIH are merit-based allocation of resources and a carefully balanced approach to addressing scientific opportunity and public health need, as determined by peer investigators and public health officials, and informed by patient and community advocates in deliberation within the NIH. Any modification of the NIH's organization and function must adhere to these foundational principles. In addition, NIH's requisite autonomy in conducting its two-tier system of evaluating scientific merit and programmatic need, and in guiding and managing its programs with a minimum of political interposition, must be protected.

The AAMC would make the following comments on the discussion draft provided on July 12, 2005.

Organization of the National Institutes of Health – The draft proposes a fundamental regrouping of the institutes and centers into two categories: “mission-specific” and “science-enabling.” This is an artificial construct, as all of the institutes and centers have missions that are clearly identified in their underlying

statutory authorities. And all institutes and centers are “science enabling” in that they provide the resources – not limited to funding—that undergird medical research across all fields. These responsibilities include promoting strategic planning within the affected disciplines, providing logistical support, and developing new scientific talent. The draft does not make clear why this artificial divide is necessary, and the AAMC cannot discern the benefit of constructing this divide.

The draft also provides for a single authorization of appropriations for each of these categories, but does not articulate who is to make the decisions regarding the allocation of funds to the individual component institutes and centers, or when these decisions will be made. Historically, the Congress has guarded its privilege of appropriating funds to the institutes and centers based on careful assessment of accomplishments and opportunities. The draft legislation does not make clear why the dramatic change being proposed is advantageous, and it could reduce existing congressional oversight and control.

Authorization Levels – The current draft does not include funding levels for the four authorizations of appropriations that are proposed. The AAMC would strongly recommend that the funding levels be sufficiently high to continue the momentum of the research enterprise. The last three fiscal years have dramatically demonstrated the effects of funding NIH at less than the Biomedical Research and Development Price Index. These less than inflationary increases have already produced great strains for the institutes and centers in managing their new and already obligated research commitments and for the extramural community because of grants being funded at below approved levels. In addition, if the restructuring of the Office of the Director to support increased trans-NIH initiatives augers a significant increase in funding for such activities, we would caution that this increase not be provided at the expense of the underlying research programs of the existing institutes and centers.

Transfer Authorities – The draft provides authorities for the NIH Director to transfer unspecified percentages of funds between institutes and centers for the purpose of implementing the trans-NIH initiatives identified pursuant to the Division of Program Coordination, Planning, and Strategic Initiatives, and to transfer unspecified percentages between institutes and centers for other purposes authorized under Title IV of the Public Health Service Act.

As the NIH has become much more complex, the AAMC agrees that Congress should increase the transfer authority of the Director, which is currently set at 1% of the NIH budget. The AAMC recommends that the Director’s transfer authority be increased, but to no more than 3% at this time. It is important to recognize that based on the NIH’s FY 2005 budget, a 3% transfer would represent \$850 million. Reallocations of funding greater than this amount should not be done as transfers, but should be proposed and considered as part of the annual budget and appropriations process. In the present system, through a series of processes involving multiple committees, both houses, input from public and potential review by the executive branch, Congress allocates funds to the different institutes. The proposed system has little in the way of checks and balances.

Division of Program Coordination, Planning, and Strategic Initiatives – The current draft proposes the creation of this division with the Office of the Director with broad planning and grant-making authorities. The AAMC supports efforts to better coordinate trans-NIH activities, and applauds the

proposal to create enhanced analytical and planning functions through an Office of Portfolio Analysis and Strategic Initiatives.

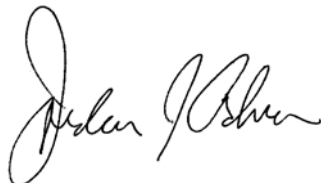
However, the AAMC is very uncomfortable with the idea of providing grant-making authority to a new centralized entity, with little specification of its competence, scope of authority or purpose, and when the scientific expertise continues to reside in the individual institutes and centers and their extramural communities. In addition, the AAMC is concerned about investing significant financial resources in an untried enterprise – as signaled by the creation of a separate authorization of appropriation – during a time of severe fiscal constraints.

Reporting Requirements – The draft outlines an extensive series of reporting requirements including plans for research on specific diseases, disorders, and other adverse health conditions, including statements of objectives regarding the research, the means for achieving the objectives, a date by which the objectives are expected to be achieved, and justifications for revisions to the plans. While the AAMC supports enhanced efforts to document and report the research conducted and supported in a coordinated and transparent manner, the draft is silent on the issues of who will collect and manage the massive amount of data required for these reports, and how this will be funded. The AAMC is concerned that some of the specifications required are more appropriately targeted to contract research than to the investigator-initiated basic research supported by grants. These requirements need reconsideration.

Timing for review and discussion – It must be noted that less than one week has been provided between the time the draft was circulated for public comment and the scheduled hearing on the legislation before the full House Committee on Energy and Commerce, with markup of the bill to follow shortly after. Given that this draft proposes a dramatic restructuring of the NIH that will have significant implications for the complex nature of the NIH and its constituent institutes and centers and the myriad relationships between the NIH and the thousands of institutions entrusted to carry out the Nation’s biomedical and behavioral research effort, sufficient time must be afforded for thoughtful consideration and discussion by all stakeholders in the medical research community. This is particularly critical since key provisions within the draft relating to levels for authorization of appropriations and for transfer authorities are incomplete.

The AAMC appreciates the opportunity to comment on the proposed reauthorization of the NIH and looks forward to working with Congress to strengthen what is regarded as the world’s leader in medical research.

Sincerely,

A handwritten signature in black ink, appearing to read "Jordan J. Cohen". The signature is fluid and cursive, with the first name "Jordan" being the most prominent part.

Jordan J. Cohen, M.D.