

December 3, 2002

### AAMC Statement on NIH Organization

The Association of American Medical Colleges is pleased to submit to the National Academies and the Institute of Medicine our views on general principles for organizing and managing the National Institutes of Health. We write on behalf of the AAMC's constituents, including the nation's 125 accredited medical schools, more than 400 teaching hospitals, 98 medical and professional societies representing 105,000 faculty, and 67,000 medical students and 103,000 residents. Our member institutions perform over half of all extramural research sponsored by the NIH and are at the forefront of biomedical and clinical research.

We appreciate the academies' efforts to evaluate the structure of NIH's organization, to consider proposed options for realigning its administrative components, and to attempt to moderate, if not reverse, practices that could result in an ever more fragmented, diffuse, and incoherent organization. We especially note the first question put to the committee in the description of Project Scope, namely, are there general principles by which NIH should be organized? The AAMC recognizes that the NIH has been remarkably successful and effective during the past 6 decades, and because of that believes that "tinkering" with the agency's structure for the sake of change alone would be inadvisable. Any proposals to modify NIH's structure and function should be informed by a set of credible organizing principles, as considered below. The Association's general position may be summarized as follows:

First, the AAMC agrees that the Academies should focus, as the Project Scope states<sup>1</sup>, on the new vistas and challenges of 21<sup>st</sup> century biomedical and health sciences and how the NIH might best be configured to remain a source of medical innovation and a champion for public health. The NAS and IOM are appropriate bodies to deliberate, and, as appropriate, reaffirm or reformulate the central organizing principles for NIH based upon new scientific opportunities and public health needs. Such an accomplishment would be a fitting response to help NIH continue its successful management of the nation's substantial investment in biomedical research.

Second, as Harold Varmus and other commentators have argued<sup>2</sup>, the continued proliferation of new NIH institutes and other ad hoc administrative structures threatens to undermine the agency's cohesion and impede the achievement of the agency's public health mission and its efficient stewardship of public funds. The NIH can, as it has repeatedly done over the decades, effectively target emerging areas of need and opportunities for health research without the addition of new institutes or other separate structural entities. Accordingly, it would be worth the committee's effort, albeit a very difficult challenge, to identify scientifically sound and politically viable mechanisms that might either retard such proliferation or better protect the agency's cohesion and accountability from the adverse effects of such proliferation.

The following section briefly considers previous IOM and AAMC recommendations that serve as a basis for current consideration of NIH's organizational structure. The second section examines current challenges to the agency's organization, and the final sections proffer organizational principles that should guide any reconfiguration of the NIH, and some proposals, if organizational change is deemed necessary, for re-orienting the agency around new scientific opportunities and enhancing its capacity, cohesion, and responsiveness.

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<sup>1</sup> <http://www.nationalacademies.org/nihorg>. project ID BLSX-K-01-05-A <accessed October 3, 2002>.

<sup>2</sup> Varmus H. Proliferation of national institutes of health. *Science* (2002) 291:1903-4.

## Prior Analyses of NIH Organization

As the committee is well aware, the issues before it are substantially similar to those addressed by the Institute of Medicine in 1984, when a committee chaired by Dr. James Ebert issued a series of detailed recommendations based on its analysis of NIH organization and management.<sup>3</sup> The AAMC, which had submitted comments and testimony to the Ebert committee, subsequently convened an ad hoc committee to examine and respond to the recommendations. The ad hoc committee's findings were issued in 1985.<sup>4</sup> Exhibit 1 summarizes the recommendations of the IOM and the AAMC committees; Exhibit 2 displays the relatively few explicit outcomes of the IOM recommendations. As evident from Exhibit 1, the Ebert committee's recommendations were largely, and generally vigorously, endorsed by the AAMC. In particular, the IOM concluded that:

NIH's current organizational scheme is appropriate and effective. The interplay of institutes focused on diseases and health problems with disciplinary study sections....helps NIH to meet its twin objectives of responding to health needs by capitalizing on scientific opportunity, and promoting basic science and maintaining standards of scientific excellence.<sup>5</sup>

*The committee recommended that there be a strong presumption against the creation of new institutes at NIH.* They demonstrated that, historically, the addition of new institutes had no significant impact on the growth of the NIH budget or support overall, nor was creation of a new institute a necessary condition for effectively addressing new health needs or research opportunities—there were, and have continued to be, prominent examples of new research areas and emphases that arise and integrate themselves within existing institutes.<sup>6</sup> On the other hand, the creation of new institutes threatened potential fragmentation of research programs, weakened lines of communications among researchers, and taxed the capacity of the NIH leadership effectively to coordinate programs.

Given the problems created by NIH's growing number of organizations, which had already by 1984 been perceived by the research community, the Ebert committee examined the root causes motivating proposals to create new NIH institutes (eleven proposals for one type of institute or another were under current consideration in various venues in Washington at the time of the report).<sup>7</sup> The Ebert committee's interviews and examinations led it to the conclusion that public health and patient advocates and their champions in Congress—two vertices of the so-called “iron triangle” supporting NIH research—too frequently perceived the agency as insufficiently responsive to emerging or persisting health needs. Thus, the IOM recommendations largely focused on improving the responsiveness, coordination, and accountability of the agency. Key recommendations, as noted in Exhibit 1, included:

- Strengthening the authority of the NIH director and the NIH's capacity for research planning and coordination to identify new areas of emerging concern and assuring appropriate response.
- Establishing a Health Policy Board at the level of the Secretary for Health and Human Services, which would take a broad view of the Public Health Service and provide a visible venue for discussions of how health issues are assigned across its agencies.

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<sup>3</sup> *Responding to Health Needs and Scientific Opportunity: The Organizational Structure of the National Institutes of Health.* Washington DC: National Academies Press, 1984.

<sup>4</sup> AAMC Memorandum 85-35 from President John A. D. Cooper, M.D., Ph.D, July 2, 1985. The Ad Hoc Committee was chaired by Dr. Robert W. Berliner, Professor of Physiology in Medicine, Yale University School of Medicine. Dr. Thomas Kennedy served as lead staff to the committee.

<sup>5</sup> Stoto MA, Ebert JD. The organizational structure of the NIH. *The New England Journal of Medicine* (1985) 312;25:1634-7.

<sup>6</sup> Discussed further below.

<sup>7</sup> These included arthritis and musculoskeletal diseases, nursing, and other organizational entities that were subsequently created. Also, proposals to incorporate three institutes from outside the NIH were also enacted.

- Strengthening the support and independence of NIH advisory committees, including the Director’s Advisory Committee (DAC, more recently dubbed ACD). The DAC chair should be someone not the NIH Director or otherwise in federal employ. The IOM also recommended provision of dedicated staff and budgets for advisory committees.
- Improving the capacity for public communications of the NIH, to help the public—as patients, communities, and taxpayers—keep better apprised of the ways NIH improves their lives.

A key recommendation was that the creation of new institutes and other entities should be considered last among options for changing the focus of research, and should be considered only in exceptional circumstances, after other measures had been sufficiently examined. To assist such evaluation, the committee developed five threshold criteria for screening proposals for new organizations (Exhibit 3). The committee envisioned that the Health Policy Board would serve as the venue for evaluating such proposals.

The AAMC’s ad hoc review committee commended the IOM report, but differed from the Ebert committee’s recommendations in a few areas. In particular the Association believed that the report had not gone far enough in recognizing the high levels of esteem and respect for which NIH was widely regarded in Congress and the public at large. Such esteem belied to some degree concerns that NIH was perceived as unresponsive to health needs: non-responsive agencies could hardly be so well regarded.

The AAMC also emphasized its opposition to new institutes and organizational burdens as major threats to the effective operation of the NIH and biomedical research, citing among several principal concerns:

- The span over which an NIH director can exercise control is finite, and increasing numbers of institutes will inevitably stretch this span of control beyond reasonable limits.
- A proliferation of institutes fragments the NIH research effort into ever smaller compartments, sequesters resources into programs of ever narrower scope, and makes it managerially difficult to reallocate resources when opportunity wanes or overlap problems commend redistribution. Thus programmatic agility and fiscal and flexibility are reduced.
- The narrower its scope and the more intense its focus, the more likely an institute is to underemphasize biomedical problems that, while seemingly peripheral to its central mission, are closer to it than to that of any other institute.<sup>8</sup>

Thus, the AAMC argued that the Federal Government’s position should go beyond a *presumption* against proposals to create new institutes and use a standard more analogous to judicial “strict scrutiny”, i.e., proposals for new institutes should rarely if ever survive close examination. The AAMC, like the IOM, recognized the value of establishing a public forum for the evaluation of proposals for new institutes or other initiatives and NIH’s responses as a mechanism to increase the visibility and transparency of NIH decision-making. The Association, however, opposed the creation of the Health Policy Board within the Department of Health and Human Services (DHHS). The board was considered unnecessary—as the DHHS Secretary already has broad access to available information in any event—and would most likely succeed only in politicizing debate rather than aiding informed decisions. (Indeed, recent press reports on actions to reconstitute the DHHS Secretary’s Advisory Committee on Genetic Testing and the National Human Research Protections Advisory Committee, fairly or unfairly, would seem to resonate with our predecessors’ apprehensions).

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<sup>8</sup> Adapted from the AAMC comments to the IOM Committee on the Structure of NIH, Sept. 1983. The document is included as attachment II in AAMC Presidential Memorandum 85-35.

The AAMC committee proposed a forum or process within NIH that would assure access for all interested groups to communicate and discuss concerns for NIH organization. The creation of such a process would not only enhance public trust in the integrity and fairness with which the national research enterprise is managed, but also increase the sensitivity with which the annual budget process adjusts program priorities. The AAMC proposed that:

The NIH periodically, perhaps decennially, reevaluate, reaffirm or revise its organizational structure through a process that involves the participation of a maximum number of interested government and nongovernment organizations.<sup>9</sup>

### **The Current Challenges to NIH Organization**

A robust platform for continued success and vibrancy of the NIH has been created by the historically remarkable, Congressionally led commitment for funding, and the near doubling of the agency's budget from FY1998 to the present (historically, the NIH budget has nominally doubled, on average, every nine years). As the IOM's earlier analysis indicated, the number of NIH institutes does not appear to have been a significant factor in the growth of the agency's overall budget over the years.<sup>10</sup> Critical to the support for the NIH's recent funding spurt was Congress' success in maintaining its focus on the NIH *as an integrated whole*. The rationale supporting a doubling of the entire agency's budget from FY 1998 to FY 2003 recognized the interdependence of research and training across all institutes in promoting the nation's health, and both Congress and advocates for medical research (for example, the Ad Hoc Group for Medical Research) specifically sought to avoid fractious proposals for more targeted funding.<sup>11</sup>

Contrary to assertions that NIH is unresponsive to persisting or emerging health concerns, the AAMC perceives that NIH has demonstrated time and again its ability to identify or anticipate health concerns and innovatively adapt new research directions within its existing organizational framework. The evolution of the National Heart Institute to the National, Heart, Lung and Blood Institute (NHLBI) accommodated substantial strengthening of the institute's efforts in lung research in the 1960s, and later in research on blood and circulatory disorders, while sustaining an effective, integrated program for cardiovascular and pulmonary health. The institute continues to earn abiding support from the American Heart Association, the American Lung Association, and other major health advocacy groups. Similarly, NIH's trans-institutional AIDS program, spurred in the early 1980s by the NCI's identification of AZT as the first effective anti-retroviral agent, has contributed to illuminating the molecular biology, pathology, immunology, and other fundamental aspects of HIV infection, and the development of several clinical and public health interventions. The continuing public health and humanitarian urgency of the AIDS pandemic precludes any implied complacency about these programs, but the (Congressionally mandated) NIH strategy for integrating this research across multiple institutes has clearly been effective in spearheading the nation's response to this disease. More recently, the National Institute of Allergies and Infectious Diseases has ably and flexibly responded to the heightened threat of biological terrorism and warfare by initiating new programs, coordinating with the Centers for Disease Control and Prevention and other federal agencies, and adapting organizationally to serve as the nation's research focal point in responding to this new public health menace.<sup>12</sup>

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<sup>9</sup> AAMC's comments.

<sup>10</sup> The National Cancer Act of 1971 did serve as a major stimulant not only to funding of the National Cancer Institute (NCI), which the act elevated to bureau status, but very rapidly thereafter, of all the NIH institutes.

<sup>11</sup> See for example, Senate Resolution 170, introduced by Sen. Specter (*Congressional Record*, Jan. 29, 1998, S234-6), and amendment no. 315 expressing the sense of the Senate, introduced by Sen. Mack (*Congressional Record*, May 21, 1997, S4861-8).

<sup>12</sup> "Summary of NIAID Accomplishments in Biodefense Research", September 10, 2002.  
<http://www.niaid.nih.gov/newsroom/biodresaccomp.htm> <accessed November 13, 2002>.

Now, at the end of the five-year doubling effort, the NIH must transition into a period of unprecedented challenge and opportunity with an expanded portfolio.<sup>13</sup> For the foreseeable future, the agency must manage a vastly expanded commitment base while ensuring funding for new awards. The agency is further challenged to stay current with sophisticated new technologies and facilities, while the environment for biomedical research and the nature of the research itself become more integrated and “systems” oriented, and more dependent on capital resources. Although investigator-initiated research projects appropriately remain the centerpiece of the NIH extramural program, many new areas of biomedical research increasingly rely on large, interdisciplinary research teams. Further, growth in biology’s use of and demand for sophisticated instrumentation, facilities, and information technology has well exceeded the current capacity of many research organizations. Resources are needed to support imaging and modeling of biological systems, creation and mining of large basic and clinical science data bases, and the creation of IT networks for linking laboratories and other facilities, among other requirements. The needs for information resources in clinical research are particularly acute,<sup>14</sup> given that the setting for modern clinical research is coextensive with a health care delivery system that is itself extraordinarily fragmented and complex.

The budget doubling of the NIH fairly coincided with the economic boom of the latter 1990s and the advent of federal budget surpluses. That environment has changed profoundly. National—and now homeland—security issues have returned as a major claimant to future federal budget increases, significantly changing the odds in the competition for discretionary funds. Perhaps the only certainty in the current national political environment for the NIH is that burden of disease and the public’s expectation of better health will continue to grow. In such an environment, health and patient advocates, the research community, medical specialty and subspecialty organizations, and individual members of the Administration and Congress may all push harder to expand institutes and centers that reflect their own deeply felt sense of research priorities. The pressure to create new organizational entities and initiatives that reflect constituents’ priorities will increase, while the resources available to the NIH will likely become ever more constrained.

As the NIH transitions into this new era with new rules of engagement, public policy should attend to addressing the administrative complexities and burgeoning bureaucracy that confound supply management of the agency. Since 1984—when the IOM panel advised against creation of new NIH organizations and proposed stringent threshold criteria for any proposed new institute—eight new institutes have been added to the NIH, augmenting the then-existing 11 institutes.<sup>15</sup> Additional centers have also been created. Several of the new institutes were incorporated or re-incorporated from outside the agency, and the others were created directly by actions on the part of legislators and their constituents, elevating programs to institute or center status, or reapportioning and consolidating existing programs.

The continued proliferation of new institutes and other ad hoc administrative structures, although often based on a rationale to dedicate resources to areas perceived as under-funded or under-valued, threatens achievement of NIH’s mission. As the IOM, AAMC, and others previously noted, new institutes or other organizations raise potential barriers for coordination across emerging and established lines of research. They may focus research too narrowly or disregard broader interests; they could impede NIH’s ability to respond to the profound organizational transition of contemporary biomedical research from an historic “cottage industry” to “big science;” they reduce the agency’s programmatic and fiscal flexibility, as well as the ability of the NIH to respond as a whole to new opportunities and new public health needs; and they must, sooner or later, stretch the Director’s span of responsibility and accountability beyond reasonable bounds.

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<sup>13</sup> Korn D, Rich RR, et al. Science policy: The NIH budget in the "postdoubling" era. *Science*. 296:1401-2, 2002 May 24.

<sup>14</sup> AAMC Conference Report on Information Technology in Clinical Research, forthcoming.

<sup>15</sup> New institutes include NIAMS, NIDCD, NINR, NHGRI, and NIBIB, and institutes transferred to NIH include NIMH, NIDA, and NIAAA.

The office of the NIH Director is accountable for the agency's overall direction and responsiveness to public health needs. The NIH director requires greater capability and flexibility in coordinating resources to launch new initiatives and respond to new eventualities, particularly in the case of emerging public health needs and threats, or paradigm-shifting research discoveries.<sup>16</sup> The NIH institutes currently support a modest degree of coordination and cross-collaboration, and further growth in the number of institutes would necessarily further burden this capacity. Additional institutes and centers may create duplication or dilution of effort, and administrative redundancies that will surely divert resources away from research and application, at a time when current research management and support (RMS) budgets are already sorely strained. Moreover, each NIH institute and center is funded directly by annual appropriations legislation, for which all institutes must begin planning and budgeting requests more than two years in advance. Of course, all NIH programs are subject to this planning cycle, whether they exist in established institutes or are relocated or created *de novo* within a new entity. But designation of a new institute effectively sets its programs on separate tracks for planning and administration, and diminishes NIH's flexibility to coordinate, plan, and allocate total resources across the agency.

### Central Organizing Principles for NIH

The AAMC believes that the creation of new institutes or other major administrative entities at NIH does not necessarily advance research or address public health needs in a uniquely effective way, and potentially causes harm to the effective, efficient, and responsive operation of the NIH overall. Accordingly, we suggest that the following principles should govern any proposed restructuring of the NIH's organization:

- **Reassert the NIH's autonomy in making a balanced assessment of scientific opportunities and public health needs.** Any proposed structure for the agency must allow NIH to continue to seek advice from knowledgeable or affected communities, conduct its own deliberations, and make decisions in the best interest of science and public health. The AAMC believes that merit-based allocation and a 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, should continue to be the foundational principles of NIH organization and function. The scientific community must remain ever vigilant in protecting the 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.
- **Reaffirm the NIH's processes for setting priorities.** Related to the above principle, any proposed reorganization of NIH should permit the agency to retain scientific opportunity and promise and public health need as the key indicators to determine how valuable resources can best be put to solving problems effectively. Accordingly, the NIH leadership must weigh the public health mission of the NIH, the societal and human dimensions of disease, the urgencies attending diseases, and other considerations in setting priorities and managing programs. As noted above, patient advocacy groups, voluntary health organizations, and scientific societies should be encouraged to continue to work cooperatively with the NIH to support the decision-making process.<sup>17</sup> Non-contextual creation of new institutes, or efforts to superimpose on NIH's organization and programs targets for specific areas of disease or disability, can be highly disruptive to the system. Such intervention may ultimately serve to misalign resources and undermine a coordinated, agile response to changing health needs.

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<sup>16</sup> For example, NIH Director Elias Zerhouni, has outlined a laudable "roadmap" for priority setting across NIH institutes in his remarks to the AAMC 2002 Annual Meeting, in San Francisco, Nov. 9.

<sup>17</sup> The process is described in an excellent primer written by NIH staff, at <http://public-council.nih.gov/SettingResearchPriorities.htm#science> <accessed Nov. 6, 2002>.

- **Strengthen the office of the NIH director to permit better coordination and guidance among institutes, centers, and programs.** We believe this principle was reflected in the earlier IOM-Ebert committee's recommendations<sup>18</sup> and lies at the heart of Dr. Varmus' recent commentary.<sup>19</sup> Any proposed organizational structure should enhance and not debilitate the ability of the NIH director to oversee and coordinate the nation's biomedical research portfolio. A proliferation of new NIH institutes or other organizational structures, particularly if they do not arise through the established deliberative processes of the agency, diminish the director's capacity effectively to coordinate and manage NIH resources. Moreover, the increasingly high profile of the NIH, both as an authority on emerging health issues and as a major federal cost center, requires that the director be afforded every means to remain fully accountable for so large and visible an enterprise.
- **Strengthen the credibility and functionality of the Advisory Committee to the Director (ACD) and of the respective advisory councils to NIH's component institutes.** Credible, respected, and engaged advisory committees are essential guarantors that NIH leadership receives ample, reliable information and feedback on its decision-making. They further help make NIH's management processes transparent to the public and can help demonstrate NIH's responsiveness on matters of public concerns. The ACD in particular provides a compass for guiding the agency's direction. Given its desire that NIH demonstrate its responsiveness to concerns from the health advocacy community, the Ebert committee made particular recommendations for strengthening the Director's advisory committee.

At the request of Congress, the IOM completed a study in 1998 of the NIH processes for receiving public input,<sup>20</sup> which resulted in the creation of an entirely new NIH advisory committee, the Council of Public Representatives (COPR). As the council is now established and in the process of recruiting new members, it is unnecessary to recommend any additional structures to serve this function at this time.

- **Initiate a formal review process for new institutes or other major organizational change.** Any future proposed restructuring of the NIH ought to be made subject to review and deliberation within the NIH (with input from appropriate advisory committees) and by a suitably experienced and credible external advisory body. We concur with the Ebert committee's recommendations for a formal review process with threshold criteria for new institutes, and the AAMC's own earlier recommendations for a periodic review of the NIH organization. It is paradoxical that new, relatively modest NIH research or training programs can be established only after intensive and often lengthy review within the agency and, as necessary, approval by the Administration or Congress, while entire institutes can be summarily established without formal deliberation by NIH or its councils, or even by the White House Office of Management and Budget. It is further paradoxical that the creation of new institutes or other administrative structures serves to make the NIH more bureaucratic and less flexible, and may divert resources away from research support. The AAMC is opposed in principle to any major organizational changes within NIH that do not first allow for an informed review by a respected, credible, independent external advisory body. We propose that the National Academies be designated as the periodic reviewer for proposed revisions to the NIH organizational structure (effectively, the Academies, or its member IOM, by performing all major independent reviews of the agency in past decades, have become the de facto, but typically ex post facto, organizations for this role).

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<sup>18</sup> Although we are not aware at this time of any new statutory or delegated authorities required by the NIH Director, which the Ebert committee had recommended in 1984.

<sup>19</sup> Varmus H., op cit.

<sup>20</sup> Rosenberg E., chair. *Scientific Opportunities and Public Needs: Improving Priority Setting and Public Input at the National Institutes of Health*. Washington, DC: National Academy Press, 1998.

If the Academies would consider it desirable to have additional input on regulatory or administrative issues pertinent to such evaluation, they might also seek consultation from the National Academy of Public Administration or a similarly distinguished body.

### **Suggested organizational or managerial reforms in support of these principles**

The fundamental principle governing any proposed reorganization of the agency should be *first, do no harm*. NIH over many decades has promoted and exemplified excellence as the standard of its operations. Its multi-tiered review processes, based on merit review of performance and promise, and its close management and oversight, are unexcelled in the public sector. Its benefits are reflected in the preeminence of American biomedical research and the international renown of the nation's extensive network of medical research and training institutions that have arisen in the past 6 decades spurred by NIH support, as well as in the NIH's crucial role in supporting innovation in the health care, pharmaceutical, medical device, and biotechnology industries. By the history of its development and by the dynamic and interactive nature of its association with many communities, the NIH is a highly complex organization.

*If* the National Academies determines that reorganization or reconfiguration of the NIH structure is in fact desirable for clear and persuasive reasons, then the AAMC suggests consideration of the following changes:

*Re-categorization of Institutes:* Dr. Varmus proposed a reorganization of NIH that would streamline the agency within six institutes: Cancer, Brain, Internal Medicine, Human Development, Microbial and Environmental Medicine, and a central institute responsible for trans-NIH policies and coordination, the peer review process, research infrastructure, and new research initiatives. He allowed that "this is one of many schemes that might provide long-term coherence for the NIH" and correctly advised careful deliberation in considering any change to an agency as complex and intricately balanced as the NIH.

Proposals to consolidate institutes and centers around major medical or research areas would entail great difficulty and are somewhat quixotic. It is hard to envision a viable political or advocacy consensus for the wholesale restructuring and realignment of existing institutes. However, these vital constituencies for medical research might support a compromise that allows existing institutes and centers to be aggregated within Health Science Divisions along the categories proposed by Dr. Varmus. The institutes would remain identifiable entities as "line items" in the NIH appropriation, with separate budgets and directors, but in the NIH's table of organization they would report to the Health Science Division directors who would, in turn, report to the NIH Director.

*Health Science Division Directors:* Under the reorganization scheme proposed above, Division Directors would oversee coordination and planning among their respective institutes and centers. Directors should be distinguished individuals with sterling credentials in biomedical investigation and research administration, as well as respected health advocates. The role of the divisions would be to coordinate budget and program planning, and to use transfer authority or other instruments for coordinating flexible, coherent responses to emerging research opportunities or public health concerns within their areas of responsibility. Division directors would participate in their respective institute advisory council meetings, and would also meet regularly as a group with the NIH Director and other NIH and Public Health Service (PHS) leadership to ensure coordination of important initiatives across the NIH and the public health service. It is likely that RMS functions and other administrative requirements could be substantially consolidated at the division level, with resultant cost savings. Any scheme should retain the genius of NIH's original categorization of research—favored by James Shannon and others—to address the lay public's perception and understanding of the areas of health topical to the research agenda. The largest and most complex institutes, i.e., Cancer, Heart, Lung and Blood, and Allergies and Infectious Diseases, would become divisions in themselves, but we believe that all of the other institutes, and most of the centers, could be sensibly and credibly consolidated within divisional structures.

We also suggest that Dr. Varmus' proposal of a broad "NIH Central" merits careful consideration as a vehicle for managerial facilitation and efficiency, as well as administrative cost savings.

*Establishing a formal, periodic process for evaluating organizational changes:* The Academies should recommend adoption of a rigorous deliberative process to review and comment on all proposed new major organizational changes within NIH. The process should be appropriately representative and include explicit evaluation criteria (see Exhibit 3, the proposed review criteria from the 1984 Ebert committee report).

Congress of course has first and final authority to determine the scope, character, and funding of the U.S. Public Health Service and other federal agencies. Academic and public communities committed to the vitality and effectiveness of the NIH should engage Congress to establish a periodic, independent NIH organizational review process. The NIH authorization committees, in particular, provide the statutory foundation for the long-term health and operation of the agency and could provide a forum for these discussions within Congress. The research community and leading health advocates should also endorse a moratorium on the creation of new institutes until the new review process becomes functional.

*Strengthening the Office of the NIH Director:* The responsibilities of the NIH Director are particularly challenging. The Director reports to the Secretary of Health and Human Services, must frequently interact with the Executive Office of the President and the Congress, and is called upon to represent the agency and federal medical research policies to the public and the world. While the NIH Director has authority over the directors of the component institutes and centers, the intramural program, and numerous other offices, the exercise of his/her authority in managing the NIH is in fact limited and heavily dependent on persuasion and stature, not command. For example, all NIH institutes and the major centers receive separate line item appropriations; the share of the total NIH budget actually controlled by the director is relatively small. Similarly, the institute and center (IC) directors frequently receive directions through legislation or regulation to which they must also respond, and they typically are answerable, and understandably responsive to constituents (patient advocates, researchers, etc.) with particular passion for the institute's research domain.

Some discretionary mechanisms made available to the director subsequent to the report of the Ebert committee have proven to be beneficial tools in supporting the ability of the NIH to respond to emerging issues or changing circumstances, or to coordinate the agency's progress toward long-term goals. As the agency has become much more complex, Congress should increase the transfer authority of the Director (currently set at 1% of the NIH budget), and consider establishing a discretionary fund for the Director to be used to initiate new projects or address emerging health issues in a timely and responsive way. Projects so established can later be transferred to an appropriate (division) institute or center for continued support as necessary, as Dr. Varmus has proposed.

As suggested above, if Divisions are created within NIH, Division Directors should also be provided transfer authority for programs that fall within their purview (for example, the Director of the Office of AIDS Research is provided a 3% transfer authority within the budget of the trans-institutional program).

*Strengthening NIH advisory committees:* The composition and operations of the various NIH institute advisory councils are fixed by the statutes of the Public Health Act and its organic sections. The structure of the National Cancer Advisory Board, separately authorized by the National Cancer Act (P.L. 92-218), provides, in our view, an attractive model for all NIH advisory councils. In particular, council composition should fairly represent expert biomedical and public health researchers, research administrators and policy leaders, and patient and public representatives. The chair should not be the institute director, nor a person employed by the Federal Government. The chair should work with the director to set the agenda of each council meeting and should ensure independent discussion and review of institute and NIH programs.

*Review of NIH intramural program:* NIH should undertake a thorough re-examination of the objectives of the NIH intramural program, with its roots in the 1940s and 50s, and should establish a clear mission statement for that program, relevant to circumstances of the 21<sup>st</sup> century. The intramural program should in general focus on opportunities and needs that are beyond the capabilities of the extramural research community, or to which the program can bring unique resources. Intramural research should not be duplicative or derivative of extramural research, and must be maintained to a standard of unequivocal excellence. The emergence of bioterrorism and biowarfare as issues of urgent public concern exemplify areas critically in need of innovative research in which the intramural program could well play a leadership role. Aside from the likely need for specialized resources not widely available extramurally, the possibly “sensitive” (or even classified) nature of some of this research will pose enormous problems for the academic biomedical research community. Another attractive example is the ability of NIH to generate unique programs of translational and other patient-centered clinical research within the new Hatfield Clinical Center. The most recent evaluation of the NIH intramural program occurred in 1994.<sup>21</sup> At that time, NIH was under severe budgetary stress, and the committee report urged that funding for the intramural program be maintained within a fixed percentage of the NIH budget (presently averaging about 11%). Since that time, the NIH budget has more than doubled and the Hatfield Clinical Center is nearing completion. A fresh look and fresh strategy would be timely and warranted.

*Review of the Clinical Center:* The Hatfield Clinical Center will offer the intramural program state of the art capabilities for conducting an innovative program of patient-oriented research. AAMC recommends that the Hatfield Center should be aligned with a strengthened General Clinical Research Center (GCRC) program to create a coherent, interactive system, linking these centers, laboratories, and other academic centers of clinical research and training excellence into the prototype for an urgently needed national clinical informatics network. Currently, Information Technology support for clinical research at most academic and non-academic health centers is limited to, and hobbled by, systems that have been developed for, and are dedicated to, administration and financial operations. As these centers struggle under severe financial constraints, they are not in position to make the large capital investments in technology required to support the research-oriented databases and information capabilities needed to enable clinical research to play its necessary role in translating human genomics (and its successor “omics”) into new understandings, preventions, and treatments of human disease.

The NIH’s National Center for Research Resources has begun a program of networking select GCRCs with major computational centers and with bioimaging and other laboratories. The AAMC believes that these are significant new initiatives that ought to be greatly expanded. The prospective research of most NIH institutes would benefit substantially from large-scale implementation of such networks and information systems. The integration of the GCRCs, computer centers, and the Hatfield Clinical Center would be a significant and much needed advance for clinical research.

## **Conclusion**

The transformation of the Laboratory of Hygiene at the Marine Health Service, founded in 1887, to the National Institute of Health in the 1930s successfully merged within one agency two separate communities, public health and (basic) biomedical research. The NIH historian Victoria Harden observed that NIH’s exponential growth and development over the second half of the century was actually conditioned by the fusion of these two communities.<sup>22</sup> Her chronicle of this formative period concludes with the creation of the National Cancer Institute, NIH’s first categorical institute, in 1937.

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<sup>21</sup> Marks PA, Cassell GH, chairs. *NIH Intramural Research Program. Report of the External Advisory Committee of the Director’s Advisory Committee, and Implementation Plan and Progress Report.* Bethesda, MD: US DHHS PHS, 1994.

<sup>22</sup> Harden VA, *Inventing the NIH: Federal Biomedical Research Policy, 1887-1937.* Baltimore: Johns Hopkins University Press, 1986.

Legislation in 1943 expanded NIH's contract authority to permit award of research grants, and laid the basis for the extramural research program. The era following World War II, led by James Shannon and other pioneering directors, established the central principles that have guided the agency, including its focus on basic research and clinical application, and the autonomy of the agency in making a balanced assessment of scientific opportunity and public health need.

The post-war period also witnessed the appearance of accomplished citizen advocates for medical research who have been phenomenally persuasive to Congress. This basis for strong and abiding political support of the NIH creates some side effects for NIH leadership: the emergence of new institutes, large centers, or other ad hoc administrative structures is often a prominent manifestation of constituent pressure. Historically, Congress has shown gratifying deference to NIH decision making and toward peer review; the NIH appropriation exhibits dramatically fewer directed line items or other earmarks as compared to appropriations for other large agencies. However, too often a constituency that perceives NIH administrators as being inattentive to their issue will seek a correction by legislative fiat, sometimes with benefit of hearings, sometimes without.

The AAMC, which serves both as a representative of organizations conducting biomedical research and as an advocate for public health, recognizes that any future proposed change to the organization and management of the National Institutes of Health must be designed to make the agency an even more effective steward of the nation's remarkably generous investment in biomedical research. The NIH has enabled extraordinary advancements in biomedical research, yet the agency's current configuration reflects a pattern set in the 1970s, with ever more differentiated institutes and centers, each focused narrowly on a particular line of research or public health need. The NIH functions extraordinarily well within this system to coordinate and initiate new lines of research, but a continued proliferation of institutes or other ad hoc administrative structures would inevitably weaken its operations. Given the nation's reawakened sense of the interconnectedness of public health and security, and the role of biomedical research in public health, the nation demands a medical and health establishment that is both authoritative and nimble. We believe the National Academies and Institute of Medicine have the opportunity to ensure that the integrity of NIH organization and function will be protected, and its remarkable record of accomplishment, maintained well into the future.

**Exhibit 1: Key Recommendations of the IOM Ebert Committee and AAMC Ad Hoc Review Committee Compared**

IOM Report, 1984	AAMC Ad Hoc Review Committee, 1985
<p>“The committee feels that the NIH categorical structure is an effective tool in helping to shape scientific excellence to national needs.” The Committee adopted a strong presumption against the need to create new institutes or other major organizational entities, or propose other major reorganization of NIH.</p>	<p>Strongly commended the IOM report committee and generally endorsed the report’s findings on NIH organization. The AAMC was more emphatic in its opposition to creation of new institutes or other administrative structures.</p>
<p>To respond to health needs without changing its organizational structure, the NIH must improve its ability to (1) sense emerging concerns of the public, research community, or Congress, (2) ensure through research planning that emerging needs are addressed, (3) respond to identified needs with activities matched to the magnitude and urgency of the demand.</p>	<p>The IOM committee did not go far enough in recognizing the excellence of the NIH and the high level of public esteem the agency enjoys. The AAMC wished that the IOM report had addressed the increasing tendency of Congress and the Administration to intervene in agency’s programming and management.</p>
<p>Other recommendations focused on better integration with DHHS policy, and strengthening mechanisms for communication and accountability.</p>	
<p>Rec.* 1. NIH Director should establish an agency-wide mechanism to (1) keep abreast of views/concerns of NIH constituencies (2) assess potential implications for NIH (3) plan responses.</p>	<p>Strongly endorsed the recommendation, which would in part create a visible forum for addressing public concerns, and shift the venue for such consideration from the politically charged climate in Congress to the NIH itself.</p>
<p>Rec. 2. NIH should strengthen its planning efforts at the institute level and in coordination of NIH-wide activities.</p>	<p>Also, valid, provided it is recognized that planning has inherent limitations in science and that “real roadmaps cannot be drawn for unknown territory.”</p>
<p>Rec. 3. NIH should “avail itself” of a range of activities, short of establishing new institutes, to respond to health needs and opportunities.</p>	<p>A logical and sensible consequence of accepting the first two recommendations and is supported without reservation.</p>
<p>Rec. 4. Establish a formal process to assess proposed major organizational changes in NIH.</p>	<p>See below.</p>
<p>Rec. 5. Proposed threshold criteria for new organizations: must match the NIH research and training mission; demonstrate that new research area is not already adequately addressed; reasonable prospects for scientific growth; prospects for sufficient funding; proposed change should improve communication, management, priority setting, &amp; accountability. [See Exhibit 3].</p>	<p>If recommendations 4 and 5 are adopted, the proposed criteria should be refined, extended, and tightened. AAMC has called for decennial reviews of NIH organizational structure; such reviews had been conducted earlier. Prior reviews had been strongly predisposed against expansion of NIH organizational structure. AAMC prefers such a process to any alternative suggested.</p>
<p>Rec. 6a. Establish a Health Science Board in DHHS to oversee health research. Missions, priorities, and institutional management. of PHS elements: NIH, FDA, CDC, ADAMHA, NCHS, Health Resources, and Nat. Center for Health Services Research.</p>	<p>The AAMC recognized the IOM committee’s perspective that public health concerns were broader than NIH. The IOM apparently believed that the absence of mechanisms to assure that health advocates’ concerns were adequately addressed was at the heart of Congressional willingness to create new</p>

	organizations. But the AAMC committee did not think that the creation of a Health Science Board was desirable. First, the DHHS Secretary should be free to seek advice from any quarters; second, such a board could too easily become politicized.
Rec. 6b. Health Science Board would advise Sec. DHHS through the ASH on any proposed change in organizational structure, or reassignment of responsibilities.	Per above.
Rec. 6c. Board would include 6 members appointed by Sec. DHHS, from slate nominated by ASH in consultation with NAS and NAPA.	Per above.
Rec. 6d - g. Members serve six-year terms, one third replaced every 2 years, qualifications based on scientific experience, health policy, and management. Would elect own chair, meet 4 times annually, assigned staff and budget, report to Sec. HHS through ASH.	Per above.
Rec. 7: The Sec. HHS should delegate to the NIH Director authority, direction, and control over NIH that the position does not now possess, subject to the policy direction of the ASH and to existing statutory limitations, “as recommended to be modified below.”	To the degree that necessary authorities are not sufficiently delegated to the NIH director by the DHHS secretary, the situation obviously should be corrected at once. AAMC urged that—to the extent necessary—requisite authority be provided by administrative delegation rather than by statute.
Rec. 8: The NIH Director should have greater budgetary authority and discretion in two regards: (1) a discretionary fund, not to exceed 1% of the NIH budget, with which to seed selected areas through existing institutes in accordance with a rigorous peer review process.	The request for transfer authority was virtually identical with an earlier AAMC recommendation, while the request for discretionary fund would also serve similar interests in strengthening the authority of the director....
Rec. 8 cont.: (2) limited authority to transfer up to 0.5% of the NIH budget across institute lines in response to a public health emergency.	On balance, the two elements in the IOM recommendations appear to be sound mechanisms to achieve a desirable end. “While there are not inconsequential downside risks to both proposals” the possible gains would appear to outweigh the hazards. The AAMC proposed a trial period for the proposals.
Rec. 9a: The current Director’s Advisory Committee (DAC) should be converted to a stronger and more independent NIH policy and planning council.	The AAMC feared that the proposal could actually serve to weaken the authority of the director, and duplicate within the stronger, more independent DAC functions served by the office of planning and evaluation and by other offices within the separate institutes. The AAMC found DAC as currently constituted to be ideal.

<p>Rec. 9b: The DAC should provide for the director a continuous evaluation of the research mission and function of the NIH and of its component institutes, w/ emphasis on NIH as a whole or interrelationship among institutes. It should advise the Director in the formulation of long-term plans and setting research priorities.</p>	<p>See above.</p>
<p>Rec. 9c-f: DAC should function as a major sensing mechanism and consensus builder for the director, should be composed of 12 members appointed by DHHS Sec., with terms of 6 years, one-third replaced every 2 years, selected on basis of scientific and professional competence and distinction.</p>	<p>See above</p>
<p>Rec. 9g: The council should elect its own chair, prepare its own agenda, meet at least 4 times per year and whenever requested by the director, be assigned its own staff, defined budget, and report annually to the NIH Director.</p>	<p>See above.</p>
<p>Rec. 10: Extramural research and intramural research (and related support activities) should be grouped under two deputy NIH directors each of whom has line authority over support functions outside of individual institutes and staff responsibility for extramural and intramural research programs; the staff functions in the Director's office should be reorganized to improve span of control.</p>	<p>The AAMC advised that recommendations 10 and 11 should be deferred to the judgment of NIH management.</p>
<p>Rec. 11: Where appropriate, support functions of individual institutes and other components should be clustered to reduce unnecessary duplication and expense.</p>	<p>See above.</p>
<p>Rec. 12: Each institute should provide its National Advisory Council members with full and easily understandable information on its entire portfolio of currently funded grants and grant proposals; institute directors should uniformly involve their advisory councils in broad programs and policy issues.</p>	<p>AAMC fully endorsed the objectives of recommendations 12 and 13 (to keep advisory bodies better informed and permit those groups to carry out their responsibilities more effectively), and all sound mechanisms to effect realization of these objectives.</p>
<p>Rec. 13: The NIH Director should assume overall responsibility for informing members of each Council of institute's response to its recommendations about intramural research.</p>	<p>See above.</p>
<p>Rec. 14: The role and staffing of the Office of Communications should be strengthened. The NIH Director should establish an advisory panel on public information, to assist the office in improving the breadth of distribution of current publications, and in employing additional media.</p>	<p>The AAMC wholeheartedly agreed with the recommendation intended to inform the public better about the activities of the NIH.</p>

<p>Rec. 15 Quality should continue to be overriding consideration in selecting all NIH advisory group members—scientific, clinical, and lay. The expertise of the advisory groups must be of the highest possible quality if they are effectively to fulfill their statutory responsibilities and to have credibility within the scientific community, with Congress, and with the public. Every effort should be made to reduce the levels of review and to expedite the selection process, so that advisory groups can always function at full strength.</p>	<p>This policy should be preserved and inviolate.</p>
	<p>The AAMC ad hoc committee noted what it considered important omissions of the IOM committee. Specifically, the importance to address increasingly specific levels of direction from the Administration and Congress on NIH activities and scientific freedom. The report also failed to note sufficiently the level of excellence and sterling performance associated with NIH research.</p>
<p>* Note: The IOM committee did not number all the specific recommendations of its report, but made such recommendations clear by underlining and offsetting them within the text of the report. The AAMC ad hoc review committee numbered these recommendations for clarity in its own references to these recommendations. That notation has been continued here.</p>	

**Exhibit 2: Outcomes of Major Recommendations of the 1984 Ebert Committee**

IOM Report, 1984	Outcomes
Recommendations 1 & 2: NIH Director should establish an agency-wide mechanisms for identifying public health concerns, strengthening response and coordination, etc.	Subsequent NIH directors have acted to strengthen core offices, including Science Policy, Communications and Public Liaison, Community Liaison and others, to improve NIH's capacity to identify and coordinate response to research opportunities and public health needs.
Rec. 3: NIH should avail itself of a range of activities short of establishing new institutes to respond to health needs and opportunities.	NIH has striven to accommodate new areas of research within its existing institute structure, as with its (Congressionally directed) Office of AIDS Research and other centers.
Recs. 4 & 5: Establish a formal process to assess proposed major organizational changes in NIH and apply stringent threshold criteria.	The Federal Government has not established such a process. Proposals for most new institutes established since the 1980s have been subject to Congressional hearings and other debate. The newest NIH institute was established without benefit of hearings.
Rec. 6: Establish a Health Science Board in DHHS to oversee health research missions and priorities across the Public Health Service.	The recommendation was not widely endorsed and was not adopted.
Recs. 7 & 8: Delegation of improved authorities to NIH Director. The NIH Director should have greater budgetary authority and discretion in (1) a discretionary fund and (2) limited authority to transfer up to 0.5% of NIH budget across institute lines. .	The NIH Director has been delegated 1% transfer authority, subject to limitations, etc.
Rec. 9: The current Director's Advisory Committee (DAC) should be converted to a stronger and more independent NIH policy and planning council.	Not adopted. The committee, now called the Advisory Committee to the Director (ACD) continues to be chaired by the NIH Director. The ACD continues to attract highly respected and informed members.
Rec. 10: Extramural research and intramural research should be grouped under two deputy NIH directors; the staff functions in the Director's office should be reorganized to improve span of control.	Deputy directors of the intramural and extramural programs have been appointed.
Rec. 11: Where appropriate, support functions of individual institutes and other components should be clustered to reduce unnecessary duplication and expense.	NIH has acted to improve the efficiency of its support functions. Conversely, the agency budget and portfolio has expanded without commensurate increases in research management and support (RMS) funding, a situation noted by Congress in recent appropriations.
Rec. 12: Each institute should provide its National Advisory Council members with full and understandable information and support, etc.	Institutes have attended to the care and support of their respective advisory councils. We are unaware of general concerns for adequate support.

<p>Rec. 13: The NIH Director should assume overall responsibility for informing members of each institute's Board of Scientific Counselors of that institute's response to its recommendations about intramural research.</p>	<p>This recommendation arose from the Ebert committee's interviews within the intramural program. We have not seen these concerns raised in subsequent reviews of the program.</p>
<p>Rec. 14: Strengthen the Office of Communications and establish an advisory panel on public information.</p>	<p>The NIH has a very effective Office of Communications. In 1998, the NIH established the Council of Public Representatives (at the recommendation of a later IOM report). The NIH has also made exceptionally effective use of the Internet and World Wide Web in promoting public information.</p>
<p>Rec. 15: Quality should continue to be the overriding consideration in selecting all NIH advisory group members—scientific, clinical, and lay.</p>	<p>There has been no noticeable flagging in the quality and experience of the NIH's many advisory councils.</p>
<p>* Note: As noted in Exhibit 1, the IOM committee did not number its major recommendations of its report, but made such recommendations clear by underlining and off-setting them within the text of the report. The AAMC ad hoc review committee numbered these recommendations for clarity in its own references to these recommendations. That notation has been continued here.</p>	

### **Exhibit 3: IOM Ebert Committee's Proposed Threshold Criteria for New NIH Organizational Entities**

- A. The activity of a new institute or other organizational entity must be compatible with the research and training mission of NIH. If a major emphasis of the proposed new entity is in regulation, in the delivery of services, or in other non-research activities, it is not appropriate for incorporation in NIH.
- B. It must be demonstrable that the research area of a new institute or other major organizational entity (defined either as a disease or health problem, or as a biomedical or behavioral process related to a health problem) is not already receiving adequate or appropriate attention.
- C. There must be reasonable prospects for scientific growth in a research area to justify the investment in a new institute or other major organizational entity.
- D. There must be reasonable prospects of sufficient funding for a new institute or other major organizational entity.
- E. A proposed change in the NIH organizational structure, should, on balance, improve communication, management, priority setting, and accountability.<sup>23</sup>

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<sup>23</sup> The Institute of Medicine-Ebert Committee Report, as cited by the AAMC ad hoc review committee, 1985.



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December 4, 2002

Harold Shapiro, PhD  
Chair, Committee on the Organizational Structure of the NIH  
The National Academies and Institute of Medicine  
500 5<sup>th</sup> St, NW  
Washington, DC 20001

Dear Dr. Shapiro:

We appreciate your invitation to Dr. Korn to testify this past summer before the Committee on the Organizational Structure of the NIH on behalf of the Association of American Medical Colleges (AAMC), and regret that he was unable to appear due to reasons of health. The AAMC considers the subject of NIH's organization to be a most important and timely topic for review by the Academies and the IOM, and we hope your committee will perform a thorough and balanced examination of this complex (and too often, unduly politically charged) issue.

We have enclosed a copy of the AAMC's position statement on NIH organization, with suggested principles for guiding any proposed reorganization, and recommendations if, in fact, your committee determines that alterations in the NIH structure are desirable or necessary at this time. Our position derives heavily from the excellent analyses performed by the IOM and the AAMC more than 15 years ago, but addresses the many new challenges for the NIH in the present era.

Dr. Korn would, of course, be very happy to respond to or meet with the committee to amplify or clarify any aspects of the AAMC's position.

Sincerely,

Jordan J. Cohen, MD  
President

David Korn, MD  
Senior Vice President  
Biomedical and Health Sciences Research

cc: Lynn Carleton

enclosure