

Joint Oversight Hearing on Managing Biomedical Research to Prevent and Cure Disease  
in the 21st Century: Matching NIH Policy with Science

Bill Number: Oversight

Hearing Date: October 2, 2003 - 10:00 AM

Witness:

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Testimony:

Good morning, Mr. Chairman and members of the House and Senate Committees. My name is Harold Shapiro and I am currently Professor of Economics and Public Affairs in the Department of Economics and the Woodrow Wilson School of Public and International Affairs of Princeton University. I serve as Chair of the National Research Council's Committee on the Organizational Structure of NIH, and I would like to thank the Congressional Committees for this opportunity to discuss the recommendations in our report. The Research Council is the operating arm of the National Academy of Sciences, National Academy of Engineering, and Institute of Medicine.

The Committee on the Organizational Structure of NIH was assembled by the Academies in response to a Congressional request for a study to examine whether, given the many changes in both our health concerns and the nature of the scientific frontier the organization and structure of NIH are optimally configured to most effectively pursue its mission in research and training given the realities of the Twenty-first Century. The Congressional request was a wise acknowledgement that the world we live in is changing rapidly, with science, evolving health concerns and the structure of the institutional mechanisms supporting science and advanced research training being among the most fast-paced areas of change. All enterprises, be they large or small, need to be able to adapt to change and must continually consider new ways to meet the challenges of the future if they are to remain effective. The greatest risk to successful organizations is the danger of becoming entrenched in the very things that have made them successful at the expense of needed adaptability.

The composition of the Committee on the Organizational Structure of the National Institutes of Health was designed to ensure that the views of the basic science, clinical medicine, and health advocacy communities were all adequately represented. In addition, the Committee has members who are experienced in the management of large and complex organizations, including a former NIH director, two former NIH institute directors, two persons with backgrounds in senior management of major industrial entities, and a specialist in organizational issues. Several Committee members also had considerable experience in government operations.

The Committee held six two-day meetings over the ten months between July 2002 and April 2003. At its initial meetings, past and present representatives of NIH, Congress, voluntary health groups, scientific and professional societies, and industry were invited to provide perspectives on the issues before the Committee. The Committee met publicly

with the current NIH director as well as several former directors, and also heard presentations from or interviewed staff in the NIH Director's Office and the directors of 18 institutes or centers. Prior reports and relevant literature were reviewed. Finally, several Committee members conducted town meetings at their home institutions and elsewhere, inviting scientists, administrators, and students to tell us their views. Thus, the Committee was able to hear, consider, and discuss a diverse range of facts and opinions about the organizational structure of NIH. The Committee completed and released its final report, "Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges", in late July, and I would be happy to submit a copy of the report for the record along with my testimony.

The strong system of federal support for US science and technology has produced five decades of discovery and innovation that have literally changed the way we live and yielded great social dividends for the citizens of our country and beyond. In many ways, NIH is unsurpassed among the array of federal agencies that support scientific research, providing 80% of the federal government's contribution to biomedical research. From a humble beginning in the late 19th century as a one room laboratory with a \$300 government allocation, NIH has grown into a \$27 billion per year organization that justifiably enjoys enormous public and Congressional support. NIH's success in its mission of science in pursuit of fundamental knowledge and the application of that knowledge to extending healthy life and reducing the burdens of illness and disability has been enormous. NIH's investment in biomedical research has helped produce remarkable results in terms of declining rates of disease, longer life expectancy, reduced infant mortality, and improved quality of life. All those who have played a role in making NIH such a success over the years, including many of you on the House and Senate Committees that have organized this hearing, have earned the gratitude of current and future generations.

Although not explicitly articulated in the charge to our committee, it has been suggested that one key underlying motivation for Congress's request for our study is the concern that the large number of institutes and centers at NIH, which now total 27, has fragmented the agency and made it too unwieldy to address effectively the research and training challenges now emerging on the biomedical frontier. While extremely mindful of this concern we approached our task in a considerably more general fashion by asking ourselves what organizational changes, including the widespread consolidation of existing units, would be most likely to enhance the vitality of NIH and increase its flexibility and responsiveness. Our deliberations were also influenced by the fact that there is much more to assessing an organization's effectiveness than reflecting on the number of units on its organization chart, and we assessed, therefore not only the organizational configuration of NIH, but also the key processes, internal cultures and authorities that all play key roles in determining the quality, creativity and imagination that might characterize NIH-wide decision making.

Although the Committee spent a significant amount of time at every one of its six meetings debating the merits of various proposals to drastically consolidate NIH's institutes into a far smaller number of entities, in the end we came to the consensus view that the widespread consolidation of institutes and centers is not the next best organizational step for NIH to undertake, as the expected benefits of such a strategy would in our judgment be less than the expected costs involved. What does the

Committee mean by “costs”? Any thoughtful major reorganization would necessitate a lengthy and complex information gathering and decision making process that would include numerous hearings involving members of Congress and their staff and a wide variety of interests in the various health advocacy and scientific communities. Our discussions, correspondence and meetings made it quite clear that there would be very little agreement among these communities on what the right way to reorganize NIH is, and there would probably be dozens of conflicting ideas in play and few clear avenues for narrowing these down. Moreover we believe that these discussions and negotiations would be long and contentious and with a quite uncertain outcome. More importantly, the Committee is firmly convinced that many of the goals that might be achieved through large-scale consolidation of institutes, such as giving NIH a greater capacity to respond to new challenges, enabling NIH to respond as a whole to critical strategic initiatives, making NIH’s research portfolio less risk averse, and launching a major reorganization of its clinical research activities could be achieved more rapidly and effectively through other changes dealing with authorities, culture and processes.

NIH has developed as a loose federation of units that operate largely independently of both each other and the Director. Moreover the individual institutes and centers have operated in a very decentralized manner reflecting the view that the best ideas flow up from the laboratories of individual scientists. This policy has demonstrated its power and we believe that this approach should remain the bedrock of NIH’s program. However, given the changing environment in the biomedical sciences and the nature of our evolving health concerns we believe that this basic strategy needs to be supplemented by a series of new approaches. One reason that NIH has the complex federated structure it has today is that in the past, the response to new problems or opportunities has often been to create new organizational entities, such as the Office of AIDS Research or the National Human Genome Research Institute, to deal with them. If, however, there were other ways for the NIH leadership to redirect or reconfigure resources, this would obviate the need to create new entities as the only institutional response. Our Committee came to believe strongly that the creation of new organizational entities at NIH is not the best or most effective means of ensuring that a problem receives adequate attention in the biomedical research portfolio, and that NIH needs a better mechanism for responding. Instead, the Committee recommends that NIH begin to use a process for identifying major crosscutting, or “trans-NIH” (for research that cuts across the purview of several, if not all, the institutes and centers), research initiatives via periodic— perhaps every two years —strategic planning that engages all of NIH and is open to input from the public as well as the scientific community. Such research is especially important given the increasingly interdisciplinary nature of science today. Although individual institutes do mount new initiatives on their own, these are usually directed primarily at the interests of their own constituencies and rarely closely coordinated with the work of other institutes. An example of the kind of area that would make a good focus for such a trans-NIH initiative is proteomics, for which the institutes could benefit from the development of common tools and approaches if they worked closely together. Another is the study of obesity, which is rapidly becoming a major national health problem. Because obesity is associated with a variety of health problems that cut across the concerns of many institutes, such as heart disease, diabetes, and arthritis, the responsibility for dealing with it does not fall clearly into the portfolio of any one institute. As a result, it is difficult for NIH to

demonstrate that there is any systematic and coordinated approach to addressing the causes and consequences of obesity. The same would be true in many other areas. In the absence of such a demonstration, a variety of health interest groups are calling for the creation of a National Institute on Obesity. But the Committee believes that a trans-NIH strategic initiative to address such problems often would be a far better solution than the creation of a new institute or center.

For this to become workable, however, Congress must give the NIH Director more authority. The Director currently has very little ability to insist that ‘best practices’ spread quickly across all units, or to reconfigure NIH’s resources or mobilize funding for new initiatives except at a very small scale. We believe that Congress should amend NIH’s authorizing legislation to formally charge the NIH Director to conduct such trans-NIH strategic planning, and that the Director should be able to require the institutes and centers to commit a certain percentage of their budgets for their participation in the trans-NIH research identified through the strategic planning process. The individual Institutes, however, would retain the authority to decide just which of the trans-NIH initiatives they wish to participate in. We suggest that five percent of each institute's and center's budget should be invested the first year of the program, but that number could grow to 10 percent or higher within four to five years. While this may initially sound like a proposal to cut institute budgets by diverting funds elsewhere, our thinking is that an open and inclusive strategic planning process in which all institutes participate would generate enough excellent ideas for trans-NIH initiatives that each institute would readily be able to identify one or more of these ideas that would be of relevance to their own interests and portfolios. Thus, we believe that participation in one or more trans-NIH initiatives would enhance the research portfolio of all the institutes. To underline these points we are not suggesting that any funds be moved among institutes or to the Director’s Office for the trans-NIH initiatives. Rather the percentage of funding to be invested in any given year, for example, five percent, of an institute’s budget would be held in “escrow” until the Director certifies the acceptability of that institute’s plans for participation in the chosen strategic initiatives.

I would like to comment also on the committee’s recommendations that affect the Director’s Office. First, the Committee recommends that a special projects program be established in the NIH director's office to fund risky, cutting-edge research that offers high potential payoffs in terms of scientific breakthroughs, and new treatments. We imagine this program being patterned after the Defense Advanced Research Projects Agency, or DARPA, in the Department of Defense. The NIH director's special projects office could help overcome some of the hindrances to the pursuit of highly innovative, or “risky,” research that exist now. High-risk proposals, which may have the potential to produce quantum leaps in discovery, do not fare well in the review system and are rarely funded by NIH because they are often not backed up with extensive preliminary data. This is because the review system is driven toward conservatism by a desire to maximize results in the face of limited funding, large numbers of competing investigators, and considerations of accountability and equity. Another unintended effect of this conservatism is a bias against young investigators. The peer review system at NIH has served this country very well and should continue to do so over the next decades. However, it is our view that NIH also needs a complementary strategy that would help overcome the inherently conservative bias of the existing peer review framework. The

committee believes that the new program would succeed best if it were located in the NIH director's office and were funded with new money. We recommend that Congress provide 100 million dollars for the director's special projects program in the first year, with the budget eventually growing to as much as one billion dollars a year.

Second, the Committee does not believe that the Operations budget for the Office of the Director (OD) is adequate. Although the overall OD budget may look substantial, most of it is earmarked for the various program offices that have been created to address particular topics, such as the Office of Research on Women's Health and the Office of AIDS Research. When a problem that affects NIH as a whole arises, the Director frequently has to go "hat in hand" to beg for contributions of funds from the institutes to respond, which, to say the least, is highly inefficient and not guaranteed to produce satisfactory results.

Turning back now to the number of institutes and centers, the Committee made one other very important recommendation. Although the committee did not believe that a wholesale consolidation is called for at this time, we do not believe that NIH's organizational structure should remain frozen. As the pace and nature of scientific discovery continues to quickly advance, and as our health concerns evolve, some institutes and centers will become more relevant than others. Therefore, we recommend that a formal public process be established for reviewing whether institutes and centers should be added, eliminated, or combined with others. This process should involve Congress, the scientific community, patient advocacy groups, and the NIH Council of Public Representatives and other NIH advisory committees. Although Congress would still need to vote on whether or not to change the number of institutes, this formal review process could be initiated by the NIH director. We would also hope that Congress would not take action on proposals to create, combine, or eliminate institutes or centers until there has been an opportunity for this process to play out and for the NIH Director to thoroughly consider its results and make his or her recommendation to Congress.

The Committee suggests that this public process should be used first to review two mergers favored by the committee. First, we believe that the National Institute on Drug Abuse should be combined with the National Institute on Alcohol Abuse and Alcoholism. These two groups share a similar mission and the causes of, as well as the treatment for, drug- and alcohol-abuse are likewise similar. Second, we think that the National Institute of General Medical Sciences should merge with the National Human Genome Research Institute. Now that the genome institute has successfully completed its namesake mission, it makes sense for it to rejoin the general medical sciences institute, from which it originated and which has a lead role in funding basic biomedical research. Moreover, the cultures of these two units might very well invigorate each other. Again, I would stress that although the Committee saw merit in these proposed consolidations, it is our recommendation that no action be taken until the public process we propose has been conducted.

On the other hand, because of unusually persuasive arguments and exceptional needs, the Committee did recommend that one reorganization be acted upon immediately. We strongly believe that several intramural and extramural clinical research programs should be combined into a new entity that replaces the National Center for Research Resources and transforms it into a National Center for Clinical Research and Research Resources. The importance of clinical research in translating the knowledge produced by basic

science into improved health cannot be overstated, but this translation is today hampered by high costs, regulatory uncertainties, incompatible databases, and a shortage of qualified investigators and willing patient participants. We believe that putting clinical research under this new umbrella will trigger new collaboration and data sharing among researchers from different fields. The recommended consolidation of clinical research under one roof builds upon the recommendations made by other prestigious groups and leaders in recent years that NIH needs to do more to facilitate the translation of basic research into cures and treatments.

As I said earlier, we identified several other organizational and administrative changes and mechanisms that could, as the title of our report suggests, enhance the vitality of NIH. Let me touch on a few of them.

To begin with, we looked at the length of terms served by the director and the heads of the institutes and centers. We decided that the NIH director should serve a six-year term unless removed sooner by the president. Having a term of six years may — like that for the director of the National Science Foundation — allow the director to transcend changes in administration. Re-appointment to a second and final six-year term should be contingent on a performance review by outside experts and the recommendation of the Secretary of Health and Human Services.

Directors of the institutes and centers should be appointed to five-year terms with the option for a second, and final, five-year term. And authority to hire and fire these directors should be transferred from the HHS secretary to the NIH director. We believe that the service terms we've recommended will provide stability as well as fresh ideas to NIH.

We also took a second look at the special status of the National Cancer Institute. The NCI director is appointed by the president and NCI's budget — about 17 percent of the overall NIH budget — bypasses the desk of the NIH director and is completely outside the director's influence. The Committee suggests that Congress reexamine the appropriateness of the special status given to NCI.

With regard to the effort by HHS to centralize or outsource administrative functions, known as the "One HHS" initiative, the committee felt strongly that, while eliminating government inefficiency is always a worthwhile goal, the "One HHS" initiative may fail to appreciate the strong link between administrative functions at NIH, such as personnel recruitment and aspects of grants management, and the larger scientific enterprise. Any move to centralize or outsource these functions should be carefully reviewed first to determine how it may affect NIH's special mission of scientific and medical discovery. We also noted that the Research Management and Support budgets, which pay for administrative and facilities management costs at the institutes and centers, have barely grown in the past decade despite the huge increases in the overall NIH budget. As a consequence, NIH is left with inadequate funds to cover overhead costs. Congress should increase Research Management and Support budgets.

We also addressed concerns that many of NIH's advisory committees are restricted to pro forma roles, populated by too many individuals with conflicts of interest, and are sometimes perceived as being politicized. We concluded that participation in these committees should be solely based on a person's scientific or clinical expertise or on his or her substantial involvement in a health or research issue. NIH should also reform their advisory council system to ensure that these bodies are sufficiently independent, are

routinely involved in priority setting and planning and are engaged in discussions with institute and center leadership to provide it with honest feedback and enhance its accountability.

Finally, our committee understood that it is the quality of leadership at all levels, as opposed to organizational structure, that is central to NIH's vitality. In the long run, the recruitment of outstanding leadership, the commitment to individual scientists as the main sources of new discoveries, and reliance on the competitive review system for determining grants will remain the essential keys to NIH's continuing success.

Thank you again for the opportunity to discuss the recommendations of our report. I would be happy to answer any questions you may have.