

SPECIAL REPORT

Reorganizing The National Institutes Of Health

A review of an important National Research Council–Institute of Medicine report to revitalize the NIH.

by **Richard A. Rettig**

ABSTRACT: A committee of the National Research Council and the Institute of Medicine recently released a report on reorganizing the National Institutes of Health (NIH). This report responds to a request by Congress in connection with the fiscal year 2001 budget for the NIH. The report contains some pragmatic proposals, avoids postulating an ideal NIH but does propose a radical new “special programs office” that would function as does the Defense Advanced Research Projects Agency, and advocates that clinical research be strengthened.

IN CONNECTION WITH its fiscal year 2001 appropriation to the National Institutes of Health (NIH), the U.S. Congress called for a National Academy of Sciences study on whether the existing NIH organization was “optimally configured for the scientific needs of the twenty-first century.” Congress was concerned about the proliferation of new entities within the NIH (institutes, centers, and program offices) that has occurred over time and their potential to impair coordination and functioning within the NIH—not an unreasonable concern now that the NIH budget approaches \$30 billion a year.

On 29 July 2003 a blue-ribbon committee of the National Research Council (NRC) and the Institute of Medicine (IOM) released its report.¹ The committee, chaired by Harold Shapiro, president emeritus of Princeton University and former president of the University of Michigan, included representatives of basic and clinical research, health advocacy, and science and technology.

Although the NRC-IOM report will be of interest mainly to biomedical researchers, it should also interest health services research-

ers. Estimates place NIH support for health services research at \$800 million, compared with \$300 million for the Agency for Healthcare Research and Quality (AHRQ).² The capacious NIH mandate includes aging, alcoholism, drug abuse, mental health, and many other health services research issues. Behavioral factors are increasingly identified as major causes of health problems. Also, the current deputy director, Raynard Kington, is a health services researcher. Finally, although not mentioned in the report, a suggestion floating around for some time would incorporate AHRQ as one institute within the NIH.

Every twenty years or so, concern is raised about the organization of the NIH. In February 1965 an expert committee reported to President Lyndon Johnson on “Biomedical Science and Its Administration,” triggered by the fact that the NIH budget was then approaching \$1 billion.³ “The most important organizational need of NIH,” that report indicated, “is the strengthening of its capacity for long-range planning, for determining the optimum use of its funds, and for ensuring that its activities and policies have the continued understanding

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and approval of the scientific and lay public.” The committee called for strengthening the position of the NIH director and for decreasing the NIH’s dependence on “a handful of unusually competent men in positions of authority.”

In 1984 a distinguished IOM committee reported to Margaret Heckler, then secretary of the Department of Health Human Services (HHS), on NIH organization. The stimulus in this case was the increasing number of categorical disease institutes within the NIH. The IOM committee recommended the establishment of “a formal process to assess proposed major organizational changes in NIH and to interpret the need for change from a broad perspective.”⁴ It also recommended steps to strengthen the authority of the NIH director.

Mission And Organization

■ **Research versus health.** The NRC-IOM committee was conscious that structure and function could not be separated. Consequently, it discussed its recommendations in its view of the NIH mission, “to advance the scientific frontier in areas of special relevance to human health needs.” This reflects a subtle but important underlying tension between the dual missions of the NIH as a biomedical research agency and as a health agency. The report was silent on a third NIH mission, added by Congress in the Bayh-Dole statute, to promote the transfer of NIH-sponsored research to the private sector for the commercialization of those research results.⁵

Both prior reports wrestled with the health-research mission of the NIH. In 1965, the broad mission of the NIH encompassed “virtually all aspects of the Nation’s health,” but this required the NIH “to concentrate most of its effort on basic research.”⁶ In the 1984 report, the NIH mission “demands that its leaders pursue two principal objectives,” first by responding to health needs, “achieving reductions in the burden of illness by capitalizing on scientific opportunities,” and second, “to promote basic science and maintain standards of scientific excellence.”⁷

The view that the NIH mission is to advance the science of medicine to improve the

health of the American people is, in my judgment, far closer to the public view of why the NIH exists than the NRC committee’s formulation and suggests why NIH funding has always outstripped that for the National Science Foundation (NSF). The relative emphasis between research and health affects how funds are allocated within the NIH budget. Arguably, the emphasis should change over time as the scientific foundation of medicine becomes more firmly established toward exploiting the health benefits of medical science.

The NIH mission is of sufficient importance that Congress might consider writing a statutory mission statement. It did so in the Food and Drug Administration Modernization Act (FDAMA) of 1997, both stipulating the Food and Drug Administration’s (FDA’s) traditional consumer protection role and making clear that its public health role was to make therapeutics more readily accessible to the public. That clarity of mission, useful for the FDA, could also serve the NIH well.

■ **Institutional autonomy.** A major concern of the NRC-IOM report, confronted directly but discreetly, is the relation of the NIH to its parent department, HHS. The NRC-IOM committee clearly wished to reinforce the autonomy of the NIH from higher-level political interference. The first recommendation is that “centralization of management functions” under HHS, now under active negotiation, be undertaken only after “careful study.” The thirteenth recommendation, addressed obliquely to the White House, is that appointments to advisory councils “should be based solely on a person’s scientific or clinical expertise.”

■ **Proliferation and its antidote.** The decentralized architecture of the NIH was established long ago with three features: (1) categorical disease institutes; (2) study sections, or expert panels, to review grant proposals, which have varying degrees of independence from the categorical institutes; and (3) intramural research programs that are tied nominally but loosely to their categorical institute home.⁸

In many ways, this structure has served to insulate medical science from politics. However, insistent political demands from dis-

ease-oriented interest groups, coinciding with the personal interests of legislative and executive branch sponsors, have resulted in the proliferation of new institutes, centers, and program offices attached to the Office of the Director (OD). The latter, for example, include AIDS research, women's health, disease prevention, and social and behavioral research. Arguably, the proliferation of new entities reflects the failure of the existing structure to respond adequately to legitimate health needs of the public, especially in times of a growing NIH budget. Indeed, proliferation might be viewed as evidence that the public sees the "mission" of the NIH mainly as research in support of health.

The proliferation of institutes and centers within the NIH, according to the NRC-IOM report, "has been a cause of both concern and celebration for decades."⁹ (In fact, it was the major stimulus to the 1984 report.) The immediate stimulus to this 2003 report was a March 2001 article in *Science* by Harold Varmus, published after he had left the NIH director's position.¹⁰ Varmus recommended a sweeping consolidation of existing institutes into six major entities: the National Cancer Institute, the National Brain Institute, the National Institute for Internal Medicine Research, the National Institute for Human Development, the National Institute for Microbial and Environmental Medicine, and NIH Central.

The NRC-IOM committee took a more pragmatic view of reorganization and quickly laid the Varmus option aside. Instead of focusing "exclusively on whether or not there should be widespread consolidation of NIH's institutes and centers," it took "a more general approach to inquire if there were any significant organizational changes...that would allow the NIH to be even more successful in the future."¹¹ Varmus expressed disappointment with the report. He was quoted in *Science* as saying, "There are a lot of good ideas, but they never really took on the issue of how NIH would be ideally configured. Otherwise, there will be tremendous resistance to these [recommended] fusions."¹² The *Washington Post* quoted Varmus as saying: "They had an opportunity to

say what would be the ideal NIH and then wrestle with the problem of how to get there. They missed some opportunities."¹³

Instead of seeking a Platonic ideal NIH, the NRC-IOM report modestly suggested, without recommending, consideration of two potential mergers: first, the merger of the National Institute on Drug Abuse and the National Institute on Alcohol Abuse and Alcoholism; and second, the National Institute of General Medical Sciences and the National Human Genome Research Institute.¹⁴ The committee noted the 1984 IOM report, which recommended a formal process for considering new entities, and essentially endorsed the same approach (recommendation no. 2). It recommended that when initiatives to add new institutes or centers arose, the NIH director "should initiate a public process to evaluate scientific needs, opportunities, and consequences of the proposed change," including the likelihood of public support and the availability of additional resources.¹⁵ Given the two decades since a formal process was initially recommended in the 1984 report and the nature of politics in this country, it is far from clear that reiteration of this approach will have any immediate or lasting effect.

■ **Strengthening the OD.** Deep in the report one finds this statement: "The Committee has come to believe that the NIH's current structure, governance, and management mechanisms have become barriers to its effectiveness in using its resources most efficiently to foster progress in both large and small scale science that directly affects human health."¹⁶ This judgment goes to the heart of many of the committee's recommendations, which deal with the weakness of the OD within the decentralized NIH.

Of those who have served as NIH director, James Shannon (1955–1968) and Varmus (1993–2001) loom as two giants who led by personal strength. But the OD has weak formal authority, a small budget, limited discretion to reprogram funds, and a limited role in selection of key personnel.

The weight of the NRC-IOM committee's report falls on redressing the balance between

the OD and the rest of the NIH. The recommendations include granting the NIH director “a more adequate budget” for management and greater discretion in reprogramming funds (no. 5), creating a special projects program in the OD (no. 7), charging the director with establishing a trans-NIH planning process (no. 4), and transferring appointment authority for institute and center directors to the NIH director from the HHS secretary and establishing a process for the NIH director to review institute and center directors annually (no. 10). Improved data management capabilities, a function of the center, are also recommended as essential to effective management (no. 9).

■ **National Cancer Institute.** The National Cancer Act of 1971 weakened the NIH director by granting considerable autonomy to the director of the National Cancer Institute (NCI).¹⁷ The changes introduced by the act involve appointment authority, reporting channels, advisory bodies, and budgetary relations. These provisions made sense at the time, as they were a compromise between creating a separate National Cancer Authority independent entirely of the NIH or retaining the NCI within the NIH but with greater autonomy. Nevertheless, the provisions of the 1971 legislation have weakened the position of the NIH director and arguably have had little discernible effect on progress in the diagnosis, treatment, or prevention of cancer. The report calls for Congress to “reassess the provisions of the National Cancer Act of 1971, particularly as they affect the authority of the NIH director to hire senior management and plan and coordinate the NIH budget and its programs in their entirety” (no. 12). This is a salutary and welcome recommendation, notwithstanding the political landmines that lie in the path of those who would pursue it.

Conservatism And Boldness

Underlying the committee’s concern is the

inherent conservatism that is embedded in the existing NIH structure. The report calls for boldness in several ways. Congress is asked to charge the director “to lead a trans-NIH planning process to identify major crosscutting issues and their associated research and training opportunities” (no. 4). The report also recommends that the intramural research program “take risks and be innovative” (no. 8).

Perhaps the most breathtaking recommendation to this reviewer is that a director’s special projects program be created, fashioned after the Defense Advanced Research Projects Agency (DARPA) (no. 7). (The report was publicly released July 29, just as DARPA’s terrorism futures market was being eliminated in response to scathing political criticism.)¹⁸ In the committee’s view, Congress should fund this program initially at \$100 million, be prepared to have that amount grow to \$1 billion annually, and commit to supporting it for eight to ten years “so that a sufficient number of projects can reach fruition and a full assessment of program efforts can be made.”¹⁹

The high-risk, high-reward DARPA approach is weakly supported by examples of DARPA-like opportunities that confront the NIH. The argument that a special initiatives program would work, or work well enough to sustain scientific and political support, is highly speculative and rests on a corporate model that might be inappropriate. The DARPA strategy involves both supporting leading-edge research and carrying that through to application in a “research, development, test, and evaluation” process wholly owned by the Department of Defense (DOD). It is based on the “common defense” clause of the Constitution, which grants the DOD a virtual monopoly in national security matters. The NIH, which flies under the public health and general welfare clauses of the Constitution, does not own the entire process from bio-

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medical research to application in clinical practice. The issue, therefore, of who defines defense needs for DARPA raises the question of who might define health research needs for the NIH. (Back to mission we go.) Moreover, DARPA is largely sheltered from public view, whereas any special programs office in the NIH will exist in a domestic fishbowl and be scrutinized by the scientific community, clinical medicine, and disease-oriented advocates, to say nothing of the working press.

Clinical Research

One of the more surprising committee recommendations is to “strengthen clinical research” (no. 3)—surprising because this issue was not part of the congressional charge (that the NIH “should pursue a new organizational strategy to better integrate leadership, funding, and management of its clinical research enterprise”) or of the committee’s formulation of its task.²⁰ The committee would combine several intramural and extramural programs in a new National Center for Clinical Research and Research Resources. It also recommends the creation of a deputy director for clinical research in the OD.

This recommendation is also surprising because one would not assume that a study of NIH organization would naturally lead in this direction. Perhaps the committee was aware of the 2002 Senate Appropriations Committee report on the NIH regarding the importance of clinical research: “The accumulation of fundamental knowledge for its own sake is of little value unless it finds its way to hospitals and physicians [for] use in promoting good health or diagnosing, preventing and treating disease.”²¹ The Senate committee placed this statement squarely in the context of the doubling of the NIH budget over the prior five years.

The recommendation is constructive, especially in its suggestion that there be a deputy director to carry the clinical research portfolio. It might reflect a growing awareness that pumping money into an institutionally conservative system ultimately must be judged by the return on investment in the improved health of the American public.

Strategic Intent

One largely unexamined issue was the study-section system for peer review of research grant proposals. Instead, the committee deferred to “ongoing reforms” being pursued by the NIH.²² Arguably, the study-section system is the source of the inherent conservatism that exercised the committee. It is the structure that decentralizes, fragments, gives greater emphasis to research than to health, and remains controversial because many believe that it slights clinical research.

But the overriding concern of the NRC-IOM committee, or at least of its chairman, was the limited capacity of the NIH, acting through its director, to give “strategic intent” to the entire biomedical research enterprise. (Shapiro reiterated this phrase several times at the July 29 release of the report.) This concern for strategic intent, far more than the specific organizational changes recommended by the committee, deserves serious attention by Congress. The inherent conservatism of the existing structures and the inability of the NIH to mount high-risk, high-return research initiatives in response to major scientific opportunities ought to be regarded as a profound challenge and treated with the gravity it deserves. Specific recommendations should be examined systematically in that context.

How Congress responds to these recommendations will be worth watching. Many recommendations will require action by the legislative committees, not the appropriations committees, with which the NIH has traditionally had close working relations. Mission and organization, research and health, conservatism and boldness: these are the topics raised by the NRC-IOM committee report on NIH reorganization.

Addendum

On 30 September 2003 Elias Zerhouni, director of the NIH, released an “NIH Roadmap” that had been two years in development.²³ It called for several initiatives grouped under three themes: new pathways to discovery; research teams of the future; and reengineering clinical research. The Roadmap, widely cov-

ered, has already been the subject of a congressional hearing.²⁴ Witnesses at the hearing included Zerhouni, Varmus, and Shapiro.

The Roadmap affirms the NRC-IOM report in many ways. The two reports should be read together, however, the former focusing on structure, the latter emphasizing function. Several key issues deserve attention. First, will the weak authority of the NIH director and his office, documented in detail by the NRC-IOM, allow Zerhouni to implement the Roadmap? Second, will NIH resources be adequate? The NIH budget was doubled in five years, at annual rates of increase of 15 percent, but the Senate markup for the FY 2004 appropriation is only \$1 billion, or 3.7 percent, on a \$28 billion base and is unlikely to go higher. Given the deteriorating fiscal situation of the federal government, the hoped-for “soft landing” of 8–10 percent annually appears as substantial as a morning fog disappearing in the sunlight.²⁵ Third, will the “reengineering of clinical research” materialize or be a resource-based casualty of laboratory research “haves” versus clinical research “have-nots?” Fourth, will Congress probe the issues raised by these two efforts in depth, or will a single three-hour hearing record its interest? Finally, will the parties to this discussion take the long view, to the benefit of all, or will the challenges of the NRC-IOM report and the NIH Roadmap be dismissed summarily in a hasty return to business as usual?

NOTES

1. National Research Council–Institute of Medicine, *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges* (Washington: National Academies Press, 2003).
2. *Ibid.*, 56.
3. Office of Science and Technology Policy, *Biomedical Science and Its Administration: A Study of the National Institutes of Health, Report to the President* (Washington: White House, February 1965).
4. IOM, *Responding to Health Needs and Scientific Opportunity: The Organizational Structure of the National Institutes of Health* (Washington: National Academies Press, 1984), 3.
5. 35 U.S. Code, sec. 200-212 (2000).
6. OSTP, *Biomedical Science*, 2.
7. IOM, *Responding to Health Needs*, 1.
8. C.J. Van Slyke, “New Horizons in Medical Research,” *Science* (13 December 1946): 559–567.
9. NRC-IOM, *Enhancing the Vitality*, 1.
10. H. Varmus, “Proliferation of National Institutes of Health,” *Science* (9 March 2001): 1903–1905.
11. NRC-IOM, *Enhancing the Vitality*, 3.
12. Quoted in J. Kaiser, “A Low-Stress Scheme for Overhauling NIH’s Structure,” *Science* (1 August 2003): 575.
13. C. Connolly, “Panel Suggests Management Changes at NIH,” *Washington Post*, 30 July 2003.
14. NRC-IOM, *Enhancing the Vitality*, 7–8.
15. *Ibid.*, 7.
16. *Ibid.*, 84.
17. R.A. Rettig, *Cancer Crusade: The Story of the National Cancer Act of 1971* (Princeton, N.J.: Princeton University Press, 1977).
18. See C. Hulse, “Swiftly, Plan for Terrorism Futures Market Slips into Dustbin,” *New York Times*, 30 July 2003; S. Murray, “Pentagon Retreats from Terror Futures,” *Wall Street Journal*, 30 July 2003; and B. Graham and V. Loeb, “Pentagon Drops Bid for Futures Market,” *Washington Post*, 30 July 2003.
19. NRC-IOM, *Enhancing the Vitality*, 10–11.
20. *Ibid.*, 8.
21. Senate Appropriations Committee, Subcommittee on Health, Education, and Labor and Pensions, Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriation Bill, 2003, Report 107-216, 107th Cong., 2d sess., 22 July 2002, 149.
22. NRC-IOM, *Enhancing the Vitality*, 45.
23. E. Zerhouni, “The NIH Roadmap,” *Science* (3 October 2003): 63–66. Zerhouni discusses this issue with Fitzhugh Mullan, *Health Affairs* contributing editor, in an interview on the *Health Affairs* Web site, 6 January 2004, www.healthaffairs.org/Web_Exclusives/Zerhouni_Web_Excl_010604.htm.
24. See R. Weiss, “Cross-Pollination in Pursuit of Cures,” *Washington Post*, 1 October 2003; R. Pear, “Health Agency Taking Steps to Speed Results of Research,” *New York Times*, 1 October 2003; and A. Regalado, “NIH Plans ‘Road Map’ for Medical Research,” *Wall Street Journal*, 1 October 2003. See also House Committee on Energy and Commerce, Committee Hearing, “Managing Biomedical Research to Prevent and Cure Disease in the Twenty-first Century: Matching NIH Policy with Science,” 2 October 2003, energycommerce.house.gov/108/Hearings/10022003hearing1096/hearing.htm (23 October 2003).
25. D. Korn et al., “The NIH Budget in the ‘Post-doubling’ Era,” *Science* (24 May 2003): 1401–1402.