Is This Your Father's NIH? And Other Strategic Questions*

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Back in the good old days, it was said that whither General Motors (GM) goes, so goes the nation (*1*). That is an awful thought for 1992. Today one of our most heavily bashed U.S. corporations is GM. Its problems are legion. With its market share steadily eroding, GM has been forced to lay off 74,000 workers and will be closing more than 20 plants. GM has not competed effectively in the world market in the past decade. Perhaps the most devastating appraisal of GM appeared in a recent *Consumer Reports*—an appraisal that strikes at the heart of many of GM's woes. GM's Oldsmobile Division has an advertising campaign for its cars, pitched to young consumers, which says, "This is not your father's Oldsmobile." *Consumer Reports* opened its review of the latest big sedans with, "This car *is* your father's Oldsmobile" (*2*). Fortunately, GM and many others are finally catching on that we can no longer think and behave as if this were 1952.

Life in the '50s

Let's not bash the 1950s: They were a great time in this country. Under the Marshall Plan, Europe was being rebuilt, and the United States was held in the highest esteem throughout the world. Americans were exuberant as they cruised happily in long, sleek, tail-finned Oldsmobiles and Pontiacs. Our economy was booming, babies were booming, and Elvis was king. And, in the '50s, the National Institutes of Health (NIH) of today was just starting out, a favorite child, a darling of just about everyone—the Congress, the White House, the public, Mary Lasker, Frances Mahoney, and other champions of biomedical research.

Before the '50s, NIH was a small, federal research laboratory. With the Public Health Service Act of 1944, NIH was given the authority to award grants outside government to universities and non-federal research institutions. The year 1949 was the first year in which more than half of the NIH budget went into extramural grants. By 1950, outside grants were more than 78 percent of NIH's expenditures.

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As we look back, we can readily identify some strategies applied then, that shaped the NIH of today (*3*). One is that federally supported biomedical research would exist outside of the National Science Foundation (NSF) as a separate agency under the umbrella of the Public Health Service (PHS). This was a hard-won decision hammered out among many segments of government. Think of NIH today as part of NSF, and the magnitude of that decision is clear. A second strategy is that NIH would support investigator-initiated research through grants to universities and research institutions, chosen by merit through a system of peer review. This has become our Magna Carta. And third, NIH would be the National Institutes of Health (plural), and its strategic components, the institutes, would be organized by diseases. This "strategic plan" of the early NIH was very focused, very specific, targeted, and extraordinarily successful. It guided the growth and development of NIH, the child of the '50s, into NIH, the adult of the '90s.

Four Decades Later

1992 is not 1952: Our economy is not booming, and your father's Oldsmobile is not faring well against Toyota's model. The public is not exuberant, Elvis Presley is really dead, and this is no longer your father's NIH.

I count at least five ways in which NIH '92 is strategically different from NIH '52, and I suggest that each presents a major challenge to the leadership of NIH and to its constituencies. And the problems go well beyond the seeming lack of money. If we meet these challenges intelligently, U.S. biomedical research will continue to thrive. If, on the other hand, we cling to outmoded approaches, U.S. leadership in this critical area will decline. Strategic planning can help to shape the NIH of tomorrow in the context of a changing world. Such planning can have a favorable impact on resources by offering a compelling vision that inspires action, entices investment, and presents NIH to the public as a noble enterprise worthy of advancement and essential to our nation's future.

In the paragraphs that follow, I will describe several NIH-wide challenges and their implications for the future of NIH. Responding to these issues is at the heart of NIH's strategic planning. Such planning is not intended to control individual researcher's pursuit of discovery but rather to influence the forces that determine the environment in which biomedical researchers function. Within the context of the past and given where we are today, I am asking the scientific community to envision what is essential for the future success of science and of NIH and to define the steps necessary to achieve that success.

Strategic Questions: Please Respond

In seeking the participation of the scientific community and the public, we have held numerous meetings across the country; we are holding several formal working panels, and finally we will sponsor an open director's retreat in July. Fortunately, our desire to widen the window for involvement of the scientific community matches *Science*'s desire to perform a social experiment designed to improve public policy discourse. The procedure outlined in the editorial on page 307 provides a means for the scientific community to respond to the challenges and questions outlined below.

Challenge 1: Critical Science and Technologies

The "revolution in biology," which had barely started in the 1950s, has now transformed biomedical research. What has emerged are "critical technologies" representing fields of fundamental science that transcend diseases, organs, or tissues and have become vital to understanding all of them. We use the term "critical technologies" to identify broad disciplines of fundamental science that are of critical importance to this nation's needs, such as health, economic competitiveness, and energy independence. Such technologies undergird NIH's broader scientific enterprise. For example, molecular and cell biology and molecular genetics are relevant to all of health and disease. Immunology offers molecular strategies for marshaling the body's hormonal and cellular defenses against a host of illnesses, including chronic debilitating diseases, autoimmune states, and cancers, ultimately leading to "vaccines" for the broadest spectrum of chronic human ills. Structural biology is critical to advancing all biomedical research and enables us to understand and design molecules with a specificity and speed never before imaginable.

These "critical" areas of science and technology, the underpinnings of molecular medicine of tomorrow, are especially ripe for investment. They call on a sophisticated and highly trained talent pool and a rapidly

expanding base of knowledge, combined with new and quickly changing instrumentation, massive databases, advanced computers, and other emerging technologies. Meeting this challenge means a major commitment of national resources. As these technologies are the engine that drives all of NIH, the community at large must recognize the need to assure the development of those technologies as a top priority of NIH. Inherent in defining this priority is the recognition that advancing these technologies will only succeed if we ensure an environment that nurtures creativity and imagination of individual scientists. In this context, we can reaffirm the importance of investigator-initiated research as a means toward achieving success—not as an end in itself.

NIH does not exist to do science for science's sake but rather for practical and humanitarian purposes: to improve and preserve the health of the American people. Other publicly driven needs have added new dimensions of responsibility to NIH since the 1950s. The $4-billion NIH investment in "critical science and technology" has an impact on our nation's economy, an impact that is likely to grow substantially. There is increasing pressure for all agencies conducting federally funded science to define their priorities and to justify public investment, including concrete public return and economic benefit. NIH must clearly define its priorities, or others will. For example, in a recent hearing the House Science, Space, and Technology Committee's Subcommittee on Science explored how federally funded science benefits the public and how these benefits influence the setting of priorities. The members presented the chilling notion that the NSF's National Science Board become the body that provides such guidance for all federal science programs, including NIH.

Question: How can NIH best advance critical areas of science and technology as major national priorities, while ensuring maximum return on the public investment?

Challenge 2: Research Capacity

NIH's effectiveness in combating disease and improving human health is directly linked to its capacity to support both intramural and extramural research. In the 1950s, the NIH portfolio was composed of 11,000 small research project grants (RO1s), averaging between $10,000 and $15,000. The percentage of grants funded per year ranged from a rock-bottom 55 percent to more than 77 percent, and the budgets for NIH grants grew 500 percent between 1952 and 1959. Since then, the NIH portfolio has become greatly diversified with program project grants, young investigator grants, clinical research centers, specialized centers of research, research career development awards, clinical trials, control and demonstration projects, and contracts. The RO1 grants still predominate and now cost more than $200,000 per grant on average. Some RO1s exceed $1 million per year. This expanded portfolio and the diversity of institutions conducting NIH-supported research represent our nation's biomedical "research capacity." That research capacity is geographically broad, intellectually diversified, and highly successful in responding quickly to the changing health needs of the public. However, with the average success rate on applications now hovering around 25 percent, numerous meritorious research projects are not receiving NIH support—a fact that will have serious consequences for our nation's future research capacity and international standing in biomedical science. Moreover, within such a constrained environment we cannot overlook vital, indeed strategic, areas essential to our nation's health, such as nutrition, prevention, the health of women and minorities, and human health and the environment—areas that must be served by our research capacity. A strategic planning process can help ensure that such needs do not fall between the cracks of disease- or organ-oriented institutes.

The research capacity of NIH has been entrusted to the institutes and to an independent peer-review system. An often-voiced concern of the working scientist is the adequacy of the peer-review system. No one questions peer-review as a key to the success of NIH, but we hear complaints that the bureaucracy is sometimes overwhelming; that opportunities to develop new, innovative, and creative ideas are contracting; that areas of exploding science are artificially contained by study section structure; and that cronyism or capriciousness infiltrate some review groups. The emerging concerns of the great silent majority of NIH principal investigators (PIs) must be addressed, or peer review itself could be in jeopardy. The alternatives to peer review are barely imaginable, but they could only be more bureaucratic and certainly more political.

The hundreds of research institutes that underpin our research capacity are also under stress with their own financial woes, infrastructure needs, and regulatory pressures. The health of these institutions collectively is critical to the success of the biomedical research enterprise. The institutions are enormously diverse and are at times at odds with themselves and each other, as they pursue their partnership with the federal government. Nevertheless, they have become of strategic importance to NIH and to the country, and our strategic planning effort must address their health.

Another important institution within NIH's research capacity is its intramural laboratory. Intramural NIH is the flagship of our biomedical research institutions offering unique opportunities to do high-risk, long-term research. Although the extramural community is rarely concerned with the troubles of its civil servant colleagues—and at times even scorns them, perhaps jealously, for not being subjected to the travail of writing grant proposals—the fate of NIH as a whole is linked to the success of its intramural research program. Intramural scientists chafe under restrictions limiting them from participating fully in professional societies, from planning scientific meetings, from garnering honoraria, from writing or speaking about federally funded research, or from purchasing equipment without a *Federal Register* notice. However, there also are more fundamental matters of concern having to do with academic environment and resources, and these many issues are being addressed by an NIH task force of intramural and extramural scientists. Poor morale among NIH scientists is an infectious disease, and finding a cure must be a priority for the entire community.

Question: How can NIH bolster its support of our nation's biomedical research capacity and ensure the health of the partnerships among the government, working scientists, and their institutions?

Challenge 3: Intellectual Capital

The creativity, imagination, instincts, and hard work of individual scientists are the major determinants of NIH's success or failure. Ironically, the life of the biomedical scientist has become more difficult at a time when opportunities to pursue biomedical research have never been more exciting. It now takes several years longer to become a scientist and costs considerably more money. In the past, investigators with M.D. degrees did not have the demands of clinical practice that they now face in most medical schools. Writing and managing grants has become more taxing, involving large budget allocations to track and ever-growing numbers of rules and regulations to follow. Morale is down, and the brain trust is not growing, nor has it grown for a while. The number of PIs NIH supports on grants has declined in three of the last 4 years. Since grants are larger, this means more scientists are working on someone else's investigator-initiated grant. In such an environment, it is hard to ensure "equal opportunity" for all investigators and particularly hard for younger scientists to secure support for their own projects.

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Perhaps the most serious long-term problem for biomedical research is that the young seem to be shying away. Fewer scientists under the age of 40 are applying for NIH grants and the group under 45 is a fast-shrinking component of our total talent base. In immediate terms, talented postdocs are becoming harder to find, and young people trained in research are turning to other careers. NIH's postdoctoral stipend is only a fraction of NSF's, and student debt among new Ph.D.'s and M.D.'s in biomedicine runs to five and, sometimes, six digits. The "RO1s at any cost" message has been so successful that it has become a priority that cannibalizes all other lines in the NIH budget, including training.

Although NIH currently supports more training and career development in science than any other federal agency, we must consider new mechanisms to provide for the renewal and growth of the intellectual capital base essential to our enterprise. One such mechanism is the recently established Shannon Award, which has already enabled 310 investigators to conduct research projects that just barely missed funding through NIH's other grant programs. We are now exploring a grant program to fund young scientists who have finished training but who are not yet ready to compete for an RO1 (for example, a Junior-RO1 program). We need youth to replenish our brain trust, and science, as a whole, needs their creativity, boldness, and irreverent challenge.

Question: How can NIH reinvigorate the nation's declining scientific brain trust and reverse its seemingly relentless "graying"?

Challenge 4: Stewardship of Public Resources

A fourth way in which NIH has dramatically changed is in its sheer size and consumption of public resources. We are now a $9-billion "public corporation" with 20 institutes, divisions, and centers. We have close to 15,000 federal employees, almost 200 chartered advisory committees (the largest public advisory system in the government) with more than 3,400 consultants, and we partially or totally support more than 100,000 people. We have five federal facilities outside our Bethesda campus and provide grants or contracts to more than 1,800 institutions, including 500 small businesses. The entire country is NIH's campus.

Today, we have a budget almost 200 times larger than we had in 1952. At more than $9 billion, the NIH budget is also larger than the annual government budgets of many states, and larger than the budgets of more than 100 foreign entities, including Hong Kong, Singapore, Chile, Colombia, and Venezuela (*4*). It would seem self-evident that NIH should make stewardship of its resources a top priority. This is especially so since the high resources we command somehow do not seem to be enough in the view of many opinion leaders of biomedical research.

What does this mean? For one thing, it means we must examine critically how we are managing ourselves: how we are investing our resources and how we are setting our priorities. Can we do better? Are our management systems what they should be? Is our overhead too high? Do we make maximum use of our available resources? Are there things that we are doing that we should not be doing? As every corporation and every university in America is doing, NIH must ask itself these questions.

There are some facts that suggest the need for a hard look at some of NIH's financial systems. The average amount of an NIH grant varies in size by as much as $100,000 per grant, for seemingly similar activities. Indirect costs vary among seemingly like institutions by as much as 100 percent. The growth and absolute dollar cost of NSF grants in biology are a small fraction of the growth and size of NIH grants. Despite the doubling of the NIH budget between 1980 and 1992, that period saw only a 25 percent growth in the numbers of grants.

The present situation challenges us to devise a sense of what the grant portfolio of NIH should look like in 5 to 10 years and to map out a strategy for getting there. This challenge is to be able to justify growth in terms of programs and research advances that benefit the public rather than by numbers of "RO1s." Scientists and administrators need to come together on cost containment and incentives for cost efficiency.

Question: How can NIH improve its stewardship of the $9 billion it receives in public funds?

Challenge 5: Public Trust

Finally, there is yet another major way in which the NIH of 1992 looks different from NIH in 1952, and that has to do with our relationship with the public and its elected representatives. The size and complexity of our enterprise; its rapid progress; the social, legal, and ethical dimensions of today's biomedical research; and the public's expectations of our performance dictate great attention to matters of public trust. In the 1950s, public trust was taken for granted. It was never questioned. The nobility of NIH and medical research were givens. If anyone ever doubted it, they could ask Mary Lasker. Congress loved the NIH, and John Fogarty, Claude Pepper, Warren Grant Magnuson, and Lister Hill did not just like NIH, they championed it, they cherished it, and they loved it.

The first inkling that this might change came in the late 1960s. The Committee on Government Relations, headed by Lawrence H. Fountain, criticized NIH's appetite and management, rebuked NIH for administrative shortcomings, and complained that Congress might be "force-feeding" science. The Fountain Hearings questioned the quality of some NIH research, reported on findings of the General Accounting Office (GAO) about overpayments of indirect cost to some institutions, and reported on a highly permissive attitude "that allows NIH's different institutes to go their separate ways." It unhappily noted that the NIH director had stated "that after research projects are selected for support, all subsequent administrative actions are 'essentially trivial' " (*5*). Even though the criticisms of these hearings were global, and by today's standards devastating, this event was largely isolated, and even Mr. Fountain was a model of cordiality in his rebuke of NIH.

Although today NIH clearly has many modern champions, both within the Administration and the Congress, NIH-bashing has become a major endeavor for many others. As a mature agency of substantial resources and public interest, we understandably come under the gun of oversight and scrutiny. In 1950, the NIH director had a few hearings; in 1980, it was five or six; in 1991, the number was 15. We are inundated with congressional letters questioning how we pay grants, chastising our scientists for traveling to foreign meetings, scrutinizing our purchase of everything from chemicals to computers, inquiring about personnel issues, and questioning our support of virtually all areas of science, health, and disease. We are always in the midst of some 10 to 20 audits or investigations conducted by a range of oversight authorities, including the Inspector General, the GAO, and a host of individual congressional subcommittees and their staffs conducting their own inquiries. Most seem to be looking at whether NIH and the biomedical research community are doing things wrong. What I would term an undercurrent of distrust may be attributable to what Susan Garment has identified as a "deep animus against this country's scientific establishment" (*6*). In her book *Scandal*, Garment quotes a House Oversight and Investigations Subcommittee source saying that two-thirds of scientists "lie to survive" on a regular basis.

There are some internal "cultural" phenomena that are also fueling these sentiments. As some have noted, NIH has become embroiled in seemingly endless Kabuki theater on the foibles, follies, and

failings of scientific colleagues and the institutions that support them. Such theater has understandably grabbed public interest and concern. Clearly, NIH as a community has had its problems and has not always handled them well. But scientists themselves often energize the high drama, sometimes devouring each other behind the scenes without compelling reason or a spirit of fair play. For example, a short time ago, a distinguished scientist paid me a quiet visit (quietly visiting many others as well) for the express purpose of convincing me that one of his Nobel Prize–winning colleagues was a scoundrel who, in essence, stole his prize and should be publicly stripped of his medals. No evidence, no written allegations, and no facts were presented in these visits. This is only one of several secret stirrings from many quarters that I have seen bubble up to create an undercurrent of distrust that erodes public trust—over and above what such undercurrents do to an individual.

Another factor contributing to the Kabuki theater is the difficulty in getting the facts out. The penchant to handle these matters behind closed doors leads to misinformation and ambiguity, as "factoids" emerge from behind the thin veil of pseudoconfidentiality, allowing leaks to both rain and reign. The scientific community must aggressively mobilize to deal with public trust, to be forthcoming in handling matters like standards of scientific conduct and allegations of misconduct and conflict of interest, and to strengthen the means for directly and openly confronting these and other issues in science that touch on sensitive social, ethical, and moral domains. The good news is that NIH still ranks among the top two or three most respected government agencies nationally (*7*). That respect, however, is not inherent nor will it be everlasting unless continually earned.

Question: How can NIH and the scientific establishment garner and maintain the trust of the American public?

Conclusion

Do we need a strategic plan? Do we have to answer questions such as I have posed here? Must we take concrete steps to respond to each of these challenges? Surely we must if we want to help shape the NIH of tomorrow. The future *will* come, and as Peter Drucker said, "The only thing we know about the future is that it is going to be different" (*8*). Are we prepared to influence the nature of those differences? I suggest to you that we must prepare, we must participate in the NIH of tomorrow: assure its responsiveness to its magnificent mission and its ability to thrive in both good and tough times, preserve and create an atmosphere for creativity and imagination, and continually earn the trust of the public, thereby growing as a national priority.

But the final and perhaps most compelling reason why we should chart strategies to advance our noble enterprise is, quite simply, that this is our children's NIH, too.

REFERENCES AND NOTES

1. "For years I thought what was good for our country was good for General Motors and vice versa. The difference did not exist. Our company is too big. It goes with the welfare of the country. Our contribution to the nation is quite considerable."—C. E. Wilson in his testimony before the Senate Armed Services Committee on his nomination to be Secretary of Defense (15 January 1953) [quoted in the *New York Times*, 24 February 1953, p. 8].
2. Oldsmobile 88 Royale, reviewed in *Consumer Reports*, [**51** (no. 1), 38 (1992)].
3. V. Bush, *Science—The Endless Frontier, A Report to the President on a Program for Postwar Scientific Research* (National Science Foundation, Washington, DC, 1990).
4. U.S. Central Intelligence Agency, *The World Fact Book 1991* (CIA, Washington, DC, 1991).
5. U.S. Congress, House Committee on Government Operations, *The Administration of Research Grants in the Public Health Service*, 90th Cong., 1st sess. (Government Printing Office, Washington, DC, 1967), pp. 59–60.
6. S. Garment, *Scandal: The Crisis of Mistrust in American Politics* (Random House, New York, 1991), pp. 165–66.
7. In a joint survey conducted by *Fortune* magazine and the Council for Excellence in Government, NIH ranked third among the most respected government agencies and second on a list of federal agencies that provide the best return on tax dollars [*Fortune* **122**, 190 (19 November 1990)].
8. Quote attributed to P. Drucker, Clarke Professor of Social Science and Management, Claremont Graduate School, Claremont, CA.