RESEARCH FUNDING

NIH in the Post-Doubling Era: Realities and Strategies

Immediate- to long-term approaches are discussed that will minimize the negative impacts of current budget constraints and still preserve the NIH mission.

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This has been a challenging year for the National Institutes of Health (NIH) and the biomedical research community. An extraordinarily tight federal budget is eroding the growth of NIH at a time when opportunities for scientific progress and advances in human health have never been greater. As I talk to scientists and administrators throughout the country, the anxiety is palpable. I share these concerns. I am most deeply troubled about the impact of this difficult situation on junior scientists, and on the ability of established investigators to maintain their laboratories.

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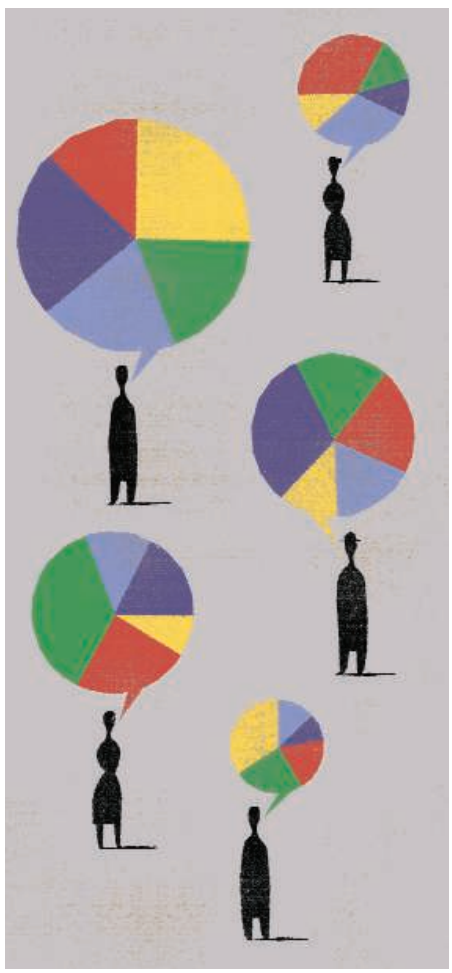
To engage in a productive dialogue about the future, I provide here some data, share my perspective about the main causes of the present situation, and outline the actions we are taking to reduce the very real strain on our scientists.

Realities

Many scientists are dismayed that it is more difficult to get funded today than it was before the NIH budget doubled. What can explain this apparent paradox? The core reason is the increase in the number of new applications and applicants for NIH grants (see figure, p. 1089). In 1998, NIH received 24,151 applications for new and competing research project grants (RPGs) (*1*); NIH expects to receive over 46,000 in 2006 and over 49,000 in 2007. The doubling in the demand for grants is primarily due to a large increase in the number of new scientists applying for grants. In 1998, there were about 19,000 scientists applying for competing awards. In 2006, NIH expects to receive applications from approximately 34,000 scientists and forecasts that over 36,000 scientists will apply in 2007. Remarkably, the largest surge in demand for grants occurred at the end of the doubling period and continues today. This "perfect storm"—the imbalance between supply and demand for grants—is the fundamental reason for the painful circumstances in which we find ourselves.



The principal cause of this remarkable growth in grant demand is the unprecedented expansion of research capacity across the country that began in 1999. Stimulated by successive administrations' and Congress's calling for more research on emerging health issues, academic institutions responded. Using philanthropic, local, and state resources, as well as loans, they expanded the scientific infrastructure and workforce to address the growing scope and complexity of our scientific challenges. For example, the American Association of Medical Colleges projects that an estimated $15 billion have been committed to new research facilities between 1998 and 2007, compared with $3.2 billion between 1990 and 1997. Allowing for the lag time necessary to build facilities and train scientists, this expansion is now being felt in the form of a rapid surge in applications. It should not go without mentioning, however, that this increased investment by our research institutions is resulting in the development of entirely new fields of research, leading to an acceleration of the pace of promising research advances across the entire spectrum of the biomedical and behavioral sciences. This is just what the nation wants and needs.

Unfortunately, our ability to sustain this expanded research enterprise is now at risk. Some of the tension is due to inflation. Since 1998, the average size of RPGs grew by about 40%, and NIH budgets have not kept pace with biomedical research and development inflation since 2003 (*2*).

Increased demand, inflation effects, and flat budgets are the main drivers of today's challenges. It has been suggested that decreased success rates are the result of NIH's excessively shifting its emphasis to applied research and clinical trials through large solicitations and projects at the expense of unsolicited, investigator-initiated basic research. This is simply not the case. In 1998, 54% of the total budget of NIH was dedicated to basic research, 40% to applied research (including clinical trials), and 6% to infrastructure programs. Funding for basic science is currently above 55% and is slated to grow beyond 56% in 2007; at which point, applied research will reach 41%, and 3% will be devoted to infrastructure needs.

NIH embraces the importance of investigator-initiated research. We are firmly committed to independent grant mechanisms such as the unsolicited R01. Although the absolute number of requests for applications (RFAs) (*3*) grew during the early part of the doubling, their proportion relative to the NIH budget decreased since the doubling ended. Today, 91% of funded RPGs are unsolicited, compared with 88% in 2003, and 92% in 1998. Of our extramural grants budget, 78% remains dedicated to RPGs (*4*) as compared with 81% in 1998. The difference is primarily due to growth in centers and contract mechanisms to address emerging public health priorities.

It has also been suggested that the NIH

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Roadmap (*5*) is a major cause of reduced success rates. In fact, the Roadmap represents only 1.2% of the fiscal year (FY) 2006 NIH budget. The science within the Roadmap is peer-reviewed and very competitive. It is not a monolithic program, but rather supports over 345 principal investigators at 133 extramural institutions through a variety of mechanisms, including R01s. It does not significantly affect overall success rates. The planned Roadmap budget represents a balanced portfolio, with 40% going to basic research; 40% to clinical and translational research; and 20% to interdisciplinary and high-risk research, such as the Pioneer awards.

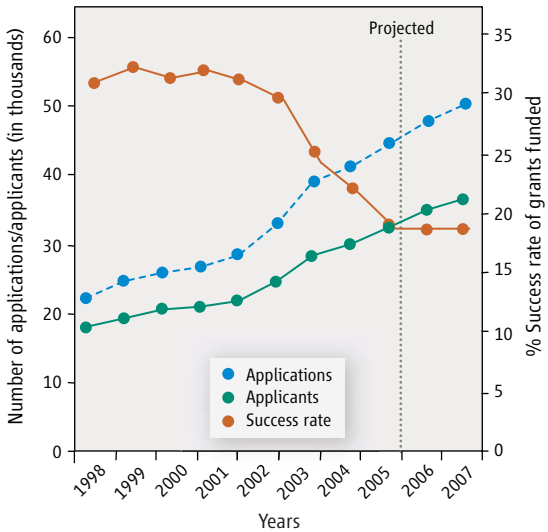
I believe that any organization of the size and complexity of NIH needs to have an explicit and dynamic process for supporting critical scientific programs that cut across scientific areas and that none of the individual institutes could support on its own. In an era of rapid convergence of (and emerging opportunities in) science, the Roadmap process allows NIH to support innovative and high-risk research, incubate new ideas, and stimulate the development of transforming strategies that can benefit the entire scientific community. To ensure vitality, no initiative will be funded for more than 10 years, with most lasting 5 years. In my opinion, the greatest risk for science is to stop taking risks. The Roadmap process allows NIH to remain responsive even in constrained times. It has been and will continue to be developed through wide consultations with members of the scientific community. The Roadmap process was well received by Congress and the administration and served as an important part of the rationale for NIH's small budget increases in 2004 and 2005.

Strategies

Given these facts, what strategies for the future should we, as a community, consider? Pragmatic and prudent steps need to be taken to minimize the long-term negative impact of the hopefully short-term budget woes. We must develop unified, informed, and proactive strategies.

We need to remain focused on our core values and to pursue our fundamental mission of discovery—translating new knowledge into tangible benefits for the American people. This must remain our top priority. This means maintaining, to the greatest extent possible, the ability of scientists at all stages of their careers to continue their work.

Preserving future generations of scientists. Like farmers during difficult times, we should not "eat our seed corn," but protect it. To accomplish this, we have implemented three specific strategies to encourage and support junior scientists and new investigators: (i) Every institute and center is working to ensure that the success rates of new investigators are not disproportionately affected by flat budgets, through various mechanisms such as differential pay line considerations. (ii) Because new investigators may not have the resources to sustain long peer-review cycles, they now receive their critiques within 1 week of review and can apply up to 3 weeks beyond the next receipt date. This dramatically decreases the length of the application review cycle without compromising the rigor of peer review. (iii) Outstanding new investigators still in postdoctoral training may now apply to the Pathway to Independence awards program launched in 2006 (*6*). It will fund 150 to 200 postdoctoral candidates for each of the next 5 years. These scientists will receive up to 2 years of mentored training support, followed by 3 years of R01-level funding, contingent upon securing a tenure-track position with appropriate institutional support and resources. This strategy is designed to retain promising scientists and to give them the opportunity for independent research at an earlier stage of their career. Some institutes and centers are looking to expand this and other pilot programs in the future.



"Pragmatic and prudent **steps need to be taken** to minimize the long-term negative impact of the hopefully short-term budget woes."

I remain concerned about how long it now takes for a scientist to launch his or her independent research program. Today, the average age at which a scientist receives a tenure-track faculty appointment has increased to 38, and the average age for receiving a first independent award from NIH is above 40. This trend must be reversed, and the new Pathways program is one component of our strategy to do so.

We all agree on the urgency of developing new and better ways of maintaining the attractiveness, joy, and excitement of a research career while eliminating the daunting obstacles and rigid traditions that junior researchers are facing in our academic systems. Now is not the time to discourage young scientists, but to find bold ways of improving their career prospects and opportunities.

Balancing supply and demand. NIH spends more on funding grants today than ever before, but over 80% of its budget is committed to ongoing projects. In any given year, the only resources available for new grants are those that come from ending projects that started 4 to 5 years before, plus any new increase in the overall budget. Our large commitment base, the unexpected budgetary impact of hurricane Katrina, the fact that in 2006 the only funds available were those freed up from grants started when the NIH budget had not reached its peak, along with the growing number of applications, compounded our difficulties. To alleviate the strain, we made the hard decision to reduce the committed budget of existing awards by 2.35% for 2006, freeing up some resources for new and competing awards. In the coming years, as we recycle funds from the higher funding years of 2003 to 2005, more uncommitted funds will become available, and thus more new and competing RPGs can be awarded.

Although strategic priority setting and careful management of these recycled funds will help stabilize success rates, they will not be sufficient to satisfy the much larger demand for grant funding, if the budget remains flat and inflation continues to erode our purchasing power. While these potential solutions will have an impact on NIH as a whole, we recognize that neither the problems nor the solutions fit every institute and

center. This is why we asked each institute and center to adjust its overall portfolio to preserve individual success rates to the extent possible. The difficult decisions that these adjustments require are made in consultation with institutes' and centers' outside scientific advisory councils.

At the NIH level, we are also redirecting priorities. The intramural program, NIH administrative costs, and infrastructure expenses are being kept well below inflation.

> "**... the greatest risk for science** is to stop taking risks."

Given the current environment, Roadmap budgets are also reduced, and no new initiative within the Roadmap can be undertaken unless it fits within the budget agreed to by all the institute and center directors. This means that for the foreseeable future, new Roadmap initiatives can only begin as other Roadmap initiatives conclude.

Improving peer review. Exacerbating current frustrations for investigators and reviewers is the burden associated with the submission of even more grant applications by applicants seeking to improve their chances of success. In 2006, success rates per application fell to about 20%, while the funding rate for applicants was higher at about 25% (*7*). This is due, in part, to the fact that we now receive on average 1.4 applications per applicant, compared with 1.2 before 2003. NIH is reevaluating its review system to reduce the length of the review cycle for all applicants, shorten grant applications, reduce unnecessarily burdensome procedures, and further improve the quality of our peer-review system.

Communicating the benefits of medical research. NIH and the scientific community need to better educate the public about the extraordinary return on investment in the NIH. The value of NIH is so self-evident to our community that we often do not realize that it is not evident to many others. In a survey last year, 73% of Americans could not name NIH as the government agency that funds most of the medical research paid for by U.S. taxpayers (*8*). I have placed a high priority on enhancing NIH-wide public education efforts, and want to commend the efforts that have been made by all stakeholders, but this is not enough. Congress continually asks me to demonstrate the benefits of the NIH doubling to the American people. We testified to this effect numerous times (*9*). For example, the estimated total cumulative investment in cardiovascular research at NIH per American over the past 30 years is about $110, or approximately $4 for each American per year over the entire period. In return, we enjoyed a 63% decrease in mortality due to heart disease. The value to Americans of this increase in life expectancy has been estimated at about $1.5 trillion per year over the 1970–90 period (*10*). This is an impressive return on investment by any measure, even if only a fraction of the gain came from medical research.

Nonetheless, we all need to do better in demonstrating our value to society. Since 83% of the NIH's budget goes to more than 3000 research institutions across the country, it is a shared responsibility to communicate clearly and consistently to the public the linkage between NIH and advances at the local and regional levels.

This renewed effort on communicating the value of NIH to the American public by all stakeholders is critically important. During a recent debate in the House of Representatives about a bill to reauthorize the NIH, the chief sponsor of the bill, Congressman Joe Barton, measured NIH's success in simple terms: "It helps my family. It helps every American family" (*11*). Representatives made uniformly positive comments about the importance of supporting NIH and increasing its budget by 5% per year for the next 3 years. The bill passed by a strong bipartisan vote of 414 to 2 (*12*), a hopeful sign.

Defining a compelling vision for the future. Continued support for NIH will not be based on past performance, but on a shared and compelling vision for a future that serves the fundamental needs of our society. Today, health-care costs are rising at an unsustainable rate. Scientists need to be an intrinsic part of the solution to this problem. Marginal reform of how health care is delivered will not suffice. We need to radically change what is being delivered. There is an urgent need to transform health and medicine from the curative and onerous paradigm of today to the vision of a more predictive, personalized, and preemptive world of health care. The only hope to do so is to further our fundamental understanding of biology and behavior through sustained scientific discovery.

Since 1945, United States success in scientific research and development has been the result of the implicit partnership that exists among academia, the federal government, and industry. In this model, research institutions take the risk of building and developing our national scientific capacity; the federal government, through a competitive peer-review process, funds the best science; and industry plays the critical role of bringing new, safe, and effective products to the public. This strategy is the keystone to sustaining American competitiveness, and must be preserved.

As a community, we are accomplishing a great deal, but we are in particularly difficult times. Although these are very challenging and painful days, I am confident that we will weather this storm. Now more than ever, an informed, proactive, and unified strategy will be key to advancing the science needed to improve the health of the world. I welcome comments and suggestions on how we can come together as a community to achieve this goal.

References and Notes

1. The major funding instruments used by NIH to fund extramural research are financial assistance award grants and cooperative agreement grants. Research project grants are awarded to institutions on behalf of a principal investigator to support medical research activities in the areas that represent both the specific interests and competence of the principal investigators and also the NIH institutes' identified program needs. These are generally initiated by the investigator.
2. Price indices, NIH Office of Budget, http://officeofbudget.od.nih.gov/UI/GDP_FromGenBudget.htm.
3. A request for application (RFA) is the official statement that invites grant or cooperative agreement applications to accomplish a specific program purpose. RFAs indicate the amount of funds set aside for the competition and generally identify a single application receipt date. Applications for R01s and other types of grants submitted in response to RFAs are also known as solicited applications.
4. The extramural grants budget includes research project grants, research centers (grants to support long-term, multidisciplinary programs of medical research), other research grants, such as grants for research career development, and other small grant programs. The extramural grant budget represents 70% of the total NIH budget.
5. NIH Roadmap, http://nihroadmap.nih.gov/.
6. NIH new investigator programs, http://grants1.nih.gov/grants/new_investigators/index.htm.
7. Success rates indicate the percentage of reviewed research project grant (RPG) applications that receive funding. This is computed on a fiscal-year basis. Applications that have one or more amendments in the same fiscal year are only counted once. Success rates should not be confused with funding rates. Funding rates indicate the percentage of competitively reviewed applicants for RPGs that receive funding in any fiscal year. This is calculated by dividing the number of applicants that received an RPG award by the total number that competed for any RPG in the same fiscal year (some individuals apply for more than one RPG).
8. M. Woolley, S. M. Propst, *JAMA* **294**, 1380 (2005).
9. Testimony before House and Senate Appropriations Committees, 6 April and 19 May 2006.
10. R. Murphy, K. M. Topel, *The Economic Value of Medical Research* (Univ. Chicago Press, Chicago, rev. ed., 1999).
11. Statement of Representative Joe Barton (R–TX) on House floor, 28 September 2006.
12. Vote on NIH reauthorization on House floor, 28 September 2006.

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