From progress to regression: biomedical research funding

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Despite great advances in health-related research and health care, major challenges remain regarding the causes and cures of many diseases; these may be overcome with further research. Our society is enthusiastic about fostering such investigations. However, available federal funds limit many such projects. Previously there have been sizable increases in the NIH budget, but because of the escalating cost of scientific investigation and the pressures of financing other much-needed governmental programs, recent growth in biomedical research funding has barely kept up with inflation. This article focuses on select attempts to sustain the record of scientific achievement enabled in the past by continued increasing investment and also suggests some solutions.

Introduction

Over a decade ago, Nobel laureate Leon Lederman commented that continued robust and groundbreaking accomplishments in life sciences research and science education would be required for the United States to maintain its history of innovation and productivity as well as its reputation as a world leader in science and technology (1). In early 2004, the United States National Science Board reiterated this conclusion (2). A small portion of funding for biomedical research derives from private agencies, including the Howard Hughes Medical Institute and various organizations promoting cures for specific diseases. However, the NIH has been responsible for funding most US biomedical research, and small but steady increases in the NIH budget are required to sustain the exciting momentum of scientific breakthroughs of the past. There is also a need to establish consistent, long-term funding policies and to enhance funding for allied governmental agencies such as the Centers for Disease Control and Prevention, the National Science Foundation, and the Department of Energy, that support research in the disciplines of chemistry, physics, engineering, and bioinformatics, etc., which are fundamental to biomedical research. Attainment of these goals not only represents a profound investment in our healthcare and quality of life but also assures the continued economic competitiveness of our nation, which is dependent on and has greatly profited from key contributions of scientific research (3). The biomedical research community has depended primarily on investigator-initiated (R01) research grants awarded by the NIH. Despite past increases in the NIH budget, the likelihood of funding an individual NIH grant has not increased.

We believe that optimal operation of US research efforts requires additional moneys. The needed reevaluation of our national security has resulted in some lengthy bureaucratic precautions that impede the essential recruitment of foreign students and scientists as collaborators in US research. Furthermore, congressional challenges based on ideological pursuits have been leveled at the peer review process itself. If continued, these interferences could jeopardize the careful scientific-merit evaluation of research applications, proposals, and approaches. Finally, the increased cost of health care and changes in health care reimbursement policies have subjected our academic health centers to financial pressures that have limited their ability to serve the health care needs of many Americans. These issues are described in greater detail below.

History of NIH funding: the major contributor to the success of US biomedical research

The NIH began to support biomedical research in 1938, with a total appropriation of $464,000. This amount has grown steadily over the years to become the major source of funding by the US Government for health-related research. For fiscal year 2004 (FY2004), the total NIH appropriation was $28 billion (4). Of that amount, approximately 10% of the allocation was designated for intramural research, 18% for research centers and research and development contracts, 3% for research training, and 54% for research project grants.

An accelerated pace of scientific discoveries and increasingly strong political support fueled the doubling of the NIH budget over a five-year period, from FY1999 through FY2003. However, the FY2004 allocation grew only 2.9%, an increment barely matching inflation. For FY2005, the administration requested $28.5 billion, or 2.6% over the FY2004 enacted level (5).

Members of the bioscientific community are extremely concerned that these already reduced levels of annual increases fall even below the annual change in the Biomedical Research and Development Price Index (BRDPI) — the science-related inflationary index indicating the amount by which the NIH budget must change to maintain purchasing power. The Bureau of Economic Analysis of the US Department of Commerce estimated that the BRDPI increased by 4.6% for FY2003. The NIH's Office of Science Policy and Planning, which serves as the principal resource for science policy, analysis, and development on issues of significance to the agency and the medical research community, projects that the BRDPI will increase by 3.8% for FY2004 and 3.5% during FY2005 and FY 2006 (6). However, calculations developed by officers of several large and influential leading American biomedical-related organizations (Association of American Medical Colleges [AAMC]; Federation of American Societies for Experimental Biology [FASEB]; and the Association of American Universities) have demonstrated that maintaining the current

Nonstandard abbreviations used: FY, fiscal year.

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momentum of the nation's biomedical research enterprise would require an 8–9% annual increase in the NIH allocation (7). Such growth would help to maximize US investment in research, permit the funding of a greater percentage of grant proposals deemed worthy of funding during the peer review process, allow the peer review system to work more effectively, and attract talented young people into research careers. While members of the research community recognize current constraints on the federal budget, we must look ahead to realize the maximum benefit that discoveries in health, made possible by medical research, can provide. It is essential to continue the momentum of funding the most promising of the many new imaginative ideas made possible by recent biomedical breakthroughs. An enormous number of new opportunities have arisen. They should now be evaluated, and the best should be funded. This will probably not be possible under the presently proposed 2.6% increase in the NIH budget. Furthermore, a significant portion of that increase is intended specifically for biodefense research. The valuable contributions provided by the doubling of the NIH budget over the earlier five-year period may, in fact, be negated if we now lose this momentum (7). Once lost, this chance for progress may never return. The title of this article reflects the lost ground and reveals a decrease in actual purchasing power for biomedical research resulting from the minimal NIH incremental budget as proposed.

Spokespersons for biomedical science

Several traditional, highly respected organizations, such as FASEB and the AAMC, ably represent ideas and opinions of biomedical and life scientists, particularly those related to public policy issues. FASEB is an umbrella organization composed of basic life science disciplines; its members are affiliated with a variety of employers, such as government, industry, research institutes, universities, disease foundations, and medical schools. Until recently, the AAMC, through their administrative efforts, focused primarily on the functioning of medical schools and hospitals. Its Council of Academic Societies is organized by medical and scientific discipline and addresses issues relating to multiple scientific, medical, and disease specialties. In the past few years the AAMC has also become more focused on faculty and medical school departmental issues, setting a national agenda for medical education, biomedical research, and health care.

The National Caucus of Basic Biomedical Science Chairs (NCBBSC, or the Caucus) is independent of FASEB and the AAMC. It discusses basic life science and preclinical medical school faculty, issues relating mainly to teaching and research, as represented by department chairs. Other larger and better-established organizations with similar aims include the Ad Hoc Group for Medical Research Funding and the public affairs offices of FASEB and of the American Society for Microbiology, as well as various groups primarily concerned with finding cures for specific diseases. The NCBBSC has attempted to keep in close contact with most of these organizations to promote coordination and achieve common aims with maximal effectiveness.

Role of the NCBBSC. Founded in 1991, the Caucus is composed of presidents and other representatives of national associations of the chairs of basic biomedical science departments in our nation's 125 medical schools. It includes chairs of anatomy, biochemistry, genetics, microbiology, neurobiology, pathology, pharmacology, and physiology, representing preclinical medical school faculty devoted to teaching and research. Although the organization represents the basic sciences, its overall interests and activities relate to all health research and include the translation of results of basic science made at the bench to treatment of patients. Emphasis has been devoted to the maintenance of adequate financial support for the nation's research initiatives since that is a prerequisite for research (8).

The authors are former chairs of pharmacology departments. H.G. Mandel has been chairman of the Caucus since its inception in 1991, and E.S. Vesell has been a long-term member of the Caucus. Meetings have been held once or twice a year in the Department of Pharmacology & Physiology of the George Washington University School of Medicine and Health Sciences with about 20 participants from all parts of the country at each meeting. Because of rotations of officers in the chair organizations, a high percentage of the membership is new to the Caucus each year. This article is written from the perspective of the Caucus, which has focused on the issues described, although other concerns remain. Because of space limitations, they cannot all be addressed here.

Departmental chairs at our medical centers are especially aware of the struggles of their faculty members, particularly more junior colleagues, to receive sustained extramural funding. Such support is required to develop their innovative scientific ideas. Their professional future depends, in large measure, on patient and successful pursuit of novel, imaginative ideas, as judged by their peers and especially by peer reviewers of their grant applications to funding agencies. Extramural financial support is generally required for academic appointment, promotion, and tenure in an increasingly competitive medical center environment (9). Similarly, for the more experienced faculty members, continued financial research support is essential not only to stimulate and preserve departmental productivity and stability but also to attract and retain talented, well-trained scientists as faculty members for the purposes of research and teaching in our academic institutions.

R01 grants

NIH R01 grants fund applications from individual investigators who have initiated innovative research plans based on results strongly suggesting a pending scientific breakthrough that may lead to improved global health and well being. This grant program has been the mainstay of funding for a very large group of academic biomedical researchers. Annually, about $9 billion supports R01 grants, which include competing and noncompeting awards; an average award encompasses a four-year period (10). Therefore, approximately $2.5 billion, about 10% of the NIH budget, is allocated annually for competing R01 awards (a similar R29 award, designated for new investigators, was terminated in FY2000 and its funds combined with the R01 grant pool). R01 grants account for about two-thirds of the research project grants awarded by the NIH. An additional award category, request for application (RFA), is solicited by the NIH to accomplish a specific program purpose, and these are reviewed and handled separately from R01s.

Figure 1 shows success rates of applications for new grants and renewal of previously approved and ongoing grants in relation to the total NIH budget over the past decade (11). In many cases these applications were not funded as originally submitted, requiring one or more revisions before eventual funding. Success rates for new grants rose from 17.2% in 1993 to almost 26% in FY2000 but have remained relatively stable since then (for FY2003, it was 24.1%) despite major increases in the total NIH budget. This means a 75% failure rate for new grant applicants. The total number of submitted applications has remained almost constant, except for FY2003 when it increased by about 10% (Figure 2). A decisive increase in applications with a fixed total budget would have

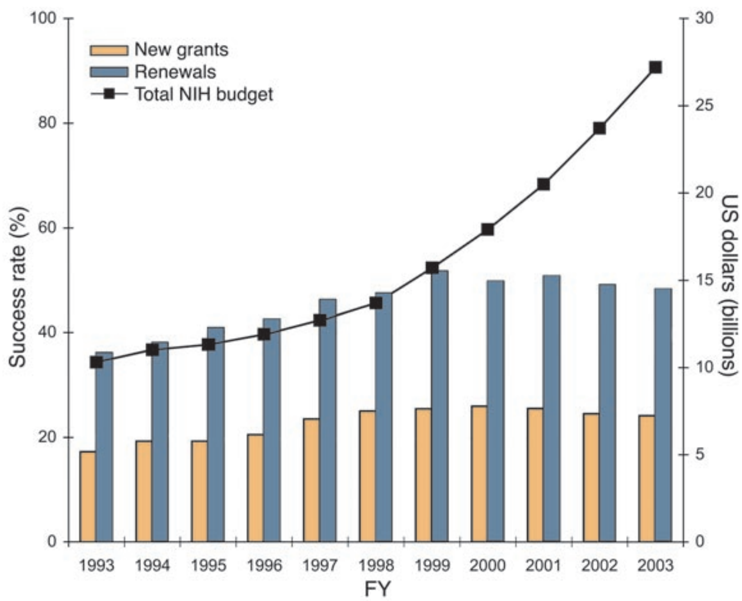

Figure 1
Success rates of funded R01 applications, new and renewals (orange and blue bars, respectively) by FY. Line, total annual NIH budget allocation, in billions of dollars.

required a reduction of the success rate, but that did not occur. Reapplication does increase the chance for success, but this is a slow, time-consuming, and inefficient process, taking almost a year for each resubmission. Although the peer review process often results in stronger applications, this is not always the case. Where the revision is minor, performing research instead would in some cases be a more productive and efficient use of the extra time.

Similarly, for grant renewals, there has been a gradual increase in the continuation of ongoing programs that have previously passed peer review. However, in the last five years, there has been no change in the success rate. The resulting cessation or interruption of support has led to the breakup of successful research teams and has become extremely discouraging for active and productive researchers, many of whom have decided to change careers. Notably, with the plateau in the percentage of successful grants, the number of such grants funded has remained almost constant for the past five years. However, the total dollars awarded for new and renewal grants have risen in line with the increased NIH budget allocation in recognition of a necessary increase in the size of grants due to an escalation in the cost of undertaking research.

Since 1991, the Caucus has been tracking success rates of unamended R01 applications (de novo funding applications not previously reviewed or revised) (8, 12–15). This assessment provides scientists an estimate of the probability that their R01 research grant proposals to the NIH will be funded. Subsequent amendments to the application will improve the chance for success, but it could take two or three revisions (and years) before the research request is finally funded. When recalculated for unamended applications, in FY2000 the success rate for new grant applications was only 20.2% (15). In other words, four out of five applicants were denied funding of their recently submitted proposals. Discussion between the Caucus and numerous peer reviewers of R01 grants has revealed that most grant reviewers would recommend (with the increased quality of applications in recent years) funding 30–40% of submitted new grant applications, a figure in agreement with the above-mentioned report (7).

Recommendation regarding funding of R01 grants

To fund new applications in keeping with the desired 30–40% success rate from the present 20% of unamended applications would require a boost in the funding pool of competing R01 grants. This allocation, presently about $2.5 billion, should be increased by $1.3–1.5 billion in the first year. For subsequent years, a somewhat smaller increase would be needed since under the current system, a significant portion of revised applications following denial is already being funded. This budgetary adjustment would reduce the need for reapplication and greatly increase scientific productivity. In addition, efforts should be made to accelerate the evaluation process after resubmission of revised applications. These changes would also encourage larger numbers of the best and brightest of our youth to foresee an exciting and professionally gratifying future in a biomedical science career because of new discoveries and the likelihood of further success in the battle against disease. Indeed, the doubling of the NIH budget from 1999 to 2003 and the resulting increase in scientific opportunities have now provoked greater interest in biomedical graduate studies. It is necessary, however, to maintain adequate increases in the funds for health research to avoid discouraging new, able scientific investigators from pursuing an academic career because of the difficulties and uncertainties of obtaining, and subsequently maintaining, research support. The high failure rate of 80% for new investigators seeking NIH-funded R01 grants compounds this issue since continued extramural support is usually required to sustain a career in research and teaching at a US medical school (9).

Several other concerns should be addressed when considering current science policy and development. First, for scientific investigators aged 35 years or younger, the likelihood of receiving NIH grants has decreased sharply from 23% in 1980 to below 4% in 2002 (16). This is a serious concern because many new, productive, and imaginative ideas emanate from younger scientists. In part this change is related to increased average age at which a PhD is obtained and longer periods of post-doctoral training before reaching independence.

Second, success rates of research grant applications from MD investigators have not matched those of basic scientists. To rectify this problem, additional funds have been allocated for clinical research career awards (17). It is important that MD researchers be represented in higher proportions on grant review panels (18). An increased pipeline of well-trained clinical investigators must be developed in order to achieve delivery of better health care, made possible by advances in basic scientific research. About 30% of NIH extramural support is currently devoted to clinical research (18). It should be noted that clinical research tends to be more costly than basic research. Also, because of recent changes in academic medicine, as discussed in this paper, the impact has been especially harmful to clinical investigators.

The NIH Roadmap for Medical Research, proposed by NIH director Elias Zerhouni in the fall of 2003, contains excellent approaches for improving the outcome of biomedical research and strengthening efforts of the entire research community. The plan should permit better and more efficient translation of laboratory discoveries into effective therapeutics and practices used in patient care. The proposed initiative (19) includes creation of molecular libraries, national biocomputing and nanomedicine centers, and innovator awards to encourage unexplored avenues of creative research that carry a relatively high risk of failure but also a greater chance of pro-

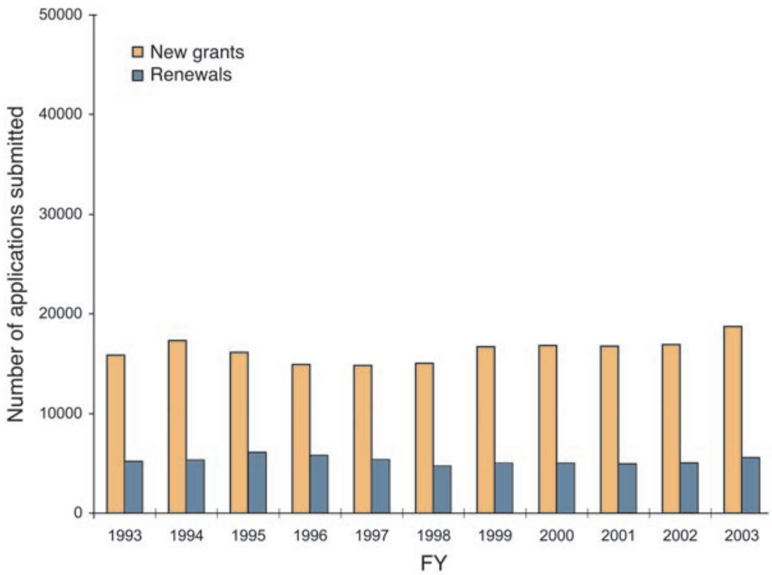

Figure 2
Total number of new (orange bars) and renewal (blue bars) R01 applications submitted to the NIH for review, by FY.

ducing groundbreaking discoveries. There will be more emphasis on team science, public-private partnerships, and a multidisciplinary approach to research. Modern technology, including easier, more rapid means of communication, should simplify and encourage interdisciplinary and interinstitutional cooperation. About $0.25 billion will be devoted to the Roadmap in FY2004. These ideas may be particularly pertinent for individuals trained in MD/PhD programs rather than for physicians whose time is already fully occupied. Although these approaches are desirable, funds for team science projects should not replace R01 grants to individual scientists with outstanding and imaginative ideas. Historically, major innovative breakthroughs have frequently occurred through discoveries made by individual scientists funded by R01 grants, which allow unexpected observations that would have been missed by rigidly planned group approaches. The history of Nobel laureates in biomedical sciences amply illustrates this principle.

Politics versus peer review

Objective and fair scientific peer review of research applications is essential in selecting the most valuable projects proposed by researchers whose expertise in their given areas has been demonstrated. There is no question that the scientific community should be held accountable to the public since taxpayers' money ultimately supplies NIH-funded research. Furthermore, Congress and our political representatives must oversee federally funded research agendas and priorities. However, proposals to Congress in 2003 suggested the imposition of ideologies and religious doctrine on the selection of federally funded grants, thereby attempting to subvert the peer review system that has served the best interests of both the scientific community and the public (20). The Toomey amendment, sponsored by Representative Pat Toomey (R-PA), attempted to deny funding for four previously approved grants because they proposed to study certain ostensibly taboo subjects (sexual behavior associated with disease transmission in certain populations, such as Asian prostitutes and transgendered Native Americans; men's sexual habits; female sexual arousal) (21). The applications for these grants had previously passed rigorous scientific peer review and had been approved for funding by the NIH's National Advisory Councils (20). Fortunately, because of responsible efforts by political leaders and scientists, the House defeated the Toomey amendment, thereby preventing the cancellation of these grants, but only by a vote of 212 to 210. Subsequently, a religious group called on Congress to challenge the funding of almost 200 grants dealing with HIV/AIDS prevention, risky sexual behavior, and pregnancy prevention (22). Reflected in the close vote is the likelihood that attempts to assert political control over scientific issues will again arise.

It must be recognized that successful studies of risk behavior and its relevance to the prevention of disease or its spread among drug users and sex partners are of considerable value. Such studies may lead to a reduction in infection, drug abuse, and violence. It should also be stressed, however, that scientists filing grant applications need to use the utmost care in preparing their research proposals to make clear to both reviewers and the public the potential significance of the research to public health. It is especially important to choose an appropriate title and develop a carefully worded abstract to avoid misconstruing for political posturing.

Hurdles for foreign students and scientific collaborators

Foreign students and scientists training or collaborating with US investigators, and those who wish to do so, have been and continue to be subjected to frustrating and undeserved bureaucratic hurdles. National security concerns, of course, are real, but a number of individuals have experienced unnecessary and severe delays or denial upon attempting to enter or reenter the US. Extensive anecdotal evidence exists of brilliant foreign students who could not meet US immigration requirements in order to enroll in programs to which they had already been admitted and of foreign colleagues detained on reentry into the US after, for example, participating in an international meeting. There has been a decrease in the number of new applicants from foreign countries to US graduate schools in science, particularly in the disciplines of computer and physical sciences and engineering (23). However, it is acknowledged that the reasons underlying this change are complex, often difficult to ascertain, and not related solely to excessive security precautions or bureaucracy. In addition to significant annual expected fluctuations in the number of foreign applicants, other explanations for such decreases include (a) limitations in the number of foreign students our programs can accommodate because of space or funding; (b) an increase in the number of US applicants; (c) the slowing of our economy (which has made prospective job opportunities in the US more uncertain); and (d) improvements in the graduate education system and professional atmosphere in countries outside the US (24). NIH director Zerhouni recently stated that we need an effective system to attract extraordinary young people from other nations, as have supported and enriched our homegrown scientific power in the past, without sacrificing public safety (25). Because there is a recognized need for extreme vigilance, a more realistic and timely balance between national security and the desire for international scientific collaboration is required.

Financial health of academic medical centers

The current fiscal health of our nation's medical centers should be considered more seriously by the government because of major financial difficulties facing these irreplaceable institutions. Several factors contribute to this fiscal crisis. For some years, the increasingly competitive health care market, managed care, reduction in insurance reimbursements, and reduced federal payments have greatly diminished clinical service revenue for medical centers (26). Previously, some clinical income was used to help defray costs of medical education and research. Budget restraints have made both basic and clinical investigators almost entirely dependent on extramural support for their research. Many clinical faculty members, who face great pressure to remain scientifically competitive, must decide between full-time commitment to clinical practice and nonpractice activities. Accordingly, for them, participation in research programs and teaching has become a luxury. Although it is hoped that investment in medical research will eventually lead to a reduction in the cost of medical care, the present fiscal pressures on our academic medical centers further delay translation of basic scientific discoveries into earlier diagnosis, prevention of disease, and development of therapies that will ultimately serve to improve the nation's health.

Establishing communication to implement proposals

Various public affairs groups have opened discussions with key political leaders in order to explain the need for improved comprehension of the issues that hamper more rapid progress in the understanding and treatment of disease. The Caucus, through its meetings, has focused on establishing a dialogue with members of the Senate and the House and their staff and also with present and previous leaders of the Office of Science and Technology of the White House, NIH directors, National Science Foundation officers, presidents of the Howard Hughes Medical Institute, and officers of the American Association for the Advancement of Science. A Caucus-led congressional breakfast and also a lunch with key news media specialists attracted governmental leaders to hear experienced communicators effectively express their enthusiasm for health research and the urgent need for increased NIH appropriations.

Scientists must realize that unless they communicate their perceptions about health research to our political leaders as well as to the general public, needed policy changes are unlikely to occur. Through the effective efforts of Research!America, surveys covering almost all areas of the US clearly demonstrate that our population is supportive of increasing health research expenditures (27). However, it must be realized that our government faces enormous financial pressures from many different fronts, including, but not limited to, the sluggish economy, the war in Iraq, the previously underestimated cost of a continued US presence in Iraq, the growing national debt, increased budgetary requests for all other governmental programs, and the desire for reduced taxes.

Our political leaders must discriminate among the virtues of the various requests they receive. We must constantly remind them of the valuable contributions medical research has made to the health of our nation. They need to be encouraged to make every effort to support the realization of new discoveries to combat disease and improve the quality of life of our society. Scientific investigators are also encouraged to contact congressional representatives in their home districts in order to reinforce the accomplishments of their local medical schools and research institutions. This approach, which many scientists are hesitant to undertake, could be most productive. It has been successful in the past.

Since most health research specialists have calculated that an 8–9% annual increase in the overall NIH budget is essential to maintaining our momentum of progress in the battle against disease (7), biomedical scientists should advise our political leaders to aim for this target.

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