

CRS Report for Congress

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Medical Research Funding: Summary of a CRS Seminar on Challenges and Opportunities of Proposed Large Increases for the National Institutes of Health

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ABSTRACT

This report summarizes the proceedings of a CRS seminar for congressional staff on appropriations for the National Institutes of Health (NIH), held September 23, 1999 against a backdrop of congressional deliberations over increases in NIH's budget. The seminar featured journal editor John K. Iglehart as moderator, former appropriations staffer Michael A. Stephens, newspaper columnist Daniel S. Greenberg, and patient advocate Myrl Weinberg as panelists, and Dr. Lana Skirboll as respondent from NIH, with Pamela W. Smith as CRS coordinator. Topics discussed included the recent funding history of NIH and current proposals to double its budget in 5 years, ideas on what NIH could do with substantial new resources, cautions and questions about NIH's ability to make maximum efficient use of such resources, the desire of patient advocacy groups to be more involved in NIH research priority-setting, and current NIH activities responding to these various issues. This product will not be updated. For background on NIH generally, see CRS Report 95-96, *The National Institutes of Health: An Overview*, and for information on appropriations activity, see the NIH section of CRS Issue Brief IB10051, *Research and Development Funding: Fiscal Year 2001*.

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Summary

In September 1999, Congress was struggling with the FY2000 appropriations acts for the Departments of Labor, Health and Human Services, and Education, including consideration of a second substantial increase in the budget of the National Institutes of Health (NIH) to follow the 15% increase of FY1999. To help inform the debate, CRS held a seminar for congressional staff on the challenges and opportunities posed by proposals to further increase the NIH budget. The seminar was made possible, in part, by a grant from the Robert Wood Johnson Foundation.

Moderator John Iglehart reviewed NIH's long history of bipartisan support from the Congress, manifested in discussions over how rapidly the agency's budget should be increased. Key legislators have favored doubling the NIH budget over the 5 year period from FY1998 to FY2003, while the Clinton Administration has supported a slower pace. Panelist Michael Stephens discussed how NIH spent its \$2 billion increase for FY1999, especially for more peer-reviewed grants. He also showed that the 5-year doubling proposal, generating \$13.6 billion, could accommodate substantial increases in grants, training awards, infrastructure improvements, and inflation, and still have an estimated \$5.4 billion to devote to new initiatives. He proposed some possibilities for innovative uses of the money: establishing another intramural campus on the West Coast or elsewhere, investing more heavily in foreign partnerships, helping build additional megacenters of research, expanding interdisciplinary research with other sciences, expanding training, and developing genomics research resource centers. He also advocated greater NIH involvement in disseminating knowledge of new breakthroughs to patients and providers.

Panelist Daniel Greenberg was skeptical of NIH's ability to make good use of large sums of new money. He acknowledged the political popularity of the agency, but called for greater congressional oversight in several areas: the productivity of the intramural program, the conservatism of the peer review system, the lack of an electronic system for handling grants, and the desirability of setting up a new federally-funded research organization separate from the traditions of NIH. Panelist Myrl Weinberg said that patient advocacy groups want more opportunities to influence NIH's research priorities and want NIH to make the priority-setting and resource allocation process more understandable. She praised NIH's recent efforts in establishing the Council of Public Representatives (COPR) and publishing a booklet on priority setting, but urged greater accountability for the NIH Director and more trans-NIH planning, budgeting, and reporting. Respondent Lana Skirboll said the NIH institutes would soon publish planning documents on their research agendas; NIH is doing more cross-institute planning; it is funding more clinical research training grants; COPR members could help clarify the explanation of priority setting; and NIH is working with industry on various fronts to reap practical benefits from research. (Final FY2000 funding gave NIH an increase of \$2.2 billion or 14.2%.)

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Introduction

In an era of partisan political conflict that has divided Members of Congress on a wide variety of issues, the bipartisan support enjoyed by the National Institutes of Health (NIH) stands out as a strong vote of confidence in the federal government's major health research agency. Reflecting this level of support, NIH's budget has grown at a time when Congress and the executive branch are locked in an ongoing debate over future expenditures for many other domestic government programs. What is at issue between these two branches of government appears to be not whether to increase the budget of NIH, but how rapidly its annual spending plan should be increased. Key legislators favor doubling the agency's budget over the 5-year period from FY1998 to FY2003, while the Clinton Administration has supported a timetable that spans closer to a decade. If the enactment of a \$2.2 billion increase (14.2%) in the agency's FY2000 budget over the previous year serves as any guide, the shorter timetable could prevail. But how the agency should allocate this major increase in its spending capacity remains an open question.

Indeed, it was the central question addressed in September 1999 by panelists who participated in a symposium sponsored by the Congressional Research Service (CRS) and made possible in part by a grant from the Robert Wood Johnson Foundation. The audience was composed largely of staff members of legislators who will weigh in on how NIH allocates its larger budget over the next decade. The panelists who addressed this question and related subjects were Michael A. Stephens, who, for 20 years, worked as a professional staff member of the House Appropriations Subcommittee on the Departments of Labor, Health and Human Services (HHS), and Education; Daniel S. Greenberg, a newspaper columnist and a long-time observer of the biomedical research scene; and Myrl Weinberg, president of the National Health Council, to which 110 national health-related organizations such as the American Cancer Society and the American Heart Association belong. Dr. Lana Skirboll, director of the Office of Science Policy at NIH, was invited to be the first respondent to the formal presentations. John K. Iglehart, founding editor of the health policy journal *Health Affairs* and a national correspondent to the *New England Journal of Medicine*, served as moderator and rapporteur for the session.

NIH: Research Agency to the World

Begun in 1887 as a one-room Marine Hospital laboratory, NIH has grown to become the pre-eminent biomedical research enterprise in the world, relied on for its innovation by countries spanning the developing and industrialized world. Today, NIH comprises 18 institutes, 3 centers, and the National Library of Medicine. Each institute specializes in particular diseases, areas of human health and development or aspects of research support, and each entity receives a separate appropriation. NIH operates 78 buildings on a 300-acre main campus in Bethesda, Maryland, and also occupies off-campus sites in Maryland, North Carolina, Montana, and other locations. With an FY2000 budget of \$17.8 billion, NIH's research monies flow to some 2000 institutions and 50,000 investigators, but, as Stephens pointed out, "the vast bulk of the money goes to about 30 large institutions in this country which are the megacenters of academic research – the Johns Hopkins', the Harvards, the Yales and so forth."

Stephens, based on his experience with the House Appropriations Committee, opened his remarks by noting the contrast between debates over maintaining congressionally imposed budget caps on federal discretionary spending and the actions being taken that day by the House Labor-HHS-Education Appropriations Subcommittee that vastly exceeded the caps. The proposed doubling of the NIH budget began in earnest with its FY1999 appropriation, which increased from \$13.6 billion the previous year to \$15.6 billion. That increase came on a base of several previous years' increases in the range of 6% to 7% annually. Stephens showed a slide detailing how NIH was spending the \$2 billion increase, including the award of about 9,100 new investigator-initiated research project grants, and a total portfolio of about 31,000 research grants, up from 28,000 in FY1998. Such grants, awarded through a competitive, peer-reviewed process, are considered by the agency to be its "engine of discovery," as Stephens characterized it. He also discussed a slide on the proposed \$13.6 billion that would be gained over 5 years if the budget were doubled from the FY1998 level, to impress upon the audience what a vast sum of money that effort represents. Even after paying for "first priority" increases in the number and size of grants, training for more researchers, infrastructure improvements (new and renovated buildings, new instruments, improved clinical research capability), and inflation, there would still be an estimated \$5.4 billion available to devote to new initiatives.

Stephens mentioned several possibilities for innovative uses of the money. First, he noted that the intramural research facilities at the Bethesda campus are already overcrowded, and that county authorities might doubt whether additional facilities should be constructed there. Some have suggested that NIH could establish another large intramural campus run by the federal government on the West Coast or elsewhere. A second idea involved investing more heavily in foreign partnerships. Stephens said: "I think that we have dramatically underinvested in foreign partnerships in science." He noted that out of the very small percentage of the NIH budget going to foreign awards, the largest portion goes to Canada. "So we have made a minuscule investment in partnerships with other parts of the world, many of which have very rich, albeit, undeveloped and sometimes inexpensive biomedical research enterprises which NIH could invest in." Other possibilities for NIH to consider, Stephens continued, would be to help build another 25 to 30 megacenters of research, since the

current ones cannot expand much; to develop new partnerships with the disciplines of physics, chemistry, mathematics and computational science, an idea supported by Dr. Harold Varmus, who directed NIH for 6 years until the end of 1999; to review the manpower personnel needs to staff this vastly larger enterprise; and to invest in developing four or five huge genomics research resource centers around the country where investigators at universities could collaborate.

Finally, Stephens suggested that another opportunity NIH could address would be to close the gap that exists between practicing physicians and the new knowledge that researchers continue to gain through their pursuits. Myrl Weinberg also identified this gap as “a significant problem for this country.” Stephens observed that studies have shown that many practicing physicians do not read medical or scientific journals on a regular basis. “Thus, the ability to disseminate new breakthroughs to patients and providers more quickly is clearly a priority.” Indeed, this has been a congressional priority for many years and has taken different forms. Congress created the Regional Medical Program in the 1960s that had as one of its major charges the rapid diffusion of medical innovations to patient care uses in the community. The Office of Technology Assessment, before its termination in 1995, devoted resources to this same task, as has the Agency for Health Care Policy and Research (recently renamed the Agency for Healthcare Research and Quality). This translational activity has never been one of NIH’s core missions. But, Stephens recounted, former Iowa Representative Neal Smith, who was briefly the chair of the House Appropriations Subcommittee on Labor, Health and Human Services and Education, had suggested that Congress should consider creating a circuit-rider system of federal employees or contract employees (much like the Agricultural Extension Service) that would inform practicing physicians and community hospitals about new medical innovations.

NIH and a Voice of Skepticism

Dan Greenberg, a far more skeptical voice regarding NIH’s capacity to deliver research results that approach the value of a doubling of its budget, conceded in his opening remarks that NIH is “a revered, politically untouchable institution. No one can speak unkindly about NIH because it’s our Pentagon of the war on disease, and the American people are quite fearful of disease. We all want to live forever and we want to live without pain forever. NIH promises a great deal. What’s interesting about NIH politically is that it is probably the most under-scrutinized federal agency in the whole large inventory of federal agencies. The Congress, which has a responsibility for oversight, rarely ever exercises it regarding NIH. The hearings that have been held by the Appropriations Committees generally are celebrations of NIH. Invariably the chairmen, through some process that I can’t quite understand, who come to head the appropriations subcommittees with responsibility for NIH, become NIH enthusiasts. NIH is the only research institution in the world where the buildings are named not after great scientists but after chairmen of appropriations committees.”

Greenberg identified a number of issues that he thought legislators should be examining more closely, including whether NIH’s intramural research program is as productive as its extramural program, how effective its peer-review system is at identifying the research proposals with the greatest potential, why the agency has not

yet installed an electronically-based grant application and award system, and the wisdom of doubling the size of its budget. Greenberg asserted: “I don’t think they can handle the money they have now I would seriously doubt that by doubling that money in a relatively few years we’re going to improve their performance. I would not establish another 30 centers under the direction of NIH There should be an altogether different organization which would be far away, maybe in California, maybe in Honolulu, but it should not be in Bethesda [We need] NIH-2, completely detached from NIH with none of its traditions, none of its people. I would say that peer review should not be ensconced or enthroned as the ultimate system.”

NIH and a Voice of Strong Support

The third presenter, Myrl Weinberg, said the National Health Council is “very supportive of NIH” but that many of her member organizations also are frustrated by the relatively few opportunities that consumer-based groups feel they have to influence the agency’s research priorities. “Some of these groups truly believe that we are just at the edge of having tremendous new potential discoveries in science and in medicine. And that is one of the reasons they are supportive of large budget increases, albeit with some improvements at NIH,” including making the agency more accountable to the public.

Weinberg noted that she served on a committee convened in 1998, at congressional direction, by the Institute of Medicine (IOM), National Academy of Sciences, that published a report entitled, *Scientific Opportunities and Public Needs: Improving Priority Setting and Public Input at the National Institutes of Health*. Weinberg said: “The fact that the Congress mandated that such a study be done was certainly indicative that there are some problems, or at least perceived problems, at NIH.” The essential problem is that the march of science is a complex enterprise that is often difficult for the general public to understand. Even patient-advocacy groups that follow NIH’s activities very closely find it a challenge to understand how the agency allocates its resources.

The issue revolves around a belief held by patient groups that there are too few opportunities for them to provide “regular and meaningful input” into the NIH decisionmaking process, in order to make the case for increased funding for particular research areas. Some of these groups say certain institutes do quite well seeking input from patient-advocacy organizations but, “on the whole, NIH has been, in their minds, lacking in having opportunities that are open and meaningful for them to have input. That sends them straight to you [legislators and their staffs] quite often because they do feel frustrated, and so the only place they can turn, and they have every right to turn, is to Congress to say we really feel that we’re not getting our fair share.”

Weinberg reported some NIH responses to these publicly expressed concerns. In the fall of 1998, Dr. Varmus announced creation of a Council of Public Representatives (COPR), a body that meets regularly to learn in greater detail of the agency’s activities and to provide the agency feedback on those activities. In September 1997, NIH published a booklet entitled, *Setting Research Priorities at the National Institutes of Health*. The booklet describes the criteria upon which NIH sets

its research priorities and allocates funding. The IOM committee and patient-advocacy groups regarded the booklet as a step forward, but Weinberg said the next step NIH must take is explaining how it actually applies these criteria in its decisionmaking processes. Weinberg added: “Patient groups also feel that NIH needs to improve the way it does some of the data collection and analyses it is conducting to inform the decisionmaking process.”

Weinberg said that, in anticipation of a large infusion of funds to NIH over several years, patient-care groups favor exploring research opportunities across institutes and diseases. These activities should be mounted in ways that make the NIH director more accountable for progress. She added: “I am sure most of you know that the institutes are fairly independent The NIH director should be able to receive, which is not necessarily the case now, from the directors of all the institutes and the centers multi-year, strategic plans including budget scenarios in a standard format on an annual basis.” With more standardized processes of planning, budgeting and reporting, Weinberg asserted, patient-advocacy organizations and the broader public could grasp more readily how wisely NIH spends its resources and, as a consequence, hold the agency to greater account for its decisions.

A Response by NIH

Dr. Lana Skirboll of NIH was the invited first respondent to the views expressed by the three panelists. She began by offering her own explanation of why the agency has enjoyed such strong bipartisan political support. “It’s a reflection of both NIH’s history of supporting research that leads to improvements in health, and I will grant you it’s also a reflection of public fear. We are all afraid of ill health – morbidity and mortality. And as the population ages, society, both from financial and social perspectives, needs to be concerned as we baby-boomers age. We need to pay attention to research issues that can improve both the quality and length of life, and the extent to which chronic illness even affects society from a financial point of view.”

At a later point in the program, Stephens offered what he said was an equally important third reason why NIH enjoys such strong bipartisan political support: “There is both a perception and a reality of NIH as an enormously well-managed, overall, government enterprise I reviewed my first NIH budget in 1975. I’ve reviewed budgets every year since then. I did three cabinet departments, 20 related agencies. NIH is the only government entity that I know of where the best people in the United States, the most highly trained, most successful, most competitive, want to work for the government because NIH is the pinnacle of biomedical research in the world.”

After asserting that NIH engaged in a great deal of planning in relation to “that wonderful, generous increase from Congress” of \$2 billion for FY1999, Skirboll conceded that, “we may not have been as clear as we might have been in the past about the internal dialogues” that occurred within the agency on how that money should be spent. In response to concerns expressed about this perceived lack of clarity, particularly as those concerns were set out by the Institute of Medicine’s monograph, Skirboll said the NIH institutes and centers intend to publish material in

the spring of 2000 which will set out how each entity plans for its research agenda, and what that agenda will be for the next few years. Skirboll noted that the documents would not be standardized. She added: "At the moment, we have asked each institute to use their own culture and scientific and patient advocacy groups to develop a planning document that they think reflects where their institute needs to go."

Later in her remarks and in answers to questions, Skirboll also mentioned several other methods NIH has started using to make its management and planning processes more open. She described planning forums convened to develop research agendas that cut across institutes in which "each institute comes forward with new initiatives for the budget year [currently FY2002]," followed by "an overarching meeting in which we even bring outside reviewers in to look at which of those initiatives are cross-cutting, which are most important for NIH in toto." NIH will use the new Council of Public Representatives as a conduit to receive feedback on how to make the research priority-setting process better understood. In addition, "one of the innovations we're trying in some arenas of clinical research is inviting patient advocates into peer review" (that is, inviting them to participate in the system through which the agency ranks grant applications). Skirboll also described how NIH has applied the requirements of the Government Performance and Results Act (GPRA) to help improve its capacity to plan. In its budget submission to Congress, NIH laid out both administrative goals and research goals, together with performance targets for which the agency expects to be held accountable.

In response to Greenberg's assertion that Congress is neglecting its oversight responsibilities regarding NIH, Skirboll said that total oversight has increased along with the growth in NIH's budget. She indicated that the "exponential increase in funding" has been matched by oversight from Congress, the General Accounting Office, and the HHS Inspector General. She added: "We expect that, we welcome that, we think we manage our money well; we think the American public and frankly Congress' support is a reflection of the good product we put out."

Questions from the Audience

At this point, the floor was opened to queries from members of the audience. One congressional staff member, a former researcher, noted that Mike Stephens urged NIH to "think out of the box" when it is deciding how to allocate its larger appropriation. "One possible way to think out of the box is to fund researchers, not research. The Howard Hughes Medical Institute does a lot of that." He described the difficulties and uncertainties of a career in research, particularly for physicians, and spoke of knowing people who had to leave research careers because they failed to obtain funding for one grant cycle. He noted that young investigators who observe such situations with their older mentors may be discouraged from pursuing research careers. He asserted that the most productive researchers spend more time writing grants than working in the laboratory, and that the system encourages "incrementalism," where each grant "just makes the little tiniest advance because you have to get funded to keep your job."

In response, Stephens said he was quite open to exploring new ways to pursue research opportunities, but he also asserted that “there is very broad agreement that one of the great strengths of the American system of funding life sciences vis-à-vis the Japanese, the Europeans, and others is that NIH does not tell people what research needs to be done. But they allow this to come from the science community The engine of discovery is driven by individual scientists looking at problems and coming up with a thousand different approaches of which some work and some do not.”

Skirboll also responded to the staff member, saying that NIH has increased support of three new “K mechanism” grants (the NIH classification number for research career programs) that address the needs of the individual clinical researcher. She described two of them as awards for clinical investigators “to buy time that’s otherwise being used up for patient care, where they have to account for every hour in the delivery of treatment, so they can’t mentor young investigators. So we’re buying salary time” both for mid-career mentors and for young investigators who want to do clinical research. The third program is the Clinical Research Curriculum Award, “a didactic program aimed at institutions to help them formally train clinical researchers in basic research design and statistics.”

Another congressional staff member voiced a critical opinion of NIH’s funding processes before she posed a question to Stephens. She said the major research enterprises – “the Johns Hopkins and the Duke Universities of the world,” are the major recipients of NIH funding “only because they [hire former NIH people] who are able to get the grants because the grant process is so complex that you need these people who understand the process to actually get the grants.” She asked Stephens whether he believed that Congress could improve the value of the public’s investment in biomedical research by pursuing alternatives to simply building onto NIH or, as she put it, “looking into the internal workings of NIH, and doing an inside-out modernization of NIH, if that’s necessary.” (Interestingly, this question anticipated remarks by Dr. Varmus in his final meeting with his Advisory Committee to the Director in December 1999, at which he proposed just such an in-depth study. Saying that the proliferation of institutes and centers was making NIH more and more difficult to manage, he suggested that Congress should commission a study of the organizational structure of NIH and the role of the director, perhaps from the National Academy of Sciences.)

Stephens responded by disagreeing with her that “you have to have worked at NIH and come through the NIH system in order to be a successful grantor. My major activity now is working for a group called the Federation of American Societies for Experimental Biology, which is 66,000 Ph.D-M.D. scientists who account for about 52 % of all research project grants at NIH. I would say that probably 10% of those, 15 % of those that are under age 60, worked at NIH. It is true that going through an NIH research training experience was sort of a credential of advancement in science for many years, and those trainees then went off and established these megacenters. But I don’t think that is true anymore.” Stephens did say he thought NIH could reach out more effectively to teach researchers how to apply for the agency’s grant support.

A final question from the audience pointed out that in the quest to develop new drugs and medical devices to treat disease, NIH only has responsibility for the initial steps in the process. The staff member said that the patient groups that visit his office

seem to focus only on NIH and not on the equally important roles of the Food and Drug Administration (FDA) and the private sector. He said, “At the end of the day, the drug companies are going to think about what’s going to be most profitable, but how do we make it more motivating for them to do things that will bring in more new and advanced treatment?” Weinberg commented in response that many of the patient groups have become active in FDA-related issues. She noted, however, that “what hasn’t happened, and what the Council is attempting to take the lead on, is putting all those pieces together so that we talk about the research enterprise as a total.” She also indicated that there is not total agreement within the Council, among the patient groups versus the pharmaceutical and biotechnology company members, on some of the issues that the industry groups feel are important, such as price controls on drugs and tax breaks for research and development costs. Skirboll gave an “example of NIH being much more aggressive recently in trying to work with industry” as she described an extremely popular conference on biomarkers. The pharmaceutical industry wants to make the clinical trial system for testing new drugs more efficient by improving the science of clinical markers for drug efficacy, and wants NIH to partner with FDA on the subject. Skirboll also noted, however, that the single biggest barrier to working with industry is disputes over intellectual property rights. She concluded, “These are complex issues not easily solved, and ones that we are trying to set up some model systems as we partner with specific industries on initiatives. They are ones that we all need to turn our attention to if we are going to reap the benefits of what is about to come out of all this basic research.”

Conclusion

There is no question NIH is an esteemed institution that subsidizes biomedical research that is of value to people the world over. But that does not remove from its vast agenda continuing controversy over how the agency should allocate its ever increasing appropriation. As a public agency supported through tax revenues, NIH will, in all likelihood, face even greater scrutiny in the future. While NIH may not always be enthusiastic about these increased demands for more information and greater oversight, it seems to clearly recognize that they come with the territory in a wide open democracy.