Public Advocacy and Allocation of Federal Funds for Biomedical Research

REBECCA DRESSER

Washington University, St. Louis

EACH YEAR, CONGRESS HEARS PLEAS FOR MORE funding to support research on a multitude of human afflictions. Requests for funds come from advocates representing individuals with specific health problems and populations with particular health concerns. The House and Senate subcommittees responsible for authorizing and appropriating funds for the National Institutes of Health (NIH) receive most of the requests, but, as the following statements illustrate, advocates present their research funding needs to other committees as well:

I am here to speak to you about prostate cancer that took my husband Congressman Dean Gallo ... from me, his family, friends, you his colleagues and his constituents...

I am now working at The Cancer Institute of New Jersey as a Fundraising Associate/Advocate. My main goal ... is the creation of the Dean and Betty Gallo Prostate Cancer Institute...

We ... seek an allocation of \$5 million to facilitate the establishment of this important resource for programs, research and education and awareness of prostate cancer.

Statement of Betty Gallo, Hearing on Appropriations before the Subcommittee on Veterans Administration—Housing and Urban Development, April 22, 1998

The Milbank Quarterly, Vol. 77, No. 2, 1999
© 1999 Milbank Memorial Fund. Published by Blackwell Publishers,
350 Main Street, Malden, MA 02148, USA, and 108 Cowley Road,
Oxford OX4 1JF, UK.

There are many important diseases which deserve attention and funding under the Department of Defense Budget, but we want to make Congress particularly aware of the bone diseases which frequently do not get the attention they deserve. . . .

Bone fractures are a major problem for the military population. We need research in determining approaches to making these fractures less common. This is a problem for both sexes, but it is particularly important for women.

Statement of Sandra Raymond on behalf of the National Coalition for Osteoporosis and Related Bone Diseases, House Appropriations Subcommittee on National Security, March 19, 1998

To help meet urgent health research needs, I would like to ask the distinguished chairman to keep in mind the importance of adequate funding for the National Institutes of Health for Alzheimer's Research. . . .

Funding has slowed in recent years. To help meet the urgent research needs, I urge the committee to approve an additional \$100 million in the Fiscal Year 1999 budget for the National Institutes of Health for Alzheimer's research.

Statement of Senator Charles Grassley, Appropriations Hearing, Senate Subcommittee on Labor, Health and Human Services, March 24, 1998

Many are excited to hear about President Clinton's new research agenda for the new millenia [sic], which is intended to double the budget in the National Institutes of Health to find the cure for cancer. The health research industry, particularly Universities and State Governments, are the winners and the Indian people are the losers who seldom realize any positive gain from this effort.

Statement of Buford Rolin, Chairman, Indian Health Board, Hearing on Unmet Indian Health Needs, Senate Committee on Indian Affairs, May 21, 1998

In 1998, at the urging of Congress and the Institute of Medicine (IOM), the NIH adopted a plan for soliciting more comments from the public on the allocation of federal biomedical research funds. NIH officials and

public advocates will confront difficult ethical and policy issues as they seek to increase public participation. For example, if single-disease interest groups are given a significant role in determining how funds are allocated, those with the resources and expertise to mount the most effective lobbying campaigns could obtain substantial amounts for research, thereby diminishing the allocations of others. At a broader level, public advocates for biomedical research could persuade federal officials to reduce funding for other types of scientific research and social programs in order to channel more money into biomedical research.

I examine here these and other ethical and policy implications of creating a formal role for public advocacy in the allocation of biomedical research funds. My analysis is based primarily on a review of recent congressional hearings and other government documents that pertain to NIH funding allocation decisions, and on an examination of the relevant science policy literature. I also draw on my own experience as a public member of the National Institute on Deafness and Other Communication Disorders Advisory Council.

I conclude that more public participation in research allocation decisions is warranted as long as three conditions are met: First, the opportunities to participate should be fairly distributed among interest groups and should be designed to elicit meaningful commentary from them. Second, the advocates should look beyond their ordinary constituencies and adopt a more inclusive perspective on how best to serve the public. Third, greater public participation will not resolve the major ethical issues underlying the funding allocation debate. With the proper assistance from officials, however, members of the public could contribute to more defensible allocation decisions. To encourage a rational and informed deliberative process, NIH officials should prepare materials that will assist public participants to understand and debate the values and trade-offs that are at stake in these decisions.

The Emergence of Research Funding Advocacy

Congress is accustomed to being lobbied by interest groups for biomedical research funds. During the 1960s and 1970s, advocacy groups endorsed the establishment of new NIH institutes and centers that were focused on specific diseases and conditions. In the past, advocacy groups

generally avoided open competition among themselves. Although they might work behind the scenes for favorable treatment, they most commonly adopted the public strategy of endorsing general increases in federal support for biomedical research, on the assumption that each interest group would benefit if more tax dollars were committed to the research endeavor (Marshall 1997; Institute of Medicine 1998).

By the mid-1990s, however, a new trend had emerged. Although some interest groups still pursued general increases in NIH funding, in the belief that "the whole of the nation's medical research effort is greater than the sum of its individual parts" (Ad Hoc Group for Medical Research Funding 1997), certain disease-specific interest groups adopted a narrower approach. Citing the success of HIV/AIDS and breast cancer lobbyists in obtaining high levels of targeted research funds, groups representing persons with Parkinson's disease, prostate cancer, diabetes, and other conditions explicitly requested congressionally mandated ("earmarked") funds to support their areas of interest (Johnson 1998). According to a representative of the Juvenile Diabetes Foundation International, "There was a time when we were very good citizens and really went up to the Hill with one message—overall [funding] for NIH. But it becomes hard as you see other disease areas advance far beyond where we are" (Marshall 1997). Advocates for persons with diabetes, heart disease, and Parkinson's disease also charged that these conditions were being unfairly neglected in the research funding process (Marshall 1997). In 1996, for example, a reporter wrote that the American Heart Association was "complaining publicly that research into heart disease and stroke is being shortchanged compared with research dollars spent per death for AIDS, diabetes, and cancer" (Agnew 1996).

Congress responded to this "threat of siblicide" (Marshall 1997) in a variety of ways. Some members adopted the approach of Senator Grassley and supported earmarked funds for conditions that affect families, friends, and constituents (Kaiser 1996; Lauerman 1998). Representatives Ernest Istook and George Nethercutt voiced agreement with interest groups that were questioning whether more than their "fair share" of the biomedical research budget was being directed to certain conditions, particularly HIV/AIDS. These representatives also challenged NIH officials to explain and defend their funding allocation decisions (U.S. House 1997). Representative John Porter (R-Ill.), chair of the NIH House appropriations subcommittee, expressed dismay at the divisiveness he saw emerging. He contended that "the worst thing that could

ever happen for biomedical research would be amendments on the floor of the Senate or House that start moving money from one place to another in response to interest groups" (Agnew 1996).

By 1997, congressional concern over increasing competition among disease interest groups led to House and Senate hearings on biomedical research priority setting (Dresser 1998). At the hearings, Harold Varbus, director of the NIH, described, and sought to justify, NIH funding allocation criteria and mechanisms. However, Myrl Weinberg, representing a consortium of patient advocacy and other health-related groups, testified that the increased pressure on Congress by disease-specific interest groups resulted from their sense of being excluded from the NIH priority-setting process (U.S. Senate 1997).

After the hearings, Congress asked the IOM to supply further information and guidance. In a 1998 report, the IOM Committee on the NIH Research Priority-Setting Process issued several recommendations addressing public participation in decisions about allocation of funds.

Over the years, the NIH has adopted mechanisms to elicit public participation. Public members comprise one-third of most of the institutes' advisory councils (which furnish guidance on general policy and funding priorities). Various NIH offices, conferences, and committees offer additional opportunities for public involvement. However, the IOM committee members found that consumers and advocates were not sufficiently represented in existing NIH groups. They also observed that because current avenues to public participation were not "user friendly," interested groups and individuals were not always able to take full advantage of them. To correct this inadequacy, the IOM committee proposed that the NIH director and each institute maintain public liaison offices to elicit comments from, and respond to, individuals and groups seeking to influence research funding. The committee also recommended that the NIH establish a "Director's Council of Public Representatives" to help the agency accomplish the following goals:

1. increase public understanding of how the NIH establishes its priorities and encourage public participation in that process
2. increase and diversify public membership on existing NIH advisory committees
3. consider the health needs of special populations, such as specific ethnic groups and traditionally underserved persons (Institute of Medicine 1998)

In sum, the committee concluded that the proper response to the concerns raised by interest group advocacy was to establish more formal, systematic mechanisms for soliciting public opinion on NIH funding allocation decisions. The committee noted that legislators want to “be able to refer people to an identifiable process at NIH and be assured . . . that the inputs of all interests have been fairly and appropriately taken into account in program and resource allocation decision making.” However, the committee did not supply a detailed description of how such a process would work.

Existing Allocation Criteria

To evaluate the issues raised by increased public participation, it is necessary to examine how research funds are currently allocated. In simplified form, the process unfolds as follows: Every year, the President, after consulting with NIH officials, submits an NIH budget request to Congress. Congress typically makes some adjustments to the request and awards a specific amount to each NIH institute and center. NIH staff then decide how this sum will be distributed (National Institutes of Health 1997).

Allocation of NIH research funds is influenced by the initial congressional decisions to create institutes and centers devoted to specific health areas, for each unit must receive some funding. When they direct funds to particular areas and projects, senators and representatives are advancing a wide array of personal and constituent interests, including those of patient advocacy organizations and other public interest groups devoted to health concerns. Members of Congress who are opposed to earmarking believe that the NIH officials who oversee the institutes and centers are more qualified to determine how much funding should be channeled to each research area.

In response to questions raised by members of Congress and by advocates, NIH officials prepared a report entitled “Setting Research Priorities at the National Institutes of Health” (National Institutes of Health 1997). The report itemized the general criteria for awarding NIH funds:

1. “public health need, as judged by the incidence, severity, and cost of specific disorders”

2. the scientific merit of individual research proposals
3. the potential for scientific advancement in different fields
4. the desire to maintain some research in a broad range of areas
“because we cannot predict discoveries or anticipate the opportunities fresh discoveries will produce”
5. the infrastructure and training programs that are needed to support current and future research

The first criterion, public health needs, incorporates the following considerations:

- the number of people who have a particular disease
- the number of deaths caused by a disease
- the degree of disability produced by a disease
- the degree to which a disease cuts short a normal, productive, comfortable lifetime
- the economic and social costs of a disease
- the need to act rapidly to control the spread of a disease

According to NIH officials, the unpredictability of science makes it difficult to estimate accurately how much research funding the NIH devotes to different health problems. Basic science and certain clinical studies produce unexpected findings that may prove helpful in areas that fall outside the designated research topics. Studies that were designed to explore one condition may ultimately yield knowledge relevant to a completely different health concern. Moreover, two or more NIH institutes and centers often contribute funds to basic and applied studies with implications for a variety of conditions. The diversity of allocation criteria and the unpredictability of science led the authors of the NIH report to assert: “There is no ‘right’ amount of money, percentage of the budget, or number of projects for any disease.”

The IOM Committee on the NIH Research Priority-Setting Process reviewed the NIH allocation criteria and labeled them “reasonable and appropriate.” Yet the IOM group also concluded that NIH decisions could be presented more clearly and systematically to ensure that they are comprehensible to outsiders. The committee stated its objections as follows: “[The] NIH should be able to show that it has considered data on health burdens and costs in a systematic fashion, in addition to considering scientific opportunity, cost differences among certain kinds

of research, non-NIH investments in health-related research, . . . and other relevant factors.” Further, the committee claimed that the NIH could improve its ability to tie research funds to specific conditions. By expending more effort on evaluating the possible applications of basic science research, the NIH could provide Congress and the public with more accurate calculations of spending by disease. Improvements in these two areas would reduce the “black box” appearance of NIH priority setting, which in turn would give Congress and the public more insight into the strengths and weaknesses of NIH funding standards.

Ethical and Policy Implications of Public Advocacy

It is hardly surprising that persons affected by disease and injury seek to increase government funding for research on their particular conditions. In this sense, research advocacy is simply an instance of the interest-group politics shaping U.S. policy in all areas. Proponents of interest-group advocacy contend that it can produce certain tangible benefits:

1. a research budget consistent with public preferences and interests
2. better-informed government officials and scientists
3. physical and psychological benefits for affected and at-risk persons.

Interest-group advocates and their congressional allies claim that NIH officials and scientists have too much authority over decisions on allocation of public funds. The challengers are dissatisfied with the traditional deference that has been accorded NIH decision makers. As Representative Istook told the NIH director, “The jealousy with which you try to say the purse strings should be under the control of persons who know better than the rest of us is an attitude that is not healthy in our society, and we are here trying to talk about public health”(U.S. House 1997).

The NIH critics suspect that scientists’ intellectual curiosity and their desire for professional advancement have produced allocation choices that diverge from public preferences and the common good. The challengers also suspect that scientists have catered to certain interest groups, neglecting equally deserving, but less effective, advocates and their

constituents. In their view, interest-group advocacy already affects NIH allocation; the problem is that every group does not have the same access to NIH decision makers. Indeed, HIV/AIDS and women's health advocates would contend that their vigorous lobbying efforts were necessary to correct a prior lack of access that had resulted in inadequate research funding for conditions affecting their constituents (Murphy 1991; Dresser 1992). From this perspective, creating a more open, inclusive framework for public participation in NIH decision making could yield allocation decisions more consistent with the needs and values of U.S. taxpayers (Sarewitz 1997).

Besides producing a more democratic research budget, interest-group advocacy augments the information used to generate federal funding decisions. Advocacy often brings government officials face to face with the human costs of an affliction. A graphic account of living with a serious illness or caring for an injured family member conveys the personal knowledge that is missing from the facts and figures Congress and NIH officials ordinarily rely on when they decide which programs to fund. Interest-group advocacy also exposes NIH scientists to the human side of their work. Besides strengthening their commitment to achieving progress in a particular area, communication with patients and families can inspire scientists "to pursue opportunities that might not have been obvious without some knowledge of the experience of disease" (*Journal of NIH Research* 1997).

Moreover, although money does not in itself ensure scientific progress, financial resources are a necessary foundation for it. Funds enable scientists to conduct exploratory research, obtain training in previously neglected areas, share ideas, and formulate new avenues for investigation. Advocates seeking increased research funding believe that "with enough money, [scientific] potential can be created in almost any area" (Marshall 1997).

Persons affected by disease can gain additional benefits from advocacy at the federal level. Besides producing more money for federal research and eventual improvements in treatment and prevention, interest-group advocacy can raise public awareness of a condition. This can result in higher rates of state and local funding and of charitable giving by the general public, wealthy individuals, private foundations, and industry. Lobbying for research funds also can produce psychological benefits for patients and families who are seeking an alternative to passive acceptance of their situations (Anglin 1997).

However, interest-group advocacy also raises ethical concerns because it can skew research budgets in several ways:

1. by exacerbating social inequalities
2. by supporting poor-quality studies on favored conditions
3. by diminishing the welfare of persons affected by disease and of the larger society

Interest-group advocacy for research funds raises issues of distributive justice. Such advocacy could promote inequitable allocation of limited public research dollars because the advocacy groups with the most effective presentations and the clearest access to officials can gain disproportionate advantage over others that are less savvy and not as well financed. For example, one explanation offered for the lack of research on improving end-of-life care is that “dying patients do not form an energetic, ongoing constituency to advocate for more research, [nor do] their survivors, [who] tend to be exhausted and grieving” (Institute of Medicine 1997).

The trouble with this situation is that the most effective advocates do not always represent the health conditions that would be assigned a high priority if they were judged by criteria such as level of burden or costs imposed on affected individuals and society, or potential for scientific progress. Funds set aside for research on one health problem are often diverted from funds once allocated to the study of other conditions (Institute of Medicine 1998). If interest-group advocacy becomes a major force in the appropriation of research funding, biomedical research could increasingly be directed toward conditions affecting mainly the rich and powerful. In the meantime, little progress would be made toward ameliorating conditions that inflict suffering, disability, and death on disadvantaged persons and populations (Sarewitz 1997).

Moreover, a decline in knowledge and in health improvements could result if decisions to fund research on particular conditions are based on intense lobbying pressures instead of on their inherent possibilities for scientific advancement or the quality of the proposed studies (National Institutes of Health 1997). Spending money on poorly designed projects would not only be wasteful; it would also conflict with public preferences and interests (Resnik 1998).

A narrow approach to interest-group advocacy also could prove short sighted and politically unwise. If more organizations abandon the quest

for increased general NIH funding in favor of the competitive approach, their individual voices could be drowned out in the general cacophony. One observer stated: "Competition between disease-interest groups has always diluted the research community's ability to 'move the needle' when it comes to funding" (Stapleton 1998). Moreover, interest-group lobbying could actually endanger long-term funding for research on specific conditions. For example, the current complaints about disproportionate allocations have contributed to an "AIDS backlash" in Congress and other venues. Representatives of disease groups, reporters, and others have attacked the idea of AIDS being an exceptional illness that merits extraordinary research attention (Murphy 1991; Stolberg 1997).

Research advocacy also consumes interest-group resources. According to the IOM committee, "Interest groups have often produced extensive data sets on disease-specific research spending" to make the case that they receive inadequate funding (Institute of Medicine 1998). More groups reportedly are hiring professionals to lobby for research funding (Institute of Medicine 1998). When advocacy organizations spend substantial amounts on lobbying for research funding rather than for improvements in health care delivery, housing, and other social needs, they may compromise the interests of their constituents. When organizations focus on increasing funds for research on one condition, they ignore the fact that many of their constituents could be vulnerable to harm from other diseases or injuries as well. Finally, vigorous campaigns to promote biomedical research funding could foster unrealistic hope for a "miracle cure" among affected persons and their families (Callahan 1998). As another IOM committee noted, "Advocacy groups that champion research to prevent or cure various diseases [often are deflected] from vigorously and publicly promoting palliative research to help those who will, inevitably, die of these causes" (Institute of Medicine 1997).

From a broader perspective, interest-group advocacy could contribute to distortions in the overall federal budget. High-profile interest-group advocacy led Congress to approve significant levels of financial support for biomedical research during the 1990s while permitting declines in support for other areas of research and development (Johnson 1998). This situation raises questions about the wisdom of investing in biomedical research "at the expense of other vital scientific areas, such as physics, chemistry, energy, and environmental sciences that may be just as worthy as medical research even though they lack its political appeal" (*New York Times* 1998). Others fear that an overemphasis on biomedical

research funding could eventually impede advances in biomedical science. As Varmus and others have pointed out, fields like engineering, mathematics, and physics often produce ideas that later prove relevant to biomedical research (*Science & Government Report* 1998; Lawler 1998).

Finally, federal tax dollars are needed to support health care, housing, education, social welfare, and other programs, many of which assist individuals with health problems. Interest-group advocacy could encourage government officials to shift funds from these programs to biomedical research, which currently enjoys strong bipartisan support. Buford Rolin's testimony, quoted above, conveys his fear that health programs for Native Americans will suffer as a result of congressional generosity to the NIH. Shifting funds from social programs to biomedical research might even conflict with the interests of persons affected by illness and injury because their access to other forms of assistance might be reduced.

Three Ethical and Policy Challenges

Interest-group advocacy to redirect and increase federal funding for biomedical research presents complex ethical and policy challenges. To promote the positive elements of public participation and minimize its negative implications, NIH officials and public advocates should address three areas: First, in a representative democracy, advocacy groups are entitled to present their views on the appropriate use of tax dollars to fund biomedical research. Because, as a practical matter, interest-group advocacy is likely to persist even in the event that it is excluded from the government's formal decision-making process, the best alternative is to construct fair and accessible mechanisms for interest-group advocacy. The IOM committee recommendations for improving and expanding NIH mechanisms for public participation are intended to achieve this goal.

The IOM committee urged NIH officials to create a new public advisory committee and to make better use of public membership opportunities on existing advisory and other committees. The IOM group maintained that existing NIH mechanisms fail to elicit the desired level and range of public opinion. To improve the situation, the committee proposed that the NIH encourage the participation of more advocates

for disease-specific interest groups and special populations and reach out to groups that have traditionally lacked access to agency decision makers.

Additional actions are required to achieve the goal of deeper and broader public representation. The IOM committee stated that public representatives should be chosen according to a process that is "fair and perceived to be fair." Huge numbers of disease-specific interest groups have a stake in NIH participation. They are joined by organizations representing women, African Americans, children, and other populations with interests in certain types of research. To implement the IOM recommendations, officials and the advocacy community must devise an acceptable selection process. Participants must also be willing to hear and respect the views each will bring to the table.

The NIH has taken some steps in this direction. In September 1998, the director held a meeting at which participants "selected to represent a broad spectrum of NIH's constituencies" discussed the potential activities of the Director's Council of Public Representatives. Based on this discussion, the agency issued a call for nominations to the Council (National Institutes of Health 1998a). To be eligible, members of the public must have "special interests" in the NIH, "for example, as a patient or family member of a patient; a health care professional; a member of a patient advocacy group; [or] an individual who works as a volunteer in the health field..." The Council's members will be diverse in terms of geography, age, gender, and culture and will represent a range of interest groups that includes the medically underserved. Members will initially be appointed to one-, two-, or three-year terms; after that, appointments will be for three years. Their mission will be to "help bring to the NIH the concerns and interests of the many external publics that have a stake in the agency's activities, programs, policies, and research." They will also work to enhance public participation in other agency activities, improve public understanding of the NIH, and raise "important matters of public interest" for discussion.

The speed and general outlines of the NIH response suggest a good faith effort to implement the IOM recommendations. The director's choice of Council members, initially and over time, will demonstrate his degree of willingness to institute a fair selection process. Fair selection procedures alone are not enough to gain fuller and wider public participation, however. The NIH must also give the Council and other public participants a meaningful voice in funding allocation decisions. A review of the past three decades reveals many instances of government

officials' adopting mechanisms for public participation in order to deflect complaints that experts have too much control over science and technology policy. Often "the input of public representatives is accepted if it reflects the values that exist within the accepted range of consensus, but is rapidly dismissed as irrelevant or disruptive if it tries to question the boundaries of this consensus" (Dickson 1988).

The success of HIV/AIDS advocates in influencing research policy suggests that mutual education is the key to effective public participation. Steven Epstein (1996) describes how lay advocates gained credibility with scientists and officials by learning enough about the relevant science and medicine to challenge established research approaches. Similarly, advocates who are invited to present their ideas on biomedical research funding allocation will gain more influence if they educate themselves about the NIH, the nature of biomedical research, and the scientific, policy, and ethical considerations pertaining to the allocation process.

In turn, NIH officials and the scientists whose work the agency supports must also have open minds. As Richard Sclove (1995) observes, injecting democracy into science and technology policy sometimes requires "a conscious effort to cultivate mutual respect and trust among collaborating lay people and technical experts." In the HIV/AIDS setting, powerful officials and researchers came to appreciate and value the contributions of informed lay advocates. Similarly, NIH officials and scientists must recognize that public participants possess knowledge that is critical to making choices about the allocation of funds.

The second area that should be addressed is the appropriate role for public participants who seek to influence funding allocation. Public advocates appointed to the Director's Council should put aside their ordinary focus on specific health problems or populations. Because opportunities for participation on this committee are limited, it would be unfair for the chosen few to concentrate only on advancing the interests of their particular constituents. The NIH has signaled its agreement with this view by stating that Council members must "agree to subordinate disease-specific or program-specific interests to broader, cross-cutting matters of importance to the NIH and its commitment to public representation" (National Institutes of Health 1998a). Advocates appointed to other NIH advisory groups also have a special obligation to consider the interests of all persons affected by the health conditions that are relevant to their advisory groups.

Moreover, all interest-group advocates seeking to influence research allocation decisions should thoughtfully evaluate the ethical and policy responsibilities associated with their role. When they lobby Congress and the NIH to obtain the maximum possible research support for their own constituents, they overlook the compelling needs of persons with other health problems. Advocates should also consider the possibility that competition among interest groups hampers overall research fund-raising efforts. Finally, they should recognize that the single-interest approach could be detrimental to their constituents' interests, for their constituents could benefit from federal support for biomedical and scientific research in other areas and from social programs that provide services like health care and housing assistance.

The third area requiring action is the creation of a framework for deliberation on funding allocation. Public participants will face the complex ethical trade-offs that are inherent in the allocation of biomedical research funds. In their report on priority setting, NIH officials claimed that there is "no right amount of money, percentage of the budget, or percentage of projects for any disease." This claim is only partly correct, however. The "right" amount or percentage is a function of values choices regarding which conditions are more important, and thus deserve more research attention. The "right" amount also is a function of scientific and practical judgments about the areas of research that offer realistic expectations of progress. The hope is that increased public participation can yield an expanded, and perhaps altered, perspective on these values and their relative importance.

Public participants, however, will need tools to cope with the complicated issues and facts pertaining to their charge. To fulfill this need, NIH officials should undertake four tasks: First, officials should follow the IOM committee's recommendation to explain the application of NIH priority-setting criteria. As Dan Callahan (1999) points out, the NIH document on research priorities fails to indicate whether one criterion is more important than another; nor does it demonstrate how to reconcile conflicts among the criteria or how to balance radically dissimilar concepts, such as infrastructure needs and public health needs. NIH officials should also prepare examples of different research initiatives that have been considered and outline the reasons certain programs were preferred over others. Second, the NIH should follow the IOM committee's recommendations to generate better data on spending by disease and to collect data on biomedical research support by other

entities. These data will clarify the current NIH priorities and reveal the extent to which certain areas of research receive support from other sources. Third, the NIH should prepare case studies presenting different possibilities for research funding. These materials should delineate the ethical, scientific, and practical dimensions of each case. Public participants could then use these cases as a basis for their discussions of the potential trade-offs in funding one research initiative rather than another. The case studies could be supplemented with background materials on the potential clinical value of basic science studies in biology and in other fields. Finally, the NIH should give participants information on other federal programs that serve individuals with health problems. Materials of this sort will enable public participants to clarify their priorities and the trade-offs they are willing to make in order to achieve them.

Conclusion

The increase in interest-group advocacy for federal research funds is one manifestation of the public's desire to play a greater role in shaping biomedical research policy. Interest-group advocacy has contributed to changes in the federal policies that govern access to unapproved medications (Epstein 1996) and control the age, gender, and ethnicity of subjects in clinical research (Weijer 1996; National Institutes of Health 1998b). Greater public participation in decisions on allocation of biomedical research funds could lead to changes in this area as well. Interest-group advocacy has pushed NIH officials to explain and publicize their decision-making criteria and procedures. Now officials and advocates face additional challenges as they attempt to integrate greater public input with scientific expertise and the government's responsibility to promote the common good.

References

- Ad Hoc Group for Medical Research Funding. 1997. *About the Ad Hoc Group for Medical Research Funding*. [Http://www.aamc.org/research/adhocgp/about.htm](http://www.aamc.org/research/adhocgp/about.htm). Washington, D.C.

- Agnew, B. 1996. Two in a Row: A Whopping Budget Boost for NIH. *Journal of NIH Research* 8(November):19–20.
- Anglin, M.K. 1997. Working from the Inside Out: Implications of Breast Cancer Activism for Biomedical Policies and Practices. *Social Science and Medicine* 44:1403–15.
- Callahan, D. 1998. *False Hopes: Why America's Quest for Perfect Health is a Recipe for Failure*. New York: Simon and Schuster.
- . 1999. Shaping Biomedical Research Priorities: The Case of the National Institutes of Health. *Health Policy Analysis*. (Forthcoming.)
- Dickson, D. 1988. *The New Politics of Science*. Chicago: University of Chicago Press.
- Dresser, R. 1992. Wanted: Single White Male for Medical Research. *Hastings Center Report* 22(1):24–9.
- . 1998. Setting Priorities for Science Support. *Hastings Center Report* 28(3):21–3.
- Epstein, S. 1996. *Impure Science: AIDS, Activism, and the Politics of Knowledge*. Berkeley: University of California Press.
- Institute of Medicine. 1997. Committee on Care at the End of Life. *Approaching Death: Improving Care at the End of Life*. Washington, D.C.: National Academy Press.
- . 1998. Committee on the NIH Research Priority-Setting Process. *Scientific Opportunities and Public Needs: Improving Priority Setting at the National Institutes of Health*. Washington, D.C.: National Academy Press.
- Johnson, J. 1998. *Disease Funding and NIH Priority Setting*. Report 97-917 (March 26). Washington, D.C.: Congressional Research Service.
- Journal of NIH Research*. 1997. Funding Priorities, Peer Review: An Interview with Harold Varmus. Vol. 9(August):21–5.
- Kaiser, J. 1996. NIH's Harvest of Special Projects. *Science* 274:167.
- Lauerman, J.F. 1998. Turning the Tables. *Harvard Magazine* (July–August):26–8.
- Lawler, A. 1998. Physician-Turned-Politician Seeks Middle Ground. *Science* 281:635–6.
- Marshall, E. 1997. Lobbyists Seek to Reslice NIH's Pie. *Science* 276:344–6.
- Murphy, T. 1991. No Time for an AIDS Backlash. *Hastings Center Report* 21(5):7–11.
- National Institutes of Health. 1997. *Setting Research Priorities at the National Institutes of Health*. NIH pub. no. 97-4265. Bethesda, Md.: NIH Working Group on Priority Setting.

- . 1998a. *NIH Policy on the Inclusion of Children as Participants in Research Involving Human Subjects*. [Http://www.nih.gov/grants/guide/notice-files/not98-024.html](http://www.nih.gov/grants/guide/notice-files/not98-024.html). Bethesda, Md.
- . 1998b. *Call for Nominations for Membership on the NIH Director's Council of Public Representatives*. Bethesda, Md.: Office of the Director.
- New York Times. 1998. Medical Research Funding. (January 6):A20.
- Resnik, D.B. 1998. *The Ethics of Science: An Introduction*. New York: Routledge.
- Sarewitz, D. 1997. Social Change and Science Policy. *Issues in Science and Technology* (summer):29–32.
- Science & Government Report. 1998. Q & A: NIH Director Varmus on Support for All Sciences. (May):2–4.
- Sclove, R. 1995. *Democracy and Technology*. New York: Guilford.
- Stapleton, S. 1998. Lobby for Labs: Biomed Research Campaigning for Funding Increase. *AMA News* (February 9):1, 29.
- Stolberg, S. 1997. New Challenge to Idea That "AIDS is Special." *New York Times* (November 12):A1, A18.
- U.S. House. 1997. *Appropriations for the National Institutes of Health*. House Appropriations Committee, Subcommittee on Labor, Health and Human Services, and Education. 105th Congress. First session. (June 10). Washington, D.C.
- U.S. Senate. 1997. *Biomedical Health Priorities: Who Should Decide?* Senate Labor and Human Resources Committee, Subcommittee on Public Health and Safety. 105th Congress. First session. (May 1). Washington, D.C.
- Weijer, C. 1996. Evolving Ethical Issues in Selection of Subjects for Clinical Research. *Cambridge Quarterly of Healthcare Ethics* 5:334–45.

Address correspondence to: Rebecca Dresser, JD, Washington University School of Law, One Brookings Drive, Campus Box 1120, St. Louis, MO 63130-4899 (e-mail: dresser@wulaw.wustl.edu).