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Disease Funding and NIH Priority Setting

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Summary

Research at the National Institutes of Health (NIH) has strong political support, but a heated debate rages over the allocation of NIH funds among various diseases. NIH contends that decisions are made based on scientific opportunity while critics of the NIH process charge that spending often follows current politics and political correctness.

The ongoing effort to balance the federal budget has reduced overall federal research and development (R&D) funding. "Between FY1995 and FY1997 total civilian R&D declined 4.1% in real terms."[1] Although overall federal R&D spending is down over the past several years, one sector of the federal R&D effort has been protected. Biomedical research funding at the National Institutes of Health (NIH) has nearly doubled over the last decade. The NIH budget has "stayed about 25% ahead of inflation as measured by the Biomedical Research and Development Price Index, a special inflation index developed for NIH to measure changes in the prices of items and services required for its R&D activities."[2] The NIH FY1998 budget of $13.65 billion represents over one third of federal civilian spending for R&D.

Clearly, NIH has received strong bipartisan support from Congress. Advocates for expanding biomedical research are none the less concerned that continuing pressure to reduce the deficit will eventually result in NIH receiving only small increases or even the flat or declining budgets experienced by the other federal R&D agencies. While funding for NIH has been relatively generous, about 75% of the research grant proposals submitted to NIH do not receive funding, leaving many scientists to find support elsewhere. This situation has resulted in many young investigators leaving research for other careers. In addition, researchers in academic health centers (AHCs--the complex of a medical school, one or more teaching hospitals and other health professions schools) are concerned over the fiscal side effects of managed care health insurance. Managed care has eroded biomedical research dollars by taking away the patient care income of the

[1] CRS Report 97-126, *Federal R&D Funding Trends in Five Agencies: NSF, NASA, NIST, DOE (Civilian) and NOAA*, coordinated by Michael E. Davey.

[2] CRS Report 95-96, *The National Institutes of Health: An Overview*, by Pamela W. Smith.

centers. "AHCs have missions in teaching, research, and patient care. Patient care revenues subsidize teaching and research to a large degree. Care in the highly specialized AHCs is more expensive than in other settings, and the centers are increasingly finding that they cannot attract patients who are covered by managed care insurance."[3]

In this atmosphere of impending budgetary constraint, health advocacy groups find themselves increasingly at odds with one another, lobbying congressional offices and NIH for more research on their specific disease of interest rather than for health research in general. Such lobbying efforts appear to have succeeded in gaining large increases for certain diseases (e.g., AIDS and breast cancer) at the expense of others. When budget resources are limited and not growing, adding funds to one area almost inevitably limits funds to another. This more than likely has added to the intensity of the already fierce lobbying for disease-specific earmarks in the NIH budget.

Those active in the lobbying effort include groups which support research on AIDS, heart disease, breast cancer, prostate cancer, Parkinson's disease, Alzheimer's disease, diabetes, and others. Advocacy groups have generated a vast and sometimes confusing array of charts and tables comparing disease-specific research funding with statistics on morbidity, mortality, and health care costs in order to advance the cause of their disease over others that receive what they perceive as "too much funding." Table 1 displays the currently available HHS budget information for a number of the diseases that are receiving increased lobbying attention. Funding information is incomplete for all the diseases listed, with the AIDS budget information being the most comprehensive.

In the July 25, 1997 House report (H.Rept.105-205) on H.R. 2264 (Departments of Labor, HHS, and Education, and Related Agencies Appropriations Bill, 1998) the House Appropriations committee asks for extensive disease funding information from HHS (p.130) on the following diseases: acute respiratory distress syndrome, arthritis, cancer, chronic obstructive pulmonary disease, depression, diabetes, heart disease, HIV/AIDS, kidney disease, liver disease, pneumonia and influenza, septicemia, and stroke. The committee requested a functional breakdown of each disease total showing the amount spent on research, prevention/education, and treatment as well as details on spending in both Medicaid and Medicare, approximations for spending by insurance in the private sector, and private expenditures by individuals afflicted with these diseases. The report was submitted to the committee on February 23, 1998.

In response to the continuing controversy over disease funding, several congressional hearings were held in the spring and summer of 1997 addressing how research priorities are set at NIH. The first was held on May 1, 1997, in preparation for work on NIH reauthorization legislation. The hearing entitled "Biomedical Research Priorities: Who Should Decide?" was held by the Senate Labor and Human Resources Subcommittee on Public Health and Safety. The Senate subcommittee heard from NIH Director Dr. Harold Varmus as well as representatives of the Institute of Medicine, academia, scientific societies, industry and advocacy groups. The June 10, 1997, hearing, "NIH Priority-Setting," held by the House Appropriations Labor-HHS Subcommittee

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[3] CRS Report 94-870, *Health Care Reform: Where Does Medical Research Fit In?* By Pamela W. Smith.

Table 1. HHS Agency Funding of Selected Diseases

($ in thousands)

	FY1997	FY1998	FY1999
AIDS:			
National Institutes of Health	$1,501,073	$1,607,053	$1,730,796
Centers for Disease Control	616,790	634,266	641,779
Agency for Health Care Policy Research	4,193	1,100	1,500
Indian Health Services	3,503	3,540	3,540
Health Care Financing Administration	3,100,000	3,300,000	3,600,000
Office of the Secretary	2,827	2,844	3,972
Health Resources Services Adm.	1,001,248	1,155,196	1,320,196
Substance Abuse & Mental Health Adm.	63,857	70,125	77,826
Food & Drug Administration	72,745	72,745	72,745
Total, AIDS	**$6,366,236**	**$6,846,869**	**$7,452,354**
Cancer:			
National Institutes of Health	2,760,698	2,941,163	3,231,804
Centers for Disease Control	185,138	192,873	196,500
Agency for Health Care Policy Research	3,945	4,400	5,600
Health Care Financing Administration	16,699,000	18,502,000	20,380,000
Office of the Secretary	2,250	1,250	1,250
Total, Cancer	**$19,651,031**	**$21,641,686**	**$23,814,904**
Diabetes:			
National Institutes of Health	319,539	373,215	414,856
Centers for Disease Control	26,277	48,977	53,788
Agency for Health Care Policy Research	2,135	2,000	2,100
Indian Health Services	41,001	41,001	41,001
Health Care Financing Administration	13,269,000	14,611,000	16,278,000
Total, Diabetes	**$13,657,952**	**$15,076,193**	**$16,789,745**
Alzheimer's Disease:			
National Institutes of Health	329,272	349,198	374,700
Centers for Disease Control	40	40	40
Agency for Health Care Policy Research	322	600	1,000
Health Care Financing Administration	339,000	362,000	387,000
Administration on Aging	7,099	7,299	7,494
Total, Alzheimer's Disease	**$698,733**	**$744,137**	**$770,234**
Heart Disease:			
National Institutes of Health	1,005,264	1,080,373	Not Available
Centers for Disease Control	5,792	14,233	
Agency for Health Care Policy Research	8,392	4,983	
Health Care Financing Administration	37,579,000	41,508,000	
Office of the Secretary		100	
Total, Heart Disease	**$38,598,448**	**$42,607,689**	
Parkinson's Disease:			
National Institutes of Health	89,000	98,000	107,000

Sources: HHS Budget Office, "HHS and National Cost for Thirteen Diseases and Conditions," Feb. 20, 1998; HHS Budget Office, FY1999 Moyer Cross-Cutting Material, Feb. 1998; and, NIH Budget Office, "NIH Research Initiatives/Programs of Interest," Mar. 1998.

Table 2: Ten Leading Causes of Death, United States, 1995

Rank	Cause of Death	Number of Deaths	Death Rate per 100,000	% of Total Deaths
	All causes	2,312,132	880.0	100.0
1	Heart diseases	737,563	280.7	31.9
2	Cancer	538,455	204.9	23.3
3	Cerebrovascular diseases	157,991	60.1	6.8
4	Chronic obstructive lung diseases	102,899	38.2	4.5
5	Accidents	93,320	35.5	4.0
6	Pneumonia & influenza	82,923	31.6	3.6
7	Diabetes	59,254	22.6	2.6
8	HIV infection	43,115	16.4	1.9
9	Suicide	31,284	11.9	1.4
10	Chronic liver disease & cirrhosis	25,222	9.6	1.1

Source: Monthly Vital Statistics Report, v. 45, no. 11(S)2, June 12, 1997. p. 23.

had NIH Director Varmus as the sole witness. At both hearings Dr. Varmus gave the same testimony on the process and principles used in making research budget decisions at NIH.

Dr. Varmus put forth a multifaceted case against the practice of "earmarking," a term often used for specifying increased emphasis on particular programs in report language on appropriations bills. He pointed out that 90% of the NIH budget is already committed to multi-year grant recipients (who receive four years of support, on average) as well as the infrastructure of the Institutes and Centers. New scientific opportunities and earmarks compete for the remaining 10% of the NIH budget. Dr. Varmus emphasized that the ability to plan for scientific discovery is limited. “Science attempts to discover what is unknown. It’s inherently unpredictable.” In his view, history has shown that when research activity is guided by an individual scientist’s imagination, there are many benefits for public health. Much of the basic research supported by NIH is difficult to classify as part of a research plan against a specific disease. Yet, he observes, it is precisely this type of fundamental research (e.g., on protein structure or cell death) which forms the foundation for practical advances against any number of specific diseases.

When Congress and the public inquire about how the NIH budget is spent, it is often in terms of how much money is spent for a specific disease. Dr. Varmus pointed out that although the coding of funds by disease category may be useful for some purposes, it is inherently imprecise. Using a series of charts, Dr. Varmus showed that there is a four-fold difference between the number of grants directly related to Parkinson’s disease, and the much larger number of grants (e.g., on nerve cell biology and nerve degeneration) that are related to the fundamental understanding and treating of this disease. “So, numbers are suspect. They are suspect in part because important discoveries also often come from totally unexpected directions that might not be represented on this chart. For this reason, there is no right amount of money or any right number of projects for any disease.”

Dr. Varmus pointed out that shifting scientific priorities in order to stimulate disease breakthroughs requires more than just budgetary adjustments. “Scientific work is not a commodity we can purchase....We need to have investigators who can do the work.” To attract new investigators to a promising area of research, NIH often holds workshops

highlighting under-explored medical and scientific areas and advertizes funding for research to resolve new public health challenges. However, it takes time to attract and train a novice researcher in a new field and for new treatments to be discovered. Congress and the public often become frustrated with the pace of medical research. Dr. Varmus testified that congressional directives to reroute dollars to specific diseases is not the best solution to these frustrations. "Many fields of medical research deserve increased financial support and could move faster with more funds. Because resources are limited, pushing funds vigorously in one direction limits the flow in others. This situation compels us to consider especially carefully whether proposals to enhance investments in certain fields are justified by new scientific opportunities, [or] by public health issues." In his opinion, existing methods for resource allocation at NIH are preferable to congressional directives. Dr. Varmus urged advocacy groups to adopt methods to heighten the interest of scientists in the public benefits of their research.

One source described the outcome of the May 1 Senate hearing as follows: "The biomedical establishment fired away at the growing boldness of disease lobbies pursuing bigger shares of the budget of the NIH. From the reaction of their Senatorial overseers, it appears that the bio-mandarins won on debating points, arguing that health research is more likely to be impeded than advanced by political edicts to focus on particular diseases. But the pressures from the so-called disease-of-the-month clubs are mounting, and it's by no means certain that the line can be held by NIH, which traditionally would rather grow than fight."[4] In September 1997 NIH released a report entitled *Setting Research Priorities at the NIH*. The 17-page report is very similar to the NIH Director's hearing testimony and describes in greater detail how NIH management determines the research allocations for each fiscal year.

Critics of the NIH funding process believe that it fails to focus on those diseases which cause the highest morbidity and mortality in the United States. In their view, NIH spending often follows current politics and political correctness, responding to media attention focused on diseases such as AIDS and breast cancer. For example, the Parkinson's Action Network claims that in 1994 NIH spent more than $1,000 per affected person on AIDS research, $93 on heart disease and $26 on Parkinson's. The American Heart Association contends that while overall NIH funding has increased 36% in constant dollars since 1986, the heart program at NIH has declined 5.5%. The Juvenile Diabetes Foundation asserts that funding at NIH's National Institute of Diabetes and Digestive and Kidney Diseases has increased only 53% over a ten-year period when overall NIH funding increased 97%. The critics argue that the NIH budget of $13 billion is taxpayer dollars, and the Congress has a constitutional duty to exercise oversight, influence direction, and demand accountability. Population statistics are commonly used when allocating funds for education, housing, transportation or other programs, and relevant numbers, such as health care costs, disease incidence and prevalence, should also be considered when making health research funding decisions.

Many representatives of disease advocacy groups claim that in the past they pushed solely for increased overall funding for basic research at NIH. However, after years of perceived neglect they are now intent on following the example of the AIDS and breast

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[4] Greenberg, Daniel S. NIH Defends Research Priorities at Senate Hearing. *Science & Government Report*, May 15, 1997, pp 3-4.

cancer lobbyists and are promoting increases for their area of interest alone. These groups believe increased lobbying of Congress and NIH is the only way they will receive more equitable funding and attention for their cause. Parkinson's disease groups have pushed for legislation which expands and coordinates such research at NIH (H.R. 1398, The Parkinson's Research Act of 1997; and H.R. 1260/S. 535, The Morris K. Udall Parkinson's Research Act of 1997). Similarly, advocates for diabetes research have lobbied for legislation that mandates a diabetes research plan at NIH (H.R. 1315, The Diabetes Research Amendments of 1997).

The Senate Subcommittee on Public Health and Safety held a second hearing on July 24, 1997, on coordination of NIH research conducted in multiple NIH institutes which also touched on the subject of disease-specific targeting and priority setting. Like the May hearing, the July hearing was held in preparation for the upcoming work on NIH reauthorization legislation in the second session of the 105th Congress.

Research priority setting was also addressed during the NIH appropriations hearings in April 1997. An amendment (S. Amendment 1075) to S. 1061 (FY1998 Labor/HHS Appropriations bill) directs that a comprehensive study on NIH research priority setting be conducted by the Institute of Medicine (IOM) and completed in the spring of 1998. The provision requires that IOM make recommendations for improvements in NIH research funding policies and processes and for any necessary congressional action. The first meeting of the IOM panel that is working on this study was held on March 6, 1998.

As it has for the past several years, the House Appropriations Committee included report language stating that in order "to enhance NIH's flexibility to allocate funding, the committee has attempted to minimize the amount of direction provided in the report accompanying the bill. For example, there are no directives to fund particular research mechanisms, such as centers or requests for applications, or specific amounts of funding for particular diseases." The House Appropriations Committee report on the FY1998 Labor/HHS Appropriations bill (H.Rept. 105-205) provides the following discussion on priority setting in research funding allocations:

> The factors NIH uses to decide how to allocate research funding among disease areas have been a topic of great concern to the Committee and the outside community. The elements the NIH leadership considers when allocating funds have been discussed repeatedly in the Committee's hearings this year, including a special hearing on the subject. It is clear there is discomfort among some Members that NIH is not thought to be paying sufficient attention to the societal and economic factors related to a disease, such as the number of citizens afflicted with a disease, the infectious nature of a disease, the number of cases and deaths associated with a particular disease, the Federal and other monetary costs of treating a disease, the years of productive life lost due to a particular disease, and trends in the way diseases affect minority populations and different geographic areas. The Committee understands these concerns and sympathizes with the disease advocacy groups who raise them, realizing that their dissatisfaction with NIH decisions is grounded in a deep commitment to bettering the lives of the patients whom they represent. The Committee does not presume to judge which of these criteria should take precedence or carry the greatest weight in individual funding decisions, but urges NIH to consider the full array of relevant criteria as it constructs its research portfolio.