Funding for biomedical research and clinical trials in the United States is under attack from cost-containment efforts. Late last year the White House Office of Management and Budget (OMB) instructed the National Institutes of Health (NIH) to "forward-fund" 646 of its 6,526 grants approved for 1985, which essentially cuts off funds for over 1,500 new and competing grants.

On another front, preliminary data shows that the diagnosis-related group (DRG) reimbursement system could make clinical trials financially unsound for hospitals.

Violates intent of Congress

Last year Congress approved a bill, signed by President Ronald Reagan, that raised the base of new and competing NIH grants from 5,000 to 6,500 per year. The OMB later devised a way to lower that base, however, by having the 1985 budget pay for the second and third years of 646 grants—money that was expected from the 1986 and 1987 budgets.

As David Stockman, OMB director, explained to the House Appropriations Committee in early February, "as we sat down in the fall for housecleaning ... we found we could not start NIH grants at 6,500 and keep it there."

"There is no doubt that the OMB directive violates the clear intent of Congress," reported Science. Senator Lowell Weicker, Jr. (R-CT), chairman of the Senate Labor, Health and Human Services, and Education Appropriations Subcommittee, requested an opinion from the U.S. General Accounting Office, which stated on March 18 that, under U.S. law, any portion of an agency’s appropriation that is not spent during the fiscal year must be returned to the U.S. Treasury.

The GAO decision is legally binding, but the Reagan Administration could still challenge it in court.

In response to complaints from research groups, Representative Henry Waxman (D-CA) introduced on February 6 a bill (H.J.R.136), which has over 100 cosponsors, directing that funds be appropriated to enable the NIH to award the original 6,500 grants. A similar bill (S.J.89) was introduced by Senator Edward M. Kennedy (D-MA), with 30 cosponsors, on March 20.

Although the original funding plan may prevail, "disbanding a research team and attempting to regroup it later is not the way in which science progresses," noted Daniel E. Kosshland, Jr., PhD, editor of Science.

Research—unnecessary frill?

Two scientists from the Association of Community Cancer Centers (ACCC) warn that under the DRG system, research that costs more than conventional care may be considered an unnecessary frill.

In the Journal of the American Medical Association (JAMA), John Yarbro, MD, PhD, and Lee Mortenson, MS, reported recent trends in the cost of clinical trials (1).

In one New Jersey hospital, where 25 of the 715 cancer patient admissions in the last half of 1982 were treated in clinical trials, monetary loss per patient in trials was $1,057, compared to $35 per admission for other cancer patients. In an Oklahoma City hospital, lymphoma patients in a treatment protocol group generated charges of $830 more per admission than patients in a nonprotocol group. In a Long Beach, CA, institution, a study of five DRG categories showed that, on average, each protocol admission cost $2,450 more than a nonprotocol case.

According to the authors, "hospitals may well be faced in the near future with a substantial financial disincentive to participate in clinical trials."

Add another DRG

Dr. Yarbro and Mr. Mortenson propose that Medicare create another DRG for research that would reimburse treatment charges in NIH-approved clinical trials.

The ACCC has proposed the research DRG to the U.S. Department of Health and Human Services (HHS). Carolyne K. Davis, PhD, director of HHS's Health Care Financing Administration (HCFA), which controls Medicare, replied that HCFA cannot accept the proposal.

In a JAMA editorial, Dr. Davis explained that Medicare was never intended to cover research costs (2). Medicare can only reimburse established, not experimental, procedures. These regulations were unaffected by the DRG system, she added.

"Under prospective payment, hospitals will likely trim away only those programs that they cannot manage efficiently, or in which they have no overriding interest. We believe that hospitals with clinical cancer research programs will choose to continue their valuable research, but not within the structure of a clinical research DRG," said Dr. Davis.

Dr. Yarbro told Newsline, however, that he and other investigators will still pursue the research DRG through Congressional legislation.

References

(1) Yarbro JW, Mortenson LE: The need for diagnosis-related group 471, protection for clinical research. JAMA 253:684-685, 1985
(2) Davis CK: The impact of prospective payment on clinical research. JAMA 253:686-687, 1985
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