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NIH Emerges From Republican Revolution With Another Increase In Appropriations

The appropriations bill approved by Congress earlier this week will give NIH $12.747 billion, an increase of $819.6 million over the current budget.

The bill gives NCI an appropriation of $2.382 billion, $134.5 million above the 1996 level.

Considering that last year's appropriation was similarly favorable for NIH, an argument can be made that the federal biomedical research effort has emerged unscathed from the appropriations battlefields of the Republican Revolution.

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In Brief

NIDR, NCI Award $2.8 Million In Grants For Oral Cancer Research Centers

FOUR ORAL CANCER research centers were funded by the National Institute of Dental Research. The center grants, which total $2.8 million this year and will provide additional funds over the following four years, were awarded to the University of Alabama at Birmingham; University of California, San Francisco, University of Chicago and Northwestern University, and M.D. Anderson Cancer Center. All but the Anderson grant are co-funded by NCI. The centers will conduct basic research, clinical investigations and rehabilitation. . . . **THEODORE KRONTIRIS** was appointed chairman and senior scientist of the newly formed Division of Molecular Medicine at Beckman Research Institute, City of Hope National Medical Center. Krontiris will design and lead research on genetic susceptibility to cancer. Krontiris was founding director, Graduate Program in Genetics, Sackler Graduate School and professor of Medicine, at Tufts University School of Medicine in Boston. . . . **CLEVELAND CLINIC** Foundation broke ground Sept. 27 for a 410,000-square-foot complex to consolidate research and education components. The complex also will house a medical library. . . **CALIFORNIA DIVISION,** American Cancer Society, announced the election of its 1996-97 Board of Directors. The new board members are: chairman, **David Bonfilio**, vice president, Union Bank of California; president, **Lisa Bailey**, surgical oncologist; secretary, **Thomas Fogel**, radiation oncologist; treasurer, **Judy Crockett**, a 20-year ACS volunteer; chair-elect, **Helen Mendel**, president of Helen Mendel and Associates; and president-elect, **Alan Henderson**, professor, California State University, Long Beach. The California Division is the largest ACS division.

For Second Year, NIH Emerges With Increase From Congress

(Continued from page 1)

In fact, as Congress slashed the budgets of other domestic programs in the 1997 fiscal year, NIH received an increase of 6.9 percent. NCI's increase was 6 percent. Last year's increases were 5.7 percent for NIH and just under 5 percent for NCI (**The Cancer Letter**, Jan. 12).

The conference bill passed this week followed the House recommendations, giving NCI and NIH substantially more money than either the Senate or the Administration recommended (**The Cancer Letter**, Sept. 20).

—NCI funding under the conference bill is only $3.2 million below the House bill. The final bill is $56.9 million above the appropriation recommended by the Senate and $101.6 above the Administration's request.

—For NIH as a whole, the conference bill matches the numbers proposed by the House Appropriations Committee. The funding level in the conference bill is $332.6 million above the Senate proposal and $370.6 million above the Administration's request.

These numbers are a clear indication that in the latest appropriations process, Rep. John Porter (R-IL), chairman of the Labor, HHS & Education Appropriations Subcommittee, had prevailed in securing and defending his funding targets for NIH.

"Once again, Congress has staked out NIH as one of the most important programs for federal commitment," said Marguerite Donoghue, executive director of the National Coalition for Cancer Research. "This level of support two years in a row is phenomenal."

"Rep. Porter has clearly taken the lead in shaping this, with strong support of Sens. [Arlen] Specter and [Mark] Hatfield," Donoghue said to **The Cancer Letter.** Specter (R-PA) is chairman of the Senate Labor, HHS & Education Appropriations Subcommittee. Hatfield (R-OR) is chairman of the Senate Appropriations Committee.

Several observers said these numbers have a down side as well: the increases are likely to make NIH a target for the constituencies of other programs in the Labor, HHS & Education bill during the upcoming appropriations process.

DOD Cancer Programs Expanded

In a related developments, the conference bill funding the Department of Defense included at least $106.5 million for breast cancer research, $45 million for prostate cancer research, and $7.5 million for ovarian cancer research.

The DOD's entire cancer portfolio will take weeks to evaluate, as government agencies, lobbyists and consumer groups comb through the budgets of each of the services.

The new funds appropriated through DOD will be spent over two years.

Prostate cancer funding includes a new item: $38 million for peer reviewed prostate cancer research. Also included was a $7 million appropriation for prostate cancer research at Walter Reed Medical Center.

With the bill safely out of Congress and on the way to the White House, CaP CURE, a group funded by the financier Michael Milken, confirmed one of the worst-kept secrets in cancer politics on Capitol Hill: that the foundation's lobbyists had secured the peer-reviewed program for prostate cancer research at DOD.

"We can take credit for that," Michael Reese, a spokesman for CaP CURE said to **The Cancer Letter**. "We have always regarded prostate cancer as a first step.

"We have been able to establish working relationships with other cancer organizations, and we

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plan to launch a more concerted and coordinated effort with them next year," Reese said.

The proposal for the DOD program first appeared as a $93 million spending authority in the Senate DOD bill, where it was introduced by Hatfield (**The Cancer Letter**, July 12). Spending authority does not have to represent a real commitment of funds. The House appropriations bill on DOD did not include a corresponding provision.

However, in conference, the $93-million spending authority became $38 million in real cash.

The breast cancer appropriation includes $100 million for peer reviewed research, $3.5 million for an advanced cancer detection center, and $3 million for computer-aided diagnostic research. Additional funds, about $25 million, would support breast cancer information and outreach programs in the military.

Now, DOD will have the mission of setting up a peer review program for prostate cancer research. The military will be likely to receive some help from the National Prostate Cancer Coalition, an emerging advocacy group.

The coalition has sponsored a meeting of scientists and patients to determine scientific opportunities and spending priorities in prostate cancer. The meeting will take place Oct. 12-13 at M.D. Anderson Cancer Center.

In a related development, the conference bill gave DOD $7.5 million for studies in prevention of ovarian cancer. The appropriation first emerged in conference. The Administration, the House and the Senate did not seek these funds.

NIH Clinical Center

In the bill that provides funding for NIH, the conferees concurred with the House recommendation to provide $90 million to cover the first year's construction costs for the NIH clinical center. The Senate bill provided $70 million for the project.

The Administration sought to fund the entire $310 million construction project in fiscal 1997.

The final bill comes closest to the Administration proposal for the funding of AIDS research at NIH.

Funding for AIDS is included in the appropriations for each Institute. However, the Institutes are obligated to transfer their AIDS money to the Office of AIDS Research, which would then disburse it to the Institutes. This mechanism is intended to allow OAR to implement its research plans.

Altogether, $1.502 billion will be allocated to AIDS research throughout NIH.

The conferees appeared to be especially generous to the NIH Office of Alternative Medicine, giving it a 50 percent boost over the Senate recommendation.

Also, the bill provided funds for an evaluation of the status of NIH research into cancer among minorities and the underserved. The evaluation will be conducted by the Institute of Medicine.

According to the report of the Senate Appropriations Committee, IOM will cover areas that include "the relative share of NIH resources allocated to cancer disproportionately afflicting minorities and the medically underserved, minority scientists' involvement in decision making on research priorities, and whether NIH has a sufficient overview of cancer among minorities to prioritize a research agenda dealing with multiple, contributing factors such as genetics, environment, behavioral factors... and access to health care."

"Our hope is that the IOM findings will reveal new research directions and opportunities, and will help overcome research shortcomings of earlier years, when minority scientists were only on the fringes of US medicine," said Lovell Jones, co-founder of the Intercultural Cancer Council and director of experimental gynecology and endocrinology at M.D. Anderson Cancer Center.

The appropriations for NIH institutes follow:

National Heart, Lung, and Blood Institute: $1.433 billion, a $78.1 million increase from FY 1996.

National Institute of Dental Research: $196 million, a $13.1 million increase.

National Institute of Diabetes and Digestive and Kidney Diseases: $816 million, a $45.4 million increase.

National Institute of Neurological Disorders and Stroke: $726.7 million, a $45.8 million increase.

National Institute of Allergy and Infectious Disease: $1.257 billion, an $88.8 million increase.

National Institute of General Medical Sciences: $998.5 million, a $51.6 million increase.

National Institute of Child Health and Human Development: $631.7 million, a $37.2 million increase.

National Eye Institute: $332.7 million, an $18.8 million increase.

National Institute of Environmental Health Sciences: $308.8 million, a $20.4 million increase.

National Institute on Aging: $486 million, a $32.5 million increase.

National Institute of Arthritis and Musculoskeletal and Skin Diseases: $257.1 million, a $14.5 million increase.

National Institute on Deafness and Other Communication Disorders: $188.4 million, a $12 million increase.

National Institute of Nursing Research: $59.7 million, a $3.9 million increase.

National Institute on Alcohol Abuse and Alcoholism: $212 million, a $13.6 million increase.

National Institute on Drug Abuse: $489.4 million, a $31.3 million increase.

National Institute on Mental Health: $701.6 million, a $41.1 million increase.

National Center for Research Resources: $415.1 million, a $24.8 million increase.

National Center for Human Genome Research: $189.7 million, a $19.9 million increase.

Fogerty International Center: $26.6 million, a $1.3 million increase.

National Library of Medicine: $151.1 million, a $1.3 million increase.

Office of the Director: $287.2 million, a $27.1 million increase.

Buildings and facilities: $200 million, a $53.8 million increase.

Foundations

Lasker Awards Note Work In Nitric Oxide, HIB Vaccine

The 1996 Albert Lasker Basic Medical Research Award was shared by Robert Furchgott and Ferid Murad for discoveries that led to the fundamental understanding of the role of nitric oxide in health and disease.

Furchgott is a researcher with the State University of New York Science Center in Brooklyn. Murad is a scientist with Molecular Geriatrics Corp. of Lake Bluff, IL.

The Clinical Medical Research Award was shared by four researchers: Porter Anderson of the University of Rochester, David Smith of the David H. Smith Foundation, and John Robbins and Rachel Schneerson of the National Institute of Child Health and Human Development. The four scientists received the award for their roles in the development of polysaccharide-protein conjugate vaccine for *Hemophilus influenzae* type b.

A new prize, the Albert Lasker Award for Special Achievement in Medical Science, went to Paul Zamecnik, of the Worcester Foundation for Biomedical Research, for work that led to the deciphering of the genetic code.

Professional Societies

ONS To Step Up Research On Health Care Economics

The Oncology Nursing Society plans to conduct research studies to document an apparent trend among hospitals to encourage "deskilling" of nurses, the society's president said.

Kathi Mooney, ONS president, said there is anecdotal evidence that hospitals, in attempts to save money, are shifting direct patient care to unlicensed personnel, moving oncology nurses to supervisory roles.

This, an other economic changes at hospitals, threaten to turn back the gains oncology nurses have made over the past two decades to improve the care of cancer patients, Mooney said to the National Cancer Advisory Board.

"We believe these changes will potentially result in diminished care rather than improved care, and so initiatives will be forthcoming from the society to address these concerns," Mooney said to the board at its Sept. 10 meeting. "We will step up our advocacy about the nurse's role and contribution to quality cancer care."

ONS, begun in 1975, has 24,000 members in 192 state and local chapters in the U.S.

In a recent reorganization, the society revised its strategic goals to emphasis research and advocacy on socioeconomic issues that affect cancer patient care and cancer nursing, Mooney said.

Following is the excerpted text of Mooney's remarks:

The mission of ONS has been revised to more prominently acknowledge our commitment to achieving quality cancer care, as well as promoting the role of the nurse in cancer care.

Since June, the Board of Directors has formulated four strategic goals to focus the society's initiatives for next three years:

The first goal is to achieve quality cancer care. We are now particularly concerned with the potential

impact of changes through health care reform and managed care that appear to threaten the quality of care that we have achieved.

We are concerned about issues of access to care, access to screening and early detection, risk reduction, access to contemporary treatments, including the opportunity to participate in clinical trials.

We are also concerned with areas nurses feel are central to nursing care: the safe delivery of treatment; safe delivery of clinical trials; access to supportive care, including symptom management; psychosocial support; survivor needs, including long term followup and rehabilitation; as well as quality end of life care.

Finally, we are concerned about who will provide that care. Access to oncology expertise is broader that simply access to oncology physicians. It also must include access to nursing and other health care providers.

The impact of the health care changes we have seen so far include the potential de-skilling of nursing, taking the registered nurse away from direct patient care in the hospital or in the clinic and using the cost saving, unlicensed assistive personnel to provide the direct line care to those with cancer and their families. The nurse then provides the supervisory role.

In addition, we have seen an increased emphasis on nurses as generalists, rather than promoting specialization in nursing. Nurses have found that they now must care for a variety of patients with multiple medical conditions, rather than being able to maintain their focus in cancer.

In the hospital setting, designated oncology units have been combined with other areas, encouraging nurses to lose their identity and focus as cancer specialists.

We believe these changes will potentially result in diminished care rather than improved care, and so initiatives will be forthcoming from the society to address these concerns. We will step up our advocacy about the nurse's role and contribution to quality cancer care.

We also will continue our emphasis on clinical issues of particular concern to nurses. I wanted to highlight two examples of these initiatives we have in progress:

The first relates to cancer pain relief. Recently, we held the National Summit on Cancer Pain Control, involving 46 organizations in looking at a way to more directly coordinate and collaborate on issues of unrelieved cancer pain. I'm proud to say the idea for this summit came in 1994 from an ONS State-of-the-Knowledge conference. We joined with the American Cancer Society and the American Alliance of Cancer Pain Initiatives to bring this summit forward. It was successful and we have made some commitments on initiatives that will help move us further along in this unresolved area.

The second initiative involves the problem of cancer fatigue, which is the most common symptom reported by cancer patients and yet has received little attention. Our FIRE project, Fatigue Initiative Through Research and Education, is funded by Ortho Biotech and is a five-year multifaceted project that includes professional education, public awareness, and research initiatives. We currently have three $50,000 developmental research grants, and next year we will fund three more of these plus a larger budgeted $500,000 study.

The research awards support multi-institutional studies that examine bio-behavioral mechanisms of cancer related to fatigue, and/or tests novel interventions aimed at improving clinical management of cancer fatigue.

Nursing Practice, Contribution To Care

The second strategic goal is to promote evidence-based oncology nursing practice. Over the past 12 years our foundation has supported a very active small grants program. To date we have funded 137 studies and awarded $1.2 million in grants and fellowships.

Nurse scientists have made significant contributions to knowledge in such areas as cancer pain, fatigue, quality of life, survivorship, the impact of cancer on the family and the cost of that, adherence to screening and early detection. A number of these programs of research have been funded by NCI.

Our new initiative this year will be to promote clinical outcomes research. The data is not yet available on what and who contributes to quality as well as fiscally responsible care, and it is essential that we roll up our sleeves and get in there and address this issue.

The third goal is to assure the registered nurse's contribution to cancer care. The society will support activities that prepare nurses for their new roles in cancer care. A particularly urgent initiative that we will be moving forward on will be the preparation of

nurses to participate in the clinical arena of cancer genetic testing.

Finally, the fourth goal reflects attention to organizational vitality. I think there is not an organization out there that has not escaped the word "redesign." We are currently implementing a new structure. The purpose of the new structure is to increase our efficiency and responsiveness, and recognize we are largely a volunteer organization and we must utilize volunteer time in an effective way for volunteers.

The radical thing we did was to disband all our committees, except our nominating committee, and we are trying to live through that. We are trying to use ad hoc work groups to accomplish our work.

More importantly for this forum is our interest to increase our collaborative relationships with outside partners, including NCI, to achieve strategic initiatives of joint interest.

NIH Funding

RFA Available

RFA OD-97-001

Title: **Informed Consent In Research Involving Human Participants**

Application Receipt Date: March 11

NCI, the National Center for Human Genome Research, the National Institute on Aging, the National Institute on Alcohol Abuse and Alcoholism, the National Institute of Allergy and Infectious Diseases, the National Institute of Child Health and Human Development, the National Institute on Drug Abuse, the National Institute of Mental Health, the National Institute of Nursing Research, the Department of Energy, and the Department of Veterans Affairs invite applications for a three year research grant program to stimulate investigations into the informed consent process in scientific research. There is an ethical as well as a legal responsibility to ensure that individuals both consent to and understand their participation in research. For consent to participate in research to be truly informed, the information imparted to potential participants must clearly explain study procedures, distinguish research from treatment, realistically portray the potential for medical or other benefits from participation and the nature of potential benefit, carefully explain the potential for discomfort, toxicity, or other risks that may accompany participation in the research, and clearly delineate the participant's rights and limits regarding confidentiality and withdrawal from participation.

The sponsoring organizations are jointly issuing this RFA because voluntary informed consent is the defining aspect of interactions between researchers and participants, and is integral to the conduct of the scientific research funded by all of these organizations. One of the goals of this RFA is to bring together perspectives of these different agencies, since their different research foci reflect a diversity of issues relating to informed consent. Of course, many facets of understanding the informed consent process are shared, and hence a combined effort is

efficient for the agencies and scientists alike.

Little empirical work exists to document the degree of understanding achieved by research participants regarding: (1) identity of the sponsoring federal agency or agencies; (2) purposes for which the research is being conducted; (3) comprehension of a study's methods and procedures; (4) relative risks and benefits (including financial) of deciding to consent or refuse participation; (5) confidentiality and any exceptions to confidentiality; (6) the implications of withdrawal from a study and (7) planned and other possible use of the data. Such data should be useful in designing informed consent procedures that are readily comprehended by prospective participants and impart all critical information. The goal of the present initiative is to develop and test alternative strategies for obtaining informed consent in diverse populations and determine optimal ways to obtain informed consent for research participation.

This RFA will use the NIH individual research project grant (R01) mechanism of support. However, specific application instructions have been modified to reflect "Modular Grant" and "Just-in-Time" procedures being used under an NIH Reinvention Initiative.

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