THE CANCER LETTER

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Charles Moertel, Mayo Clinic Investigator, Advocate Of Rigorous Trials, Dead At 66

Charles Moertel, a pioneer in medical oncology and a passionate advocate of rigor in clinical research and fair pricing of oncology drugs, died of cancer last week.

Moertel, 66, was a professor of oncology at Mayo Clinic. He was diagnosed with Hodgkin's disease last fall, but continued to see patients until two months before his death, friends and associates said.

In the final days of his life, Moertel worked on manuscripts based on his research.

"My last conversation with him was in part about fishing, and in

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In Brief

New Presidents Take Office At ONS, ONCC, ARRS; Baird Wins Awards; New VP In Houston

LINDA JOHNSON took office as president of the Oncology Nursing Society, succeeding Sandra Lee Schafer. Johnson is the nursing staff development specialist at Arthur James Cancer Hospital in Columbus, OH. President-elect is **Mary Garlick Baroni**, Imunex Corp. Other officers: **Pamela Haylock**, secretary; **Marcia Elise Rostad**, treasurer; new directors, **Linda Krebs** and **Jody Pelusi**. . . . **SUSAN BAIRD**, director of nursing and patient services at Fox Chase Cancer Center, received both the ONS/Roche Laboratories Distinguished Service Award and the ONS/Roxane Laboratories Cancer Nursing Administration Award at the annual ONS Congress in May. Baird served 12 years as editor of Oncology Nursing Forum, the society's journal. . . . **AMY STRAUSS-TRANIN**, Univ. of Kansas Cancer Center, was appointed president of the Oncology Nursing Certification Corp., succeeding **Scarlott Mueller**, who served as president since 1992. Vice-president is Kristine Turner Story, Nebraska Methodist Hospital. . . . **GEORGE LEOPOLD**, chairman of the Dept. of Radiology at Univ. of California, San Diego, became president of the American Roentgen Ray Society at its annual meeting in April. **Joseph Ferrucci** is president-elect; **Kay Vydareny**, first vice president; **Albert Moss**, second vice president; **Robert Stanley**, secretary; and **Beverly Wood**, treasurer. The society awarded its highest honor, the Gold Medal, to **Jerome Wiot**, Univ. of Cincinnati; **Joseph Calhoun**, of Little Rock, AR; and **Harley Carlson**, Mayo Clinic. . . . **DONNA SOLLENBERGER** recently became the first female vice president in the history of M.D. Anderson Cancer Center. Sollenberger, vice president for hospitals and clinics, was promoted from senior admistrator for the Div. of Surgery & Anesthesiology, a position she held since 1991. Prior to that, she was an administrator at Southern Illinois Univ. School of Medicine.

Passion For Clinical Trials, Fishing: Charles Moertel

(Continued from page 1)

part about clinical research. That was Chuck Moertel," said Michael O'Connell, chairman of the department of oncology at Mayo Clinic and head of the North Central Cancer Treatment Group, which Moertel had founded in 1977.

"The other day a good friend said, 'It was intolerable how easy he made things look,'" Moertel's son Charles said in a eulogy at a memorial service June 30.

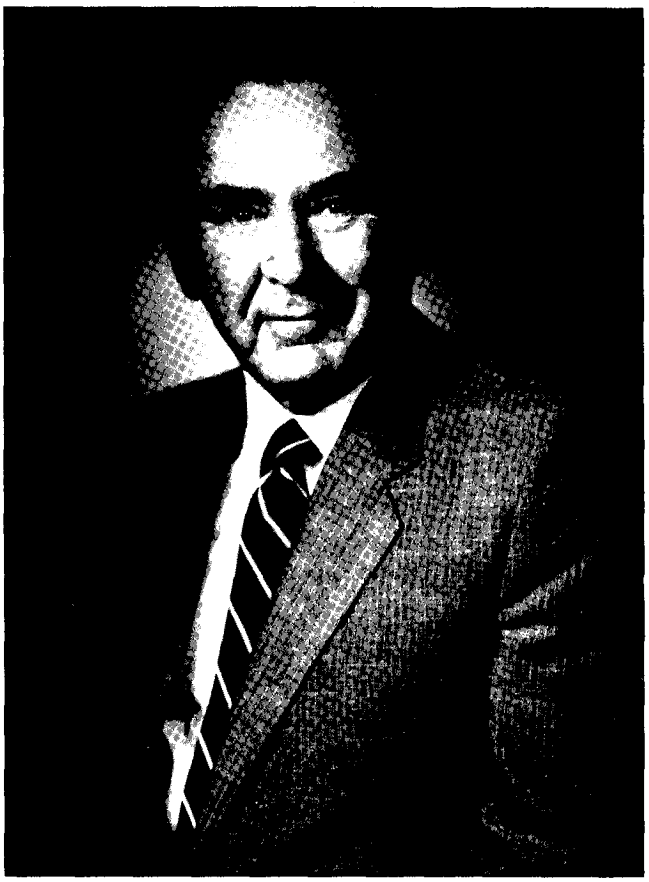
Moertel earned a medical degree from the Univ. of Illinois in 1953, and following an internship at Los Angeles County General Hospital, came to Mayo Clinic as a fellow in internal medicine. He was appointed to the staff five years later.

Early in his career, Moertel became interested in gastrointestinal cancers and the new drug, 5-fluorouracil. He started investigations with 5-FU after hours at Mayo Clinic, his son said.

When Moertel moved to the oncology section, it employed only three physicians. Ultimately, Moertel became the principal author of a proposal that made Mayo Clinic an NCI-designated Comprehensive Cancer Center. Moertel was that center's director from 1975 to 1986.

Moertel led the development of a treatment that combined 5-FU and levamisole, dramatically improving survival in Dukes C colon cancer. Also, a study led by Moertel demonstrated that chemotherapy combined with radiation can prevent recurrences and improve survival rates in patients with his risk rectal cancer.

His son said Moertel was an amateur actor "who reveled in Macbeth." Like his favorite play, Moertel's career consisted of pointing to the thin line separating right from wrong and good from evil.



Charles G. Moertel

Challenged Drug Companies

Over the years, Moertel's targets included cancer researchers who spoke from enthusiasm rather than from data; drug companies that, he said, hyped their products or gouged cancer patients; purveyors of "amazing cancer cures," including laetrile and vitamin C, which trials directed by Moertel showed to be ineffective.

As a member of the FDA Oncologic Drugs Advisory Committee, Moertel opposed approval of drugs that were not shown to improve survival.

According to Mayo Clinic lore, a challenge by Moertel once led a drug company to back out of endowing a chair at the clinic.

In another challenge in 1992, Moertel claimed that the drug levamisole was excessively priced. (The drug was substantially less expensive outside the US, and

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even less expensive in feed stores worldwide.)

As a result of that claim, broadcast nationally by Prime Time Live, drug companies were said to trim their entertainment budgets at ASCO annual meetings.

Last year, Moertel argued that CEA, a blood test commonly used to detect tumor recurrences after surgery for colon cancer, was ineffective in improving long-term survival.

Debates Over Clinical Trials

In the late 1970's, Moertel and Emil Freireich, professor at M.D. Anderson Cancer Center, engaged in a series of debates, where Moertel advocated randomized clinical trials, while Freireich advocated the use of historical controls. Though philosophically at opposite ends of the spectrum, the two had known each other since medical school and were friends.

"He was a courageous person who was prepared to take scientific investigations that other people might avoid, " Freireich said to **The Cancer Letter**.

As president of ASCO in 1979, Moertel opposed the creation of The Journal of Clinical Oncology, which he said would contribute to a proliferation of journals. Also, he opposed making business exhibits a part of the society's annual meeting.

"He refused to sit at a table when a drug company was paying for a meal," Moertel's son said. "He never wanted his work compromised or the results of his studies tainted by a conflict of interest."

Was A Knight of Malta

Moertel was a recipient of ASCO's Karnofsky Award, the Outstanding Clinical Research Award from the Association of Community Cancer Centers and the Distinguished Lecturer in Medical Sciences award from Mayo Clinic.

He was also a member of the order of the Knights of Malta, an honor bestowed on him by a patient, the grandson of Kaiser Wilhelm.

Moertel is survived by his wife, Virginia; his mother Alma Panfil of Oceanside, CA; sons Charles Moertel of Ann Arbor, MI, Christopher Moertel of St. Paul, MN, and David Moertel of Rochester, MN; daughter Heather Vick of Minneapolis; and eight grandchildren.

Contributions in honor of Moertel can be made to the North Central Cancer Group Operations Office, 200 First Street SW, Plummer 4, Rochester, MN, 55905.

Health Reform

Senate Finance Committee Reports Bill, Meeting Deadline

Meeting the self-imposed deadline July 4, the Senate Finance Committee last week reported a health care reform bill.

The measure, the language of which was not available at press time, had undergone a multitude of last-minute revisions.

However, sources said, two provisions sought by cancer lobbies—reimbursement for care of patients involved in clinical trials and establishment of a trust fund for medical research—are reflected in the legislation.

The finance committee bill, passed by a 12-to-8 vote, became the fifth health care reform package to be cleared by House and Senate committees. Now the debate has moved to the floor.

The latest bill is significant because it passed with bipartisan support and because, unlike several other panels that reported their versions of the legislation, the finance committee is regarded as representative of Congress as a whole.

Bipartisan support appears to have come at a high cost. Unlike the Administration bill, the committee bill does not include the mandate for employers to provide health insurance and does not include fall-back cost control.

Includes Biomedical Trust Fund

Capitol Hill sources said the finance committee bill includes establishment of a biomedical research trust fund, to be financed through a .25 percent surcharge on health insurance premiums.

In the final form, the measure is expected to reimburse for some investigational treatments, described in an earlier summary by the committee as "investigational treatments, including routine care provided in research trials approved by the Secretary of HHS, the Directors of NIH, the Commissioner of FDA, the Secretary of Veterans Affairs, the Secretary of Defense, or a qualified nongovernmental research entity, as defined in the NIH guidelines, including guidelines for NCI-designated cancer center support grants; or a peer reviewed and approved research program, as defined by the Secretary of HHS."

Other bills have been passed by the Senate Committee on Labor and Human Resources and

House Ways and Means Committee. The House Education and Labor Committee passed two health care reform bills.

The House Committee on Energy and Commerce gave up on its attempts to report a bill last week after the panel became deadlocked over the issue of employer mandate.

Pryor's Bill On Drug Prices Embodies Industry Fears

A bill introduced by Sen. David Pryor (D-AR) reads like a compendium of every fear pharmaceutical companies associate with control of prescription drug prices.

The measure aims to impose controls on the use of prescription drugs in Medicaid and Medicare, establishes two commissions with jurisdiction over prescription drugs and calls for uniform pricing to all drug purchasers.

While it is not formally a part of any health care reform plan, the philosophy underlying Pryor's Pharmaceutical Marketplace Reform Act (S 2239) is likely to influence discussion of competing proposals, even those that call for abolishing Medicaid and Medicare, observers said.

"I have not been convinced that the market can work to contain drug costs, and particularly the costs of new breakthrough drugs," said Pryor, introducing the bill at the Senate Committee on Finance June 24. "Because generic substitutes for these kinds of drugs do not exist, forces of competition that typically work to contain prices are ineffective."

Bill Criticized By Biotech Industry

Pryor, chairman of Special Committee on Aging, is a long-time critic of the drug industry. The bill, introduced at the Senate Committee on Finance, is cosponsored by Sen. Jim Sasser (D-TN).

Carl Feldbaum, president of the Biotechnology Industry Organization, said Pryor's bill proposes creation of new layers of government.

"[The bill] calls for the establishment of no less that six new government programs, boards or commissions—each of which is given broad authority to ride roughshod over the prescription drug marketplace," Feldbaum said. "This proposed legislation does nothing to advance the cause of credible, effective health care reform."

A summary of Pryor's proposal follows:

Changes in Medicare

—Brand name pharmaceuticals would pay a 17 percent discount off the average manufacturers retail price. On top of that, HHS would be authorized to negotiate higher discounts and to encourage doctors to use the more highly discounted drugs.

—Generic drug pharmaceuticals would pay no rebate, provided that the price of the generic drug is half the price of the innovator's brand of the drug.

—New breakthrough drugs would be subject to HHS negotiation of rebates if (1) Medicare is the primary payer for the drug; (2) the drug is not "cost effective" at the current price; (3) the new drug is less expensive in other major industrialized countries, or (4) the federal government has had a substantial role in developing the drug. HHS would be given authority to refuse coverage.

—Generic drugs would be dispensed as long as FDA has determined that the generic version is equivalent to the brand name version. An exception would be made whenever a physician indicates that a brand medication is medically necessary.

—HHS would be authorized to impose prescribing protocols.

Changes in Medicaid

—Generic drugs would be used unless a physician indicates that a brand medication is medically necessary and provides a medical justification to the state Medicaid agency.

—Generic drug expenditures would have to represent 90 percent of drug expenditures by 1996, or states would lose a part of their federal matching funds.

—States would be required to establish "therapeutic drug formularies" and establish a pharmacy therapeutics committee to provide oversight of drug use.

New Commissions

—HHS would establish the Pharmaceutical Merketplace Price Information Commission to provide information to buyers regarding pharmaceutical prices in the US and other industrial markets. The commission would also evaluate the prices of new drugs to determine whether these prices are "reasonable," based on the prices of similar new drugs, prices of the new drug in other countries, costs of making the drugs, therapeutic benefits and cost effectiveness.

—The Prescription Drug Payment Review Commission would monitor the Medicare drug program, conduct studies and make recommendations to Congress on the operation of the Medicare drug program.

Uniform Pricing

The bill would require manufacturers to establish specific, standardized terms for discounts, and to offer price concessions. "Class of trade" would no longer be a basis for discount differentials.

House Bill Gives NCI $48 Mil. Less Than Clinton Requested

The House of Representatives last week approved a $1.9 billion appropriation for NCI, $48.3 million less than the President requested, but $65.9 million above the appropriations for the current year.

The bill, HR 4606, passed by a 339 to 89 vote. The full Senate is expected to debate its version of the bill in mid-July.

Under the House measure, NIH would get $11.3 billion, $150 million below the President's request, but $384 million above last year's appropriation.

Before the measure came to a vote, Rep. John Porter (R-IL) introduced an amendment to give NIH another $100 million. However, Porter withdrew the proposal after it became clear that it did not have sufficient support.

Excerpts from the bill follow.

Report Language On NCI Appropriations:

The bill includes $1,919,419,000 for the National Cancer Institute, a decrease of $48,290,000 under the amount requested and $65,905,000 over the comparable 1994 appropriation. Funds previously included in this appropriation for AIDS research are now provided in the Office of AIDS.

Research account to be transferred back to the Institute consistent with the provisions of the 1993 NIH reauthorization. During 1994, NCI will support a total of 4,162 research grants, 1,388 research trainees, and 361 research and development contracts.

The [House Appropriations] Committee intends that within the funds provided, the highest priority be given to research in breast, cervical, ovarian and prostate cancer.

Breast cancer—NCI conducts all facets of breast cancer research, including basic studies at the genetic level; epidemiology studies focused on environmental carcinogenesis; prevention research and vaccine development; detection research, treatment studies and rehabilitation efforts.

Expansion efforts in breast cancer research include implementation of the National Breast Cancer Action Plan.

Prostate cancer—The committee is pleased that NCI has increased its emphasis on prostate cancer by expanding the funding available for a broad range of activities to improve treatment outcomes. However, the committee remains concerned that the incidence of prostate cancer continues to increase and encourages the NCI to expand its commitment to the prostate research program. During the hearings, NCI noted that African American males have a higher rate of prostate cancer than any other segment of the world's population.

The committee encourages NCI to place emphasis on research geared toward the development of effective early detection techniques and innovative treatments for the disease.

Bionutrition—Diet may rank second only to smoking in its association with cancer, according to the Institute of Medicine report on nutrition and food sciences. The committee is concerned, however, that the Institute may be reducing its investment in clinical nutrition research units (CNRU).

The committee believes that CNRU's and similar programs are essential to link basic and clinical science.

The committee also encourages NCI to further explore the role of nutrition in women's health, including breast cancer.

The committee was pleased to learn about the Institute's initiative to conduct research on the relationship between diet and cancer in African American women.

The committee is looking forward to a progress report on the initiative at the 1996 appropriations hearing.

Proton therapy—Over the past four years, at the committee's initiative, NCI has provided funds for the planning, design and construction of a competitively selected and peer reviewed proton therapy research center. The committee is pleased that the project is on schedule and urges continuation of this initiative.

Skin cancer—The committee is concerned about the rapid increase in the incidence of skin cancer,

especially malignant melanoma. Since 1980, the incidence of malignant melanoma, the most deadly form of skin cancer, has increased over 65 percent. The committee urges the Institute to make melanoma research one of its priorities and to be prepared to testify before this committee next year on its efforts to combat this deadly form of cancer.

Other concerns—The committee continues to support NCI programs focusing on tobacco-related cancers through research on carcinogenesis and on smoking control programs such as the American Stop Smoking Intervention Study (ASSIST).

The committee is supportive of the comprehensive cancer centers program and encourages the Institute to consider expansion of the number of centers if resources permit.

Excerpted Language On Office of NIH Director

Indirect costs—The committee has not included bill language proposed by the Administration that would create a one-year "pause" in indirect cost payment increases to institutions receiving research support from NIH.

The committee does not feel that the Administration's proposal addresses key underlying problems, such as the disparity in indirect cost rates among institutions.

The committee is very concerned, however, about the share of research dollars consumed by indirect costs.

With the current budgetary ceilings, funding for all research is tightly constrained, and every dollar allocated for indirect costs reduces the funding available for the direct costs of basic and clinical research.

The committee believes a revision to indirect cost allocation is urgently needed.

The Administration has indicated that the Office of Management and Budget intends to work with affected institutions to study the issue. While acknowledging that indirect costs are complex, the committee notes that the issue has been studied exhaustively and believes the time has come to implement concrete proposals.

The committee intends to serve notice that, if the Administration has not developed revisions to the indirect cost allocation process by the time the 1995 appropriations bill goes to conference, it may address the problem legislatively.

Information dissemination—Throughout the 1995 hearings, the committee expressed its concern that often NIH does not receive the proper credit for the research advances it has funded.

In addition, concern was expressed that important research findings sometimes do not reach health care practitioners and the public. The committee believes that NIH has allocated adequate resources to these efforts, but feels that existing resources must be reorganized and retargeted to produce a more unified and comprehensive approach to information dissemination.

The committee urges the NIH Director to undertake a comprehensive review of NIH information dissemination, including consulting outside experts in the field for advice. The committee would like a report on the Director's recommendations prior to the 1996 appropriations hearings.

Intramural research—Last year this committee asked that the Director establish a process for reviewing the size, organization and quality of NIH's intramural research program. NIH complied with this request by appointing a ten member outside review group to study all aspects of this research, including the key issues related to the size and design of a new clinical center facility.

The report of this review panel was submitted to the committee on April 11, 1994.

While the detailed recommendations are still being reviewed, the committee wishes to commend NIH and its extramural study group for a thorough, thoughtful and responsive report. Its recommendations provide a framework for the necessary renewal of both the personnel and facility resources needed to maintain the world's premier clinical research program.

The committee encourages the director to implement the suggested reforms as expeditiously as possible. In particular, the committee encourages NIH to present a plan as quickly as possible for the renovation of a down-sized but state-of-the-art research hospital to replace the aging clinical center facility.

This plan should include specific recommendations for the reallocation of existing resources, including intramural resources, to partially finance the cost of this facility.

Extramural research review-- As with the intramural program, the committee believes that there are questions about the organization of the extramural

research program which can benefit from a ground-up review by an impartial group of scientists and science managers.

Historical tables supplied annually to the committee show little variation over time in the portion of NIH's resources allocated among the different mechanisms of support. With a few exceptions, the mechanisms of support in 1994 are the same mechanisms used 20 years ago. This is true despite the dramatic growth of NIH's budget for extramural programs and the evolution of a larger and more diverse non-government biomedical research enterprise.

The committee directs NIH to convene a panel composed principally of personnel outside of NIH to review this area and report back to NIH and the House and Senate Committees on Appropriations their views not later than February 15, 1995.

This should, as a minimum, offer advice on the distribution of funds among mechanisms, on any fundamental changes in the design of current mechanisms, and on the need for new mechanisms which might better facilitate research goals.

Outcomes for research grant applicants—Throughout the 1995 hearings, the committee raised questions about what is known about the career paths and funding sources for those researchers who are unsuccessful in applying for NIH grants.

In a preliminary attempt to answer this question, NIH reviewed the fiscal year 1990 cohort of applicants for research project grants to see how many ultimately received NIH research funding.

The study found that, by the end of 1993, 39 percent of the applicants remained unfunded by NIH. However, only 10 percent of those whose applications scored in the top fifty percent remained unfunded.

The committee found these results very interesting and worthy of further analysis and directs NIH to conduct a more thorough, longer-term study of this question.

Such an analysis should include, to the extent possible, the participation of the unfunded researchers in other NIH grants, such as centers or research project grants, for which they are not the principal investigator.

In addition, the question of funding from non-NIH sources, such as the National Science Foundation, private industry, and foundations, should be pursued. Understanding that a properly conducted survey will require a significant amount of time, the committee does not set a precise timetable for completion, but urges NIH to begin work promptly so that some findings may be available in time for the 1996 appropriations hearings.

Women's health training—The committee is concerned about the quality of the training health care professionals receive in women's health issues and the lack of women in top leadership positions in academic health centers.

The committee encourages the ORWH to allocate resources to the development of model women's health education curricula for medical, nursing and allied health schools and to the training of women who aspire to leadership positions in health education.

Bionutrition—The committee encourages NIH to continue the trans-Institute initiative regarding bionutrition.

Bionutrition involves creating a linkage between basic and clinical science in order to translate the knowledge of basic science into improved medical care to meet human needs.

This linkage requires the support of clinical nutrition research units, centers, and program projects.

Minority issues—The committee notes that NIH has had a continuing discrimination problem with regard to minority hiring, promotions, use of minority contractors, and the participation of historically black colleges and universities in research opportunities.

In light of this fact, the committee requests NIH to provide detailed quarterly reports to the committee on its progress in addressing these issues.

Hispanics continue to be seriously underrepresented at all staffing levels at NIH, particularly in high-ranking research and policymaking positions.

According to HHS estimates, in 1993, Hispanics made up about 10 percent of the US population but only 1.6 percent of the NIH workforce and 0.4 percent of its managers. The committee urges NIH to take swift action to address these distressingly low Hispanic staffing levels.

Staffing ceilings—The committee recognizes the difficulties NIH faces in adequately staffing research areas, due to the governmentwide effort to downsize personnel.

The committee urges NIH to use its internal waiver authority within its overall staff ceiling to permit proper staffing of the highest priority research areas.

House 1995 NIH Budget Recommendations Compared to 1994

Institute	94 Approp.	House Bill	House vs 94
National Cancer Institute	1,863,514	1,919,419	+55,905
transfer, AIDS	(212,868)	(219,254)	(+6,386)
National Heart, Lung & Blood Institute	1,222,903	1,259,590	+36,687
transfer, AIDS	(54,977)	(56,625)	(+1,648)
National Institute of Dental Research	158,089	162,832	+4,743
transfer, AIDS	(11,431)	(11,774)	(+343)
Natl Inst. of Diabetes, Digestive, Kidney Diseases	705,616	726,784	+21,168
transfer, AIDS	(10,438)	(10,752)	(+314)
Natl Inst. of Neurological Disorders & Stroke	608,545	626,801	+18,256
transfer, AIDS	(22105)	(22,768)	(+663)
Natl Inst. of Allergy & Infectious Diseases	520,792	536,416	+15,624
transfer, AIDS	(542,912)	(559,200)	(+16,288)
National Institute of General Medical Sciences	851,566	877,113	+25,547
transfer, AIDS	(23,945)	(24,664)	(+719)
Natl Inst. of Child Health & Human Development	498,455	513,409	+14,954
transfer, AIDS	(56,426)	(59,519)	(+3,092)
National Eye Institute	281,879	290,335	+8,456
transfer, AIDS	(8,381)	(8,633)	(+252)
Natl Inst. of Environmental Health Sciences	258,641	266,400	+7,759
transfer, AIDS	(5,608)	(5,776)	(+168)
National Institute on Aging	418,639	431,198	+12,559
transfer, AIDS	(1,664)	(1,715)	(+51)
Natl Inst. of Arthritis, Musculoskeletal, Skin	220,409	227,021	+6,612
transfer, AIDS	(2,795)	(2,879)	(+84)
Natl Inst. on Deafness & Other Comm. Disorders	161,316	166,155	+4,839
transfer, AIDS	(1,507)	(1,552)	(+45)
National Inst. of Nursing Research	46,574	47,971	+1,397
transfer, AIDS	(4,444)	(4,577)	(+133)
Natl Inst. on Alcohol Abuse & Alcoholism	176,160	181,445	+5,285
transfer, AIDS	(9,457)	(9,741)	(+284)
National Institute on Drug Abuse	281,825	290,280	+8,455
transfer, AIDS	(143,376)	(147,677)	(+4,301)
National Institute of Mental Health	526,262	542,050	+15,788
transfer, AIDS	(87,182)	(89,798)	(+2,616)
Natl Center for Research Resources	270,532	294,877	+24,345
transfer, AIDS	(61,383)	(63,225)	(+1,842)
Natl Center for Human Genome Research	127,112	152,010	+24,898
John E. Fogarty International Center	12,825	15,193	+1,448
transfer, AIDS	(8,852)	(9,118)	(+266)
National Library of Medicine	115,237	123,274	+8,037
transfer, AIDS	(2,782)	(2,946)	(+164)
Office of Director	202,608	219,474	+16,866
transfer, AIDS	(24,582)	(25,414)	(+832)
Buildings and facilities	111,039	114,370	+3,331
Office of AIDS Research	1,297,115	1,337,606	+40,491
Total, NIH	10,937,653	11,322,023	+384,370

Source: House Appropriations Committee