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House Subcommittee Recommends $137.7 Million Increase For NCI

A House subcommittee last week recommended boosting the appropriation for NCI by $104.8 million above the level proposed by the President and $137.7 million above this year's budget.

The bill approved by the Subcommittee on Labor, HHS and Education was expected to come to a vote before the full appropriations committee Sept. 20.

The President's proposal for the fiscal year 1997 calls for increasing

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In Brief

GM Awards Shared By Six Scientists; Pollard Named President Of Salk Institute

GENERAL MOTORS Cancer Research Foundation announced the winners of its annual awards for cancer research. The Charles F. Kettering medal for outstanding contributions to the treatment of cancer was awarded to **Patrick Walsh**, director of the Department of Urology, Johns Hopkins University, and **Malcolm Bagshaw**, professor emeritus of cancer biology at Stanford University. The Charles S. Mott medal for outstanding research in cancer causation or prevention was awarded to **Paul Modrich**, professor of biochemistry, Duke University Medical Center, and **Richard Kolodner**, professor of biochemistry, Harvard University. The Alfred P. Sloan prize for basic science was awarded to **Mark Davis**, professor of microbiology and immunology, Stanford University School of Medicine, and **Tak Mak**, senior scientist, Ontario Cancer Institute. Each prize includes a gold medal and $100,000. . . . **THOMAS DEAN POLLARD** has been selected as president and CEO of the Salk Institute for Biological Studies, effective July 1. Pollard, professor and director of the Department of Cell Biology and Anatomy at Johns Hopkins University School of Medicine, will be the institute's ninth president. Pollard's selection concludes a search that began last September after **Francis Crick** stepped down as president. Pollard, an expert on the molecular basis of cell movements, plans to continue his research and provide scientific direction to the institute, as well as oversee administration and fund-raising, according to a statement. . . . **RACE FOR THE CURE** attracted about 30,000 participants, 1,000 of them breast cancer survivors, to Washington on June 15. Participants included Vice President **Al Gore** and **Tipper Gore**, **Robin Dole**, daughter of

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the Institute's budget by $32.9 million over the current year, to $2.28 billion.

Several insiders said the dramatic increase for NCI at a time of budgetary austerity is likely to make the Institute a likely target for raids from proponents of the many programs that are expected to be cut during the next fiscal year.

"All of us have to work diligently to preserve this high water mark," said Marguerite Donoghue, deputy executive director of the National Coalition for Cancer Research. "We will be challenged every step of the way."

Under the House subcommittee bill, NIH was slated to receive an increase of $820 million.

The President's proposed a $12.406 billion budget for NIH (**The Cancer Letter**, March 22, April 26), a boost of $457 million over the current budget.

Sources said the House bill recommended an appropriation of $90 million for the NIH Clinical Center next year, with additional funds to be allocated in subsequent years. The Administration's plan is to fund the entire $274 million project in a single year.

Senate Committee: $150M for DOD Breast Cancer

In another development, the Senate Appropriations Committee June 20 approved a bill that includes $150 million in funds for the Department of Defense peer reviewed breast cancer research program.

A week earlier, the House Appropriations Committee approved a $100 million appropriation for the DOD breast cancer research program.

In addition, the House committee approved $25 million in funds for improvement in the DOD health care system.

The House committee said $3 million of the money appropriated for research should fund the Army and Navy programs in computer-assisted diagnosis and image enhancement methods.

According to the House committee report, another $6 million would go for the development of a "computer-based decision support system" that would help patients understand treatment options and risks.

Also, $3.5 million would go for establishment of a cancer detection center for military personnel, the committee said.

Senate Hearing on NIH Appropriations

In the face of generosity of House appropriators, Sen. Arlen Specter (R-PA), pondered the dilemma before him:

"The House has recommended an 820 million increase [for NIH], which is substantially higher than what the President sent over," said Specter, chairman of the subcommittee on Labor, HHS and Education at a hearing June 19.

"We did not really want to get into a bidding war with the House and show our affection for NIH.

"I am sorry we can't treat everybody as well as we treat the NIH. We are looking at a very difficult budget. Every dollar we allocate for NIH in our budget comes from an allocation on drug treatment or schools."

Specter's question: Does the President's request of a $467 million increase for NIH represent an adequate boost?

"As you know, the President has the same restraints operate on your committee as he is trying to reach an optimum budget for many other worthwhile agencies," said NIH Director Harold Varmus, one of the witnesses at the hearing.

"Could we use more money in a productive way? The answer is yes. But we also operate within the context of trying to do many things. And we seem to have enough money to accomplish our goals."

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The highlights of the testimony follow:

SPECTER: "[Is there] a disproportionate flow of funds for AIDS or breast cancer, as compared to prostate cancer?"

Richard Klausner, NCI Director: "I think the way to approach this is not to interpret numbers, but rather to ask a set of questions that we agree we need to ask about prostate cancer, about breast cancer, about AIDS, and to make sure that we are addressing these questions.

"With prostate cancer, the critical question that we need to address is that we desperately need better, more sensitive, more specific screening methods."

SPECTER: "Is there adequate funding as to prostate cancer research?"

KLAUSNER: "I believe that we are addressing the important areas about prostate cancer."

SPECTER: "Is it proportional to the amount of funding devoted toward AIDS, for example?"

KLAUSNER: "It's very difficult for me to describe proportionality... Based upon what? On deaths? On opportunities for discovery?"

SPECTER: "[Based on] statistics. Individuals who have prostate cancer contrasted to those who have AIDS, and the amounts allocated to research in prostate cancer, contrasted with AIDS.

KLAUSNER: I think there are opportunities in prostate cancer that we can fund. But I would say that the major advances made in prostate cancer, as in breast cancer, are not readily definable in terms of each different entity.

"For example, supporting the clinical trials system. You wouldn't set up a prostate clinical trials system; we need a general clinical trials system.

"We need to ensure support in general of patient-oriented research, and we are addressing those toward a general set of questions that would be applicable in prostate cancer, such as the ability to read the molecular nature of prostate cancer.

"We diagnose [prostate cancer] extremely frequently, and yet we don't know which of those cancers we need to treat, and which we need to watch. Cancers are not readily coded in terms of prostate vs. breast, so that's the problem in terms of coding how much we are funding for breast versus prostate."

SPECTER: "So research in breast cancer, for example, is fully applicable to other kinds of cancer, like prostate cancer."

KLAUSNER: "Much of the research, especially the basic biological research into the molecular, the genetic, the environmental basis of breast cancer will be important and applicable to prostate cancer. Clearly, there are things that are specific.

"But in fact, broadening the advances in each of these cancers, I see much more overlap than I see distinction. That's why it's very difficult to draw simple lines based upon our preconceived notions about the differences between cancers, when ultimately what we will find is that there will be more similarities between the critical characteristics of prostate cancer that may spread and a brain tumor versus a breast cancer that may not spread and a prostate cancer that may not spread."

Role of Advocacy Groups

Sen. Connie Mack (R-FL): "The American Cancer Society indicated several years ago that we could increase the cure rate in cancer from roughly 50 percent to 75 percent without a single additional technology breakthrough.

"They say this cure rate increase could result from people taking advantage of early detection. Can you give me a sense of how much [more] goes to research, how much is in education, how much for early detection?"

KLAUSNER: "One of the dramatic and important changes in biomedical research and in medicine has been the activism of the consumers, patients, survivors, volunteer groups, that [emphasize] awareness.

"There is no question that the way to increase awareness is to make sure that it is a grassroots effort. The role that the NIH and NCI have is to provide accurate and accessible information to this enormous hunger for information about the disease, about what causes it, about what one can do to prevent it, about where one goes for treatment.

"I think there is a very good partnership now between private organizations, non-profit organizations, and especially, the explosion of activity by consumers and activists that we are working very closely with to leverage research funds to create the knowledge, and create the instruments to disseminate them, but in the end, it requires an interfacing with the community in order to get the information out there.

"I think there is a lot of uncertainty about the exact efficacy of current detection technology. I have no question that with improved detection technologies we will be able to improve the cure rate."

NCI Names Brawley To Direct Office Of Special Populations

Otis Brawley, a medical oncologist in the NCI Division of Cancer Prevention and Control, was appointed director of the Institute's new Office of Special Populations.

The goal of the new office is to oversee the Institute's development and evaluation of research, education, training and outreach programs to identify the cancer burdens in racial, ethnic, underserved and other special populations, NCI Director Richard Klausner said in a June 11 memo announcing Brawley's appointment.

"This office will serve as a focal point for planning, interacting with the community and coordinating the work of the Institute in these important areas," Klausner said. "This office will be charged with the ongoing evaluation of opportunities, needs and our progress."

The new Office of Special Populations is part of the Office of Program Operations and Planning, within the NCI Director's office.

Brawley has been a senior investigator and program director in the Community Oncology and Rehabilitation Branch of the DCPC Early Detection and Community Oncology Program since 1990.

He serves as program director of the NCI Prostate Cancer Prevention Trial, and was influential in the Institute's development of the trial, sources said. He also coordinates the Minority-Based Community Clinical Oncology Program.

Brawley's clinical work involves the treatment of patients with prostate cancer at the NIH Clinical Center, where he has been acting coordinator of the Prostate Cancer Clinic since 1995. He is a commander in the Public Health Service Commission Corps.

"My office will be conducting planning and evaluation of programs specific to special populations that we are defining by gender, economics, race, as well as people who have special propensity for disease, and even genetic predisposition to disease," Brawley said to **The Cancer Letter**. "We may learn a great deal by looking at populations in other countries that have a specific disease or don't have specific disease."

The office will not fund research, but may develop research concepts that would be put in place by the NCI divisions.

"I am also interested in access to care and patterns of cancer care," Brawley said. "I will be interacting with other groups that are interested in minority health care issues, both in government and outside government."

Brawley said he will continue to see patients at the Clinical Center, but will no longer head the Prostate Cancer Clinic. He also will transition out of DCPC by mid-July, however, he will continue to have a seat on the steering committee of the Prostate Cancer Prevention Trial.

Prior to joining NCI as a medical staff fellow in 1988, Brawley completed a residency and internship at the University Hospitals of Cleveland, Case-Western Reserve University. He received an M.D. from University of Chicago in 1985.

Owens Presides Over NCCR; Three Elected To Board

Albert Owens became president of the National Coalition for Cancer Research at a meeting of the organization's Board of Directors on June 17.

Owens, founding director of the Johns Hopkins Oncology Center and Distinguished Service Professor of Oncology and Medicine, succeeds Margaret Foti, executive director of the American Association for Cancer Research.

Owens becomes the fifth president of NCCR, a coalition that seeks to educate the public and policymakers about the value of cancer research. Owens served as chairman of the organization from 1990-1992.

At the NCCR board meeting, the coalition unanimously agreed to support events to recognize the 25th anniversary of the signing of the National Cancer Act of 1971. The coalition plans to sponsor some events and said it would support events sponsored by the Friends of Cancer Research, a group organized by National Cancer Advisory Board member Ellen Sigal (**The Cancer Letter**, May 31).

NCCR also reappointed Francis McKay, executive vice-president of Fox Chase Cancer Center, as secretary-treasurer. The coalition elected three individuals to the board: Carolyn Aldige, president, Cancer Research Foundation of America; Anna Barker, president and chief executive officer, OXIS International; and J. Frank Wilson, director, Medical College of Wisconsin Cancer Center.

NCCR, based in Washington, is a non-profit group comprised of 18 member organizations.

FDA Approves Irinotecan For Colorectal Cancer

The Food and Drug Administration has approved for marketing irinotecan (Camptosar, Pharmacia & Upjohn Inc., Kalamazoo, MI) for the treatment of metastatic colon and rectal cancer that has recurred or progressed after standard with standard, fluorouracil-based chemotherapy.

FDA approved irinotecan on June 17, just two working days after the agency's advisory panel unanimously recommended the drug for approval. FDA cleared the drug under accelerated approval regulations for new cancer treatments.

Irinotecan is a member of the new class of drugs called camptothecins, which work by inhibiting the enzyme topoisomerase-I. The drug's approval was based on three open-label phase 2 studies in patients with metastatic colorectal cancer that recurred or progressed following 5-FU based chemotherapy.

The studies, presented to the FDA Oncologic Drugs Advisory Committee at its meeting on June 13, demonstrated that irinotecan reduced the tumor size of 13 percent (39 of 304 patients) of patients with metastatic colorectal cancer, an effect that lasted an average of six months.

The most consistent responses were observed in patients beginning treatment at the recommended 125 mg/m^2 starting dose, said Dan Von Hoff, director of the Institute for Drug Development and clinical professor of medicine, University of Texas Health Science Center, San Antonio.

Of the 193 patients treated at this dose level, 29 experienced a positive response for an overall response rate of 15 percent. "That's a good response rate for a second-line cancer therapy," said Von Hoff, a clinical investigator on studies of irinotecan.

Tumors disappeared completely in two of the patients, or were reduced 50 percent in size in 27 patients.

The standard drug treatment for patients with metastatic colorectal cancer is fluorouracil (5-FU). About 20 percent of those who receive 5-FU respond favorably. However, in all of these cases the cancer eventually will progress.

"When that happens we have had no effective medical option, which is why Camptosar is so important," Von Hoff said.

"Camptosar will be the only second-line drug therapy indicated for patients whose disease has progressed following first-line treatment," said Langdon Miller, vice president of U.S. oncology development for Pharmacia & Upjohn. "It's also the first new treatment for colorectal cancer in 40 years."

Irinotecan has been associated with severe diarrhea and severe myelosuppression. Other side effects are nausea and vomiting. "Prompt recognition and treatment of these side effects is essential to optimize patient management," said Von Hoff. In particular, aggressive administration of loperamide is demonstrated to reduce the incidence of serious diarrhea.

According to Miller, it is essential to begin treatment with loperamide at the first sign of a change in bowel habits. The standard treatment for diarrhea that occurred after drug administration was loperamide 4 mg orally taken at the first sign of diarrhea, followed by 2 mg orally every 2 hours (4 mg orally every 4 hours at night) until there is complete resolution of the diarrhea for at least 12 hours.

Pharmacia & Upjohn is working to make Camptosar available to physicians and patients as soon as possible, Miller said. The company said it would assist physicians, office staff and patients with insurance coding, precertification, billing questions and appeals of denied claims for the product.

The company has established a Reimbursement Helpline, with the toll-free number 800/808-9111.

ODAC Recommends Implant For Recurrent Brain Tumors

The FDA Oncologic Drugs Advisory Committee recommended for approval a dissolving plastic wafter implanted in the brain for treatment of malignant brain tumors.

The implant, Gliadel Wafer (polifesprosan 20 with carmustine, by Guilford Pharmaceuticals Inc., of Baltimore, MD) is recommended in conjunction with surgical resection for the treatment of recurrent malignant gliobastoma multiforme.

ODAC recommended Gliadel for approval based on data from two phase III clinical studies presented at the committee's meeting June 14.

Gliadel Wafers are implanted in the cavity created when a brain tumor is surgically removed. The wafers

slowly erode in the resection cavity, releasing the chemotherapeutic drug, carmustine, directly to the tumor site in high concentrations over an extended period of time, the company said.

A study conducted in North America enrolled 222 patients undergoing surgery for recurrent malignant glioma. The six-month survival rate was 60 percent for Gliadel versus 47 percent for placebo. A second clinical study conducted in Europe involving 32 patients supported the results of the North American trial, the company said. In that study, Gliadel was used on the initial diagnosis and surgery for the disease. Survival rates at one year were 63 percent with Gliadel compared to 19 percent on placebo.

The advisory committee voted against recommending the wafer's use for the initial treatment of malignant brain tumors.

"We are pleased that the committee voted in favor of making this treatment available to patients who have few if any, available treatment options," said Craig Smith, president and CEO of Guilford. "While Gliadel has been available free of charge to patients with an acute medical need under our treatment IND, this recommendation takes us one step closer to making Gliadel more widely available in the U.S."

In a related development, Guilford announced that it had granted rights to market Gliadel to Rhone-Poulenc Rorer Inc., of Collegeville, PA, and Paris, France. RPR will market the drug worldwide, except in the Scandinavian countries.

Letter to the Editors

Middle East Consortium: Did Headline Politicize Issue?

To the Editors:

In the Letter to the Editor in the June 14 issue of **The Cancer Letter**, Richard Baehr remarked on the May 24 article on the Middle East Cancer Consortium. He seemed concerned about the reference to the ministers of health of five Middle Eastern "countries" (Cyprus, Egypt, Israel, Jordan, and the Palestinian Authority), and attributed the terminology to a "carelessness" rather than "deliberate attempt at politicizing the issue."

However, he goes on to emphasize that "it is clearly inaccurate and premature to characterize the Palestinian Authority as a country. The final status talks that will determine whether Gaza and the autonomous regions of the West Bank become a state have only just begun."

Had this politically-charged comment not been made, I as well as many others who read **The Cancer Letter** for the value of its scientific news, would have thought very little to scrutinize such passing terminology, let alone bother to define the present status of Palestinian-Israeli talks.

But with that letter entitled, "Palestinian Authority Not Yet A "Country," Talks Beginning," I wonder who was it really that politicized the issue?

Dina Ra'ad
Bethesda, MD

In Brief

Race For Cure Raises $1.2M For Breast Cancer Research

(Continued from page 1)

Republican presidential contender **Bob Dole**, 10 senators, 30 House members and several Cabinet members. The race raised about $1.2 million for breast cancer research and education, according to the sponsor, Susan G. Komen Breast Cancer Foundation. . . . **ROBERT CAPIZZI** was named Magee Professor of Medicine and chairman of the Department of Medicine, Jefferson Medical College, Thomas Jefferson University, effective July 1. Capizzi has been executive vice president, research and development, for U.S. Bioscience Inc., of West Conshohocken, PA, for more than four years. Prior to that, he was director of the cancer center at Bowman Gray School of Medicine, Wake Forest University. Capizzi succeeds **Jose Caro** as the department chairman. . . . **ADELE SEIFREID**, executive secretary of the Food and Drug Administration's Oncologic Drugs Advisory Committee for the past five years, has been named deputy director of the agency's Advisors and Consultants staff. **Jannette O'Neill-Gonzalez**, formerly a program specialist at the Health Resources and Services Administration, Division of Medicine, was appointed to succeed Seifried as ODAC executive secretary. . . . **CORRECTION:** Internet site for accessing the full text of the "Report of the Committee on Rating of Grant Applications" (**The Cancer Letter**, June 14) can be reached through the NIH home page (http://www.nih.gov/grants/dder/rga.htm). Diane Bronzert was incorrectly listed as a contact person. NIH encourages investigators to send comments or questions by e-mail to dder@nih.gov.