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ASSIST Gets Extra Year Of Funding While NCI Considers Role In Tobacco Control

NCI Director Richard Klausner has decided to extend funding for one year for the American Stop Smoking Intervention Study, the federal government's largest project to reduce the prevalence of smoking.

ASSIST, begun in 1991, was scheduled to be completed at the end of fiscal year 1997. The one-year extension is intended to allow HHS to decide which agency should run the project, Klausner said.

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In Brief

Wells Tapped For GM Cancer Foundation; Calder Named NABCO Associate Director

SAMUEL WELLS was named president of the **General Motors Cancer Research Foundation**. Wells is Bixby Professor of Surgery and chairman of the department of surgery at Washington University School of Medicine in St. Louis. As president of GMCRF, Wells will direct the planning of the foundation's scientific conference at NIH and oversee the selection of candidates for the GMCRF science awards. . . **RODGER CURRIE** was named counsel to the **House Committee on Commerce**. Currie, formerly an associate with Fox, Bennett & Turner, a Washington law firm, will work on issues related to FDA and biomedical research... **KIMBERLY CALDER** was named associate executive director of the **National Alliance of Breast Cancer Organizations**. Calder, former director of public policy for Cancer Care Inc., will assist NABCO executive director **Amy Langer**. Langer, who was injured in an automobile accident last summer, has returned to her job full time. . . **JOHN KERSEY** was named president-elect of the **American Society for Blood and Marrow Transplantation**. Kersey is director of the University of Minnesota Cancer Center. . . **PHILIP GUTIN** was named chief of the neurosurgical service at **Memorial Sloan Kettering Cancer Center**. Gutin is the former chairman of the department of neurological surgery at the University of California, San Francisco. Gutin also became the first incumbent of the Fred Lebow Chair in Neuro-Oncology, which was established in memory of the founder of the New York City Marathon. . . **HERBERT SOULE**, a cellular biologist at the Karmanos Cancer Institute, died Jan. 2. Soule developed the MCF-7 and MCF-10 human breast cancer cell lines. Soule, who was 71, died of emphysema, the cancer center said.

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ASSIST Works, Advocates Say; NCI Sees Transition Ahead

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"We intend to extend funding fully through fiscal 1998, and during that time work with ASSIST and all components of HHS to make sure that we continue—if not increase—our support for a variety of efforts in tobacco control," Klausner said to **The Cancer Letter**.

"The decision to fund ASSIST through fiscal year 1998 was made to give all of us, HHS, ASSIST, and NCI, time to work on the transition between conducting a research project and our future activities in tobacco control," Klausner said. "The discussion that needs to go on in the department is how best to house all the different tobacco control initiatives that need to be funded in research, education, and public health."

The extension may not be enough for ASSIST's advocates and advisors. The project's Scientific Advisory Committee passed a resolution Jan. 13 urging NCI to continue ASSIST for five or six years, "or until there is a committed national program at a high level."

The questions raised in debates over ASSIST are likely to define the role NCI can play in tobacco control. Is ASSIST consistent with NCI's definition of itself as the government's research agency in cancer and the Institute's efforts to steer clear of

health policy and practice issues?

Moreover, if ASSIST has demonstrated that comprehensive community-based intervention leads to a drop in smoking, then is further research necessary? Should NCI continue to fund those interventions, or should the program be run by the Centers for Disease Control and Prevention, or another component of HHS?

ASSIST provides contracts with state health departments to help the states implement community intervention projects to reduce the prevalence of smoking. The study, which operates in 17 states, is a joint project with the American Cancer Society, which provides volunteer services and support.

NCI officials are preparing a letter to notify state health departments of the extension of their contracts to Sept. 30, 1999.

The study costs NCI about \$25 million per year.

Long-Term Survival At Stake

Defending ASSIST, the project's Scientific Advisory Committee voted to send a representative to appear before the NCI Cancer Control Program Review Group, a committee established by Klausner to review the Institute's cancer control programs.

"Within NCI there is a questioning of the value of projects like this one," said David Abrams, a member of the ASSIST Scientific Advisory Committee, who also is chairman of the cancer control review group. "The fact that these studies seem to cost a lot cause people to wonder whether the money is spent well."

"The knee-jerk response is, the study costs a lot and the main results don't look that exciting or they take too long," Abrams, director of the Division of Behavioral Medicine at Brown University, said to **The Cancer Letter**. "But you can't look at a complicated study like this and expect a quick result. The community is the laboratory."

Tobacco control advocates say ASSIST is the most successful anti-tobacco program ever funded by the federal government.

"The federal government has no other tobacco program that has really shown the kind of results ASSIST has shown," Helene Brown, a senior advisor to ASSIST and director of community applications of research at the University of California, Los Angeles, Jonsson Comprehensive Cancer Center. "It is a mistake to end a very good program until you have something to take its place."



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"Dr. Klausner is on the right track to view 1997 and 1998 as pivotal years to look at ASSIST and move to broaden it," Brown said to **The Cancer Letter**. "My hope is that he will support putting a program in place in the 33 other states that is as good as ASSIST."

The program's advocates back their claims with the following data:

- Cigarette consumption in ASSIST states is 10 percent below that in non-ASSIST states, according to 1995 data presented to a meeting of the American Public Health Association last fall. The states had started at the same level in 1993. The data are statistically significant, said Marc Manley, chief of the Public Health Applications Branch, Cancer Control Program, in the NCI Division of Cancer Prevention and Control.

- Unpublished data presented to the ASSIST Scientific Advisory Committee in a closed session earlier this week indicated that the gap in cigarette consumption between the ASSIST and non-ASSIST states is widening, sources said.

- State legislatures, local governments, or major institutions in all 17 states have introduced or strengthened tobacco control and clean indoor air regulations, including increasing taxes on tobacco products and instituting smoking bans in public places and workplace smoking policies. Some states have improved the enforcement of laws restricting access to tobacco by young people.

- Newspapers in ASSIST states have published 25 percent more stories about tobacco than have papers in non-ASSIST states. Of these stories, 85 percent had a point of view that was either neutral or in favor of tobacco control.

- Local coalitions involved in ASSIST have grown from 87 organizations made up of 675 members in 1992 to 220 coalitions with over 7,000 members in 1996.

- More than 30 shopping malls in 10 ASSIST states have adopted smoke-free policies.

NCI's evaluation of the study's interim results is expected to be published later this year in the journal *Tobacco Control*.

Klausner: Concerned With the Process

Several members of the ASSIST Scientific Advisory Committee said the project would remain at NCI only if the Institute is convinced that important research questions still remain to be

answered.

"Having talked to Dr. Klausner directly about this, I think the incredible moral persuasion of the importance of tobacco control will work in the short term," said Harmon Eyre, ACS deputy executive vice president for medical affairs and research. "But he will not budge. This group has to come up with a set of research questions to keep him interested."

Several ASSIST advocates said they believed NCI would rather fund research in molecular biology than a community intervention project like ASSIST. Responding to this criticism, Klausner said his questions about ASSIST are part of routine, rigorous review of a multi-million-dollar program.

"The interpretations of my questions about this are very inaccurate," Klausner said to **The Cancer Letter**. "To assume that the director makes unilateral decisions—that's just not the way NCI is, or should be, run. Especially when it involves spending enormous sums of money without a review and advisory process.

"I would not be comfortable with extending ASSIST for several years without a review, an evaluation; without a discussion with the National Cancer Advisory Board, ACS, and all the groups involved," Klausner said. "I'm concerned with the process.

"ASSIST was set up with a research plan," he said. "In the absence of an independent evaluation, we need to know whether to extend the research component of ASSIST, which is different from the public health component.

"When a clinical trial comes to an end, we may decide there is a need to continue, based upon inadequate data, or decide that you need to disseminate and expand the application of what you learned.

"We are taking about moving from learning things to applying things," he said. "The question is, does the study require continuation, or is it time to use the infrastructure for dissemination?"

Message of ASSIST: "Do More Of It"

At the time ASSIST was started, decades of research had shown that addressing smoking as an individual issue, smoker by smoker, was slow and expensive.

Meanwhile, researchers observed that large declines in smoking occurred when major social and environmental changes took place.

The ASSIST hypothesis was that a comprehensive effort to change the social and environmental circumstances to discourage smoking and encourage quitting would reduce smoking prevalence.

The goal was to reduce smoking prevalence in all ASSIST states combined to less than 15 percent by the 1998.

"ASSIST, like the big tobacco-tax financed programs in California and Massachusetts, demonstrates clearly that the way to deal with the tobacco epidemic is large, community-based interventions, not individual smoking cessation," Stanton Glantz, professor of medicine, University of California, San Francisco, said to **The Cancer Letter**.

"ASSIST has had a huge public health impact," Glantz said. "For all the talk about tobacco in the Clinton Administration, this is the most important thing that has been done, and it actually began during the Bush Administration."

Said Glantz: "The basic message of ASSIST is: Do more of it."

Massachusetts owes its tobacco control successes to ASSIST, said Gregory Connolly, executive director, Massachusetts Department of Health Tobacco Control Program.

"Without ASSIST, [the state's Tobacco Control Program] wouldn't be around," Connolly said to the ASSIST advisory committee. "We get about \$700,000 in funding from NCI for ASSIST, and we give back to ASSIST a couple million dollars in valuable products."

The state raised the tobacco tax by 76 cents per pack of cigarettes, and new regulations will require full disclosure of additives in tobacco products.

According to surveys, nearly 70 percent of workers in Massachusetts say they work in a smoke-free environment. Vending machine restrictions have cut youth access to cigarettes by 50 percent. The percentage of adults in Massachusetts who smoke more than 20 cigarettes a day has dropped from 24 percent in 1993 to 18 percent in 1995. The prevalence of smoking among 18 to 24-year-olds has dropped from 25 percent to 22 percent.

In addition, per capita packs of cigarettes purchased in Massachusetts declined 18.5 percent in three years.

"By the year 2000, we will pretty much be a smoke-free state," Connolly said. "Given enough

time, every state in ASSIST will have a program like ours."

Connolly said he worries that when the NCI funding ends, the state employees who have become experienced in working on tobacco control will find other jobs. "We are at a critical time," he said. "It is worth having the seed money stay there."

John Garcia, project director of the ASSIST Coordinating Center, agreed. "If the sites believe the project is at an end, we are going to see good people leave," he said. "The model can be one of continued growth or we could see a faltering or discontinuation.

"We couldn't sustain ASSIST at the state and local level without some national resources," Garcia said. The coordinating center contract is held by Prospect Associates, a Rockville, MD, firm.

The ASSIST funding is small compared to the estimated \$5.23 billion the tobacco industry spends each year on advertising and promotion, ASSIST proponents said.

"The ASSIST budget is such a little, little sum," said Dileep Bal, a member of the ASSIST Scientific Advisory Committee and chief of the Chronic Disease Branch, California Department of Health Services.

The committee asked NCI to prepare an economic analysis of the project's funding compared to the cost of medical management of smoking-related health problems such as cardiovascular disease.

Tobacco use costs the U.S. \$100 billion per year in health care spending and lost productivity, according to the ACS publication, "Cancer Facts & Figures—1997."

Tobacco Industry Attacks ASSIST

Some tobacco industry supporters claim state health departments are using the NCI funds to lobby for higher state or local tobacco taxes, an action that would be illegal for state agencies.

NCI and ASSIST officials say the funds are not used for lobbying, and state health departments are trained on proper use of the funds.

Tobacco industry lobbyists have filed Freedom of Information Act requests for ASSIST documents in many of the states. The filings serve mainly as a public relations tactic as well as a method for wasting the time of state employees working on the

project, said Prabhu Ponshe, senior public relations counsel for Prospect Associates.

However, in one state, Maine, a FOIA request backfired for the tobacco industry, Ponshe said.

An industry lobbyist requested a massive number of documents on ASSIST, but when he arrived at the health department to copy the papers, newspaper and television reporters were there as well. Most of the documents were statistical analyses of tobacco-related morbidity and mortality in the state.

"The stories and editorials that came out the next day asked, 'What did the industry find out? They found out that the No. 1 cause of preventable morbidity and mortality in Maine is tobacco,' " Ponshe said.

Glantz said the attacks prove ASSIST is working. "To me, the best evidence that ASSIST is on the right track is that the tobacco industry is fighting it," he said. "The industry would like nothing better than for NCI to abandon ASSIST and make the case that NCI shouldn't do ASSIST because it's not lab science.

"The kind of questions that I ask in my lab are not appropriate here," Glantz said to **The Cancer Letter**. "If NCI requires ASSIST to be analyzed using a clinical paradigm, then NCI doesn't want to know why it worked.

"ASSIST has shown that the model can work," Glantz said. "NCI needs to make that strategy work better. That, to me, is the research question.

"In the meantime, the CDC should extend the ASSIST model to the other 33 states."

The 17 state health departments that received ASSIST contracts include Colorado, Indiana, Maine, Massachusetts, Michigan, Minnesota, Missouri, New Jersey, New Mexico, New York, Rhode Island, South Carolina, Virginia, Washington, West Virginia and Wisconsin.

Patient Advocacy

Breast Cancer Coalition To Hold International Meeting

The National Breast Cancer Coalition will hold an international conference on breast cancer advocacy March 13-16 in Brussels.

The conference will include workshops on influencing breast cancer policy issues, the international research process, informed consent

issues, scientific training for activists, and the role of the Internet in breast cancer advocacy and research.

Registration fee is \$10 to \$100, depending on what the participants can afford.

Additional information is available from the coalition, 1707 L Street NW, Suite 1060, Washington, DC 20036. Tel.: 202/296-7477.

Reimbursement Issues

NCI, VA Begin Clinical Trial Demonstration Project

The Department of Veterans Affairs and NCI have begun a demonstration project that will provide reimbursement for patient care costs for patients enrolled in NCI sponsored clinical trials.

The agreement, announced last year, went into effect Jan. 1, NCI and VA said.

The agreement, which is broader than a similar deal with the Department of Defense program that covers active duty personnel, provides reimbursement for NCI-sponsored prevention, diagnostic and treatment studies. Unlike the DOD collaboration, the VA deal covers phase I studies.

"The agreement expands the already productive relationship between VA and NCI," said Kenneth Kizer, VA undersecretary for health. "It means greater access to the full range of promising new treatments for cancer."

NCI is negotiating a similar agreement with the Health Care Financing Administration as well as with insurance companies and managed care organizations.

In negotiations with HCFA, the parties are facing congressional pressure to conclude the agreement. Sens. Jay Rockefeller (D-WV) and Connie Mack (R-FL) are expected to reintroduce a bill mandating HCFA and the Institute to establish a demonstration project, sources said.

Funding Opportunities

Foundation Offers Grants For Clinical Pilot Projects

Cancer Treatment Research Foundation, a nonprofit organization based in Arlington Heights, IL, is accepting applications for new and pilot/

feasibility clinical projects in the areas of innovative cancer therapy.

These areas include new applications of conventional anticancer therapies, biological response modifiers, immunotherapy, gene therapy, quality of life, nutrition and cancer education.

Applicants are asked to send a letter of intent to Gary Anderson, Grants Administrator, CTRF, 3455 Salt Creek Lane Suite 200, Arlington Heights, IL 60005, tel: 847-342-7430.

The initial phase of the application process will consist of a two or three page concept proposal including background, rationale, study design, budget and significance of the project in relation to the overall mission of CTRF to support research in cancer treatment options that demonstrate promise of quickly translating from the research to treatment stage while enhancing a cancer patient's quality of life.

The concept proposal will be reviewed by selected members of the CTRF board of scientific counselors. Investigators whose preliminary proposals are approved by the board will be invited to submit a formal application.

Preliminary applications may be submitted at any time. However, the board of scientific counselors recommends funding twice yearly, in April and November.

Research Fellowships Offered By AACR; Deadline Feb. 14

The American Association for Cancer Research has six research fellowships for clinical and postdoctoral fellows in 1997:

The Research Fellowships in Clinical and Translational Research, sponsored by Bristol-Myers Squibb Oncology and by Amgen Inc.; the Research Fellowship in Prevention, sponsored by the Cancer Research Foundation of America; the Research Fellowships in Basic Research, sponsored by the Sidney Kimmel Foundation for Cancer Research and Hoechst Marion Roussel; and an additional Research Fellowship sponsored by AACR.

The purpose of these awards is to foster meritorious clinical, translational and basic research by scientists at the beginning of their careers in the cancer field. Each fellowship will provide a one-year, \$30,000 grant. No indirect costs are provided.

Candidates must have obtained a medical or other

doctoral degree. They must currently be clinical or postdoctoral fellows, and must have been fellows for at least two years but not more than five years prior to the beginning of the award year (July 1997).

Candidates must be U.S. or Canadian citizens working at a academic facility, teaching hospital, or research institute in the U.S. or Canada. Applicants need not be members of AACR to apply.

Application deadline is Feb. 14.

Inquiries: Jenny Anne Horst-Martz, AACR, tel: 215-440-9300.

April Cancer Meetings Listed

Diagnosis and Treatment of Neoplastic Disorders—April 3-4, Baltimore, MD. Contact Program coordinator, Johns Hopkins CME office, tel: 410-955-2959, fax: 410-955-0807.

Management of Cancer & AIDS Pain: Challenges and Opportunities Within a Changing Health Care Environment—April 4-5, Memorial Sloan-Kettering Cancer Center, New York City. Contact Myra Glajchen, tel: 212-639-2097.

National Consortium of Breast Centers Inc. Annual Meeting—April 4-6, Orlando, FL. Contact NCBC, tel: 219-267-8058, fax: 219-267-8268.

Nuclear Oncology: From Genotype to Patient Care—April 7-9, Baltimore, MD. Contact Program coordinator, Johns Hopkins CME office, tel: 410-955-2959, fax: 410-955-0807.

International Symposium on Recent Advances in Hematopoietic Stem Cell Transplantation—April 10-12, San Diego, CA. Contact CME office, University of California, San Diego, tel: 619-534-3940, fax: 619-534-7672.

Skeletal Complications of Malignancy—April 19-20, NIH Natcher Conference Center, Bethesda, MD. Contact The Paget Foundation, tel: 212-229-1582, fax: 212-229-1502, email: pagetfdn@aol.com.

Biennial Symposium on Minorities, the Medically Underserved and Cancer—April 23-27, Washington, DC. Contact Ruth Sanchez, tel: 713-798-5383, fax: 713-798-3990.

UNC Lineberger Comprehensive Cancer Center Annual Symposium—April 30-May 1, Chapel Hill, NC. Contact Sarah Rimmer, tel: 919-966-2997.