NCI Chips In $2 Million For AACR Meeting; Advisors, Senior Staff Not Consulted

NCI has agreed to provide $2 million to help the American Association for Cancer Research pay for its annual meeting next month, The Cancer Letter has learned.

Institute officials appear to have circumvented the procedures generally used for reviewing expenditures of this size. Two advisory boards that are consulted in such cases—the National Cancer Advisory Board and the Board of Scientific Advisors—were not informed of the decision, sources said.

Even the NCI Executive Committee, which includes the Institute’s top officials, was not involved. The plan for the $2-million expenditure

In Brief:

Hendrix To Head Children’s Memorial Institute; DOD Funds 17 Ovarian Cancer Research Grants

MARY HENDRIX was named president and director of Children’s Memorial Institute for Education and Research at Children’s Memorial Hospital, Northwestern University, said Patrick Magoon, president and CEO of Children’s Memorial Medical Center, and Kirk Johnson, chairman of the board of the research institute. Hendrix is head of the Department of Anatomy and Cell Biology at the University of Iowa and deputy director of the Holden Comprehensive Cancer Center. She holds a MERIT award from NCI. In May, she was appointed by HHS Secretary Tommy Thompson to the National Advisory Council for Human Genome Research. . . . DEPT. of DEFENSE Ovarian Cancer Research Program announced the funding of 17 research proposals. The Congressionally Directed Medical Research Programs received $10.2 million from Congress to fund peer-reviewed ovarian cancer research. Two funding mechanisms were offered: the Idea Development Award mechanism and the Institutional Training Grant award. One ITG was funded at Massachusetts General Hospital to provide structured mentoring to trainees who will become independent researchers in ovarian cancer. The faculty participating in the training program span all of the major institutions and hospitals in the NCI-designated comprehensive cancer center that includes Massachusetts General Hospital, Dana Farber Cancer Institute, Brigham and Women’s Hospital, Beth Israel Hospital, New England Deaconess Hospital, the Harvard School of Public Health and Harvard Medical
NCI Declines To Reveal Funding Mechanism
(Continued from page 1)

was presented as an “informational item” at the committee’s meeting June 12, sources said. Discussion was not invited.

The Executive Committee was not told what mechanism—such as a grant or a contract—would be used to transfer the funds, which programs might be cut as a consequence, and what the government expects to get in return. The committee meetings are closed.

An NCI spokesman confirmed that the Institute will help pay for the AACR meeting, but declined to discuss the matter further. “We are definitely contributing to the meeting, but the exact amount is not known yet,” said Caroline McNeil, acting director of the NCI Mass Media Office.

Institute Director Andrew von Eschenbach was traveling in Italy and unavailable for comment, McNeil said.

Margaret Foti, AACR chief executive officer, said NCI officials told her that funds will be disbursed through a contractor, who will pay a portion of the bills related to the AACR meeting. The amount of funding is “still under discussion,” she said.

If NCI is acting through a contractor, it’s likely that the money is coming from funds set aside for support services, sources said. Government agencies frequently “park” extra funds with contractors.

Often, this is done at the end of the fiscal year, to allow the agencies to avoid having to turn over unused funds to the Treasury. Contractors can hold parked funds for as long as five years, paying the agency’s bills, purchasing various services, and even conducting research.

The NCI Director’s Reserve is another mechanism that could have been used. The reserve, about 1 percent of the NCI budget, is set aside at the beginning of the fiscal year, to be spent at the director’s discretion for internal needs or as supplements to grants.

Last April, AACR suffered a financial loss that could run into millions of dollars. Two days before the society's annual meeting was to have opened in Toronto, its leadership became concerned about the SARS outbreak in that city, and called off the meeting.

At that time, neither the World Health Organization nor the Centers for Disease Control and Prevention had issued travel advisories for Toronto. However, at least one cancer center—Memorial Sloan-Kettering—advised its clinicians either to cancel travel to Toronto, or to avoid contact with patients for 10 days after returning (The Cancer Letter, April 4).

AACR expected to make about $1 million on the Toronto meeting. Instead, the society has incurred bills of $5 million to $6 million, Foti said. An insurer has denied the association’s claim, and the bills are yet to be paid, she said.

About 16,000 cancer researchers were projected to attend the Toronto meeting. The association rescheduled the annual meeting for July 11-14, in Washington, D.C. About 8,500 have registered to attend.

Foti acknowledged having met with von Eschenbach in April to seek help. “I went to see him to get his advice and counsel, and ask if there would be some opportunity for special support under these circumstances,” she said.

However, Foti said she didn't know about the NCI decision until contacted by a reporter.

“The NCI, and especially the director, to whom we are very indebted, saw the benefits of holding the rescheduled meeting and knew that we couldn’t hold this meeting without this gesture,” Foti said. “We are grateful to the NCI for helping us in these unusual circumstances. The cancellation of this meeting was devastating to the AACR. The ability to reschedule it, and actually have the NCI make a commitment...
for a significant level of support for this meeting, was a dream.”

Foti said she and von Eschenbach “discussed the fact that no other organization presents such high-quality cancer research at its meeting, and that there was an enormous number of presenters who were scheduled to present in Toronto, and even considering at that time the notion that there might be almost 5,000 or so proffered papers that needed to be presented.”

AACR operates on a $30 million budget, and has a reserve fund of $12 million, Foti said. The loss of up to $6 million on the Toronto meeting and the $5 million cost of the Washington meeting would have drained the reserve, Foti said.

“If we do not recoup these funds, it’s a setback, but not irrevocable,” Foti said. “It’s not going to affect the viability of the AACR, but could mean we have to be more conservative about launching new programs in response to the information needs of the cancer community.”

Foti’s remarks earlier this week are consistent with those she made in April, after the cancellation of the meeting. At that time, too, Foti said that she consulted von Eschenbach “and other people at NCI” prior to making the decision to cancel, and that von Eschenbach supported the association’s decision to reschedule the meeting (The Cancer Letter, April 4).

“I’ve talked to Dr. von Eschenbach about that, and he agrees that we must work very hard to reschedule this meeting as soon as possible, given the importance of the AACR annual meeting to the cancer program,” Foti said in an interview in April.

Asked by a reporter whether that meant NCI would provide funding for the meeting, Foti said, “I don’t know yet. I think that we will certainly discuss that.”

AACR Emerged As Ally of NCI’s 2015 Goal

AACR is a key supporter of von Eschenbach’s goal to “eliminate the suffering and death from cancer” by 2015.

Achieving that goal will require new research on interventions to interrupt the “cancer process,” von Eschenbach has said (The Cancer Letter, June 13).

Last year, AACR proposed that pre-cancers, or “intraepithelial neoplasia,” be recognized as surrogate endpoints for the formation of many common cancers.

Designating the eradication of IEN lesions as a medical outcome would accelerate clinical trials of new agents for the prevention of cancer, AACR said in a position statement. Trialists would not have to wait to measure survival, AACR said (The Cancer Letter, May 30).

The approach is controversial, because little is known about pre-cancers and the risks they convey. From what is currently known, it appears that only a small percentage of pre-cancers progress to cancer, skeptics say.

The scientific literature contains many examples in cancer, heart disease, diabetes, and other diseases, where interventions to address a surrogate endpoint did not ultimately result in better or longer life. In many cases, interventions resulted in harm.

Therefore, many clinicians argue, the science is insufficient to declare IEN a medical endpoint, and taking this short-cut may result in unnecessary, harmful, and expensive treatment.

Anna Barker, the new NCI deputy director for strategic scientific initiatives and a longtime AACR activist, has championed the recognition of IEN as an endpoint.

“I think the [AACR] IEN report was a landmark report,” Barker said to The Cancer Letter last month. “It drew on the expertise of the community to put together what I think is a very cogent argument for looking at and evaluating potential chemopreventive agents. I think it sets the stage for putting science in perspective in terms of how you might be able to look at chemopreventives. It’s a new paradigm.”

An “Informational Item”

The decision to provide money to AACR stunned some NCI officials.

“There was a deal made,” one staff member said to The Cancer Letter. “You would think that expenditures that high would go to a board. We are tight on funds.”

Senior NCI officials first learned about the $2 million transfer from NCI Deputy Director Alan Rabson at the June 12 meeting of the Executive Committee, sources said.

The committee includes the Institute’s division directors, and is led by von Eschenbach. The committee’s purpose is to formulate scientific and management policy decisions, review concepts for grant and contract programs, and approve exceptions to grant funding plans.

After one committee member raised questions,
Rabson replied that the decision to commit money to AACR was being presented as an “informational item,” and was not subject to discussion, sources said. The committee was not told how the funds would be provided to AACR, sources said.

The AACR meeting subsidy would set a record for NCI conference support, sources in the Institute said. NCI funds peer-reviewed conference grants (R13s) in the range of $5,000 to $15,000. For example, NCI is funding a $10,000 conference grant to AACR for its Conference on Mouse Models of Human Cancer, according to an NCI grants database.

The decision to fund the AACR conference did not come up for discussion at the June 10 NCAB meeting, either in public or closed sessions, sources said.

The NCAB, whose members are appointed by the President, is responsible for final external review of all grant applications to NCI, with the exception of those seeking less than $50,000 in direct costs per year.

The NCI Board of Scientific Advisors, another group not consulted, reviews concepts for grant and contract programs and counsels the Institute on scientific program policy.

150 Free Registrations For NCI

Earlier this week, AACR gave NCI staff 150 free passes to the annual meeting. “The American Association for Cancer Research has granted the NCI additional registration passes to send NCI staff to their annual meeting,” Kathleen Schlom, special assistant to von Eschenbach, wrote in an internal email dated June 16.

“These will be distributed to the divisions based on the percentage of registrants enrolled,” Schlom wrote. “These free registration passes are not to replace existing registrations, but to supplement division attendance.”

The government normally pays the AACR meeting registration fees for NCI staff. The registration fee ranges from $425 for AARC members to $725 for non-members.

McNeil said 500 NCI staff had registered for the AACR meeting in Toronto.

“We did receive an offer from AACR and we looked into it, and NCI can accept it under our gift authority,” McNeil said.

Government ethics regulations include provisions allowing employees to accept free meeting attendance from meeting sponsors if the gift is unsolicited, and if proper procedures are followed, a spokesman for the Office of Government Ethics said. The gift can be accepted either by the employee personally or by the agency under its gift acceptance authorities.

“We thought, since it would be so convenient with the meeting in Washington, D.C., it would be nice to offer complementary registration to those [NCI staff] who had not been able to come to Toronto, to facilitate the participation of more NCI scientists,” Foti said. “As you know, our NCI colleagues, their salaries are not very high, and they need help, and so we are trying to help them. We wanted additional people to attend, because of the importance of the science of the meeting.”

What $2 Million Can Buy

The Institute’s action comes at a time when legislators are examining the outcome of the doubling of the NIH budget between 1999 and 2003 and questioning the value of continuing increases.

The House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor, and Pensions are gathering information about the NIH doubling, possibly preparing oversight hearings.

Though $2 million is a small share of NCI’s $4.6 billion budget, it can buy a lot of peer-reviewed research. Alternative uses could include a core grant for an NCI-designated cancer center, eight cancer center planning grants, eight Community Clinical Oncology Program grants, two large Special Population Network grants, or half of the annual budget of a cooperative group biostatistical center.

Other uses could include:

—Accrual of 1,000 patients to cooperative group trials, enough for a definitive phase III study. The budgets of the cooperative groups are being held flat this year.

—Three national tissue repositories operated by the cooperative groups. Though “genomics and proteomics” have become NCI buzz words, the Institute leadership this year declined to provide additional funding for the tissue banks, which are becoming increasingly important for genomic studies.

—Five investigator-initiated R01 grants. By accepting these funds, AACR is, in effect, competing with investigators at a time when the number of grant applications being submitted to NCI is exceeding the Institute’s ability to fund them.
“I’m always concerned about funding for cancer research,” Foti said. “We spend a lot of our time trying to increase funding for cancer research, and we are always anxious to increase that number. However, I’m assuming that, in fact, this won’t interfere with the monies that are going to grants, but I don’t have any information on that.”

NCI received an increase of $415 million for fiscal 2003. Half of the increase has been committed to research project grants, von Eschenbach said to the NCAB last week. NCI will fund 4,813 research project grants, 325 more grants than last year.

“We are continuing to see a constant expansion in the number of applications that are coming to the NCI,” he said.

This year, NCI will fund only the top 20 percent of R01 applications. Last year, R01s were funded to the 22nd percentile.

Funding increases for NCI are unlikely to remain in double-digits, observers say. President Bush proposed an increase of 3.5 percent, or $161 million, for NCI next year.

Addressing NCAB last week, von Eschenbach said researchers should prepare for leaner times.

“You can begin to see that going from 2003 to 2004, we will be looking at a significant reduction in the increase,” von Eschenbach said. “We are looking at that quite closely from a strategic point of view to decide appropriate strategies to accommodate that, including the fact that our budget has ongoing out-year commitments that we need to be sensitive to.

“But, we do believe that we have significant opportunity for those resources to be used in effective and creative ways, particularly looking at opportunities to leverage, opportunities for partnerships and collaborations,” he said.

**FDA News:**

**Rule Limits Drug Pioneers To 30-Month Patent Extension**

FDA has published a “final rule” that will make it easier for generic drugs to get on the market. Pioneer drug companies will be limited to one 30-month stay to resolve patent disputes with generics.

The new rule clarifies the legal ambiguity that allowed some pharmaceutical companies to obtain repeated 30-month extensions.

The regulation also notes the types of patents that are eligible for listing in the Orange Book, a register of approved pharmaceutical products. Claims related to packaging, intermediates, and metabolites are made ineligible for listing. The changes echo recent recommendations by the Federal Trade Commission.

Also, the agency said it will streamline procedures for reviewing Abbreviated New Drug Applications.

“The changes in the regulations alone will save consumers an estimated $35 billion over 10 years by making generic alternatives to certain more costly brand-name drugs available more quickly by avoiding time-consuming legal delays,” the agency said in a statement.

The 128-page text of the new rule is available at [www.fda.gov/OHRMS/DOCKETS/98fr/02N-0417-nfr00001.pdf](http://www.fda.gov/OHRMS/DOCKETS/98fr/02N-0417-nfr00001.pdf)

The announcement is part of the Administration’s emphasis on generic drugs. The President’s budget proposal for fiscal 2004 includes...
a $13 million increase for the FDA generic drug program, the largest one-year increase ever proposed for the program.

The increase in the FDA generics budget would allow FDA to hire 40 experts for the program, the agency said.

“Americans deserve greater access to affordable, safe, and effective medications,” FDA Commissioner Mark McClellan said in a statement. “Helping patients get lower-cost generic medicines, once the appropriate patent protection has expired, is therefore one of our major priorities. Our new rule and our new procedures are important steps in making more generic drugs available more quickly.”

To provide additional guidance for sponsors of the generics, the agency will institute a system of early communications with these sponsors. Generics have been lobbying FDA for more guidance prior to the time their ANDAs are being considered, the agency said.

The addition of staff and streamlining of the process will reduce the approval time for most generics by three months over the next three to five years, the agency projects. FDA will undertake more studies of bioequivalence, and will enhance monitoring of the safety of generic drugs on the market.

Also, the agency said it will expand its educational programs and partnerships involving generic drugs. The regulations were published in the Federal Register on June 18, and will go in effect on Aug. 18.

The FDA rule is different from an effort by Senate to change the 1984 Hatch-Waxman law. Last year, a similar bill was passed overwhelmingly in the Senate, but was killed in the House. Now, the effort to rewrite Hatch-Waxman includes Sen. Judd Gregg (R-NH), chairman of the Health, Education, Labor and Pensions Committee, who opposed the previous version of the bill.

The Pharmaceutical Research Manufacturers of America, which represents pioneer drug companies, has opposed the new legislation and has not taken a position on the FDA rule.

“The current Hatch-Waxman law works well,” Alan Holmer, PhRMA president said in a statement. “The new FDA rule revising Hatch-Waxman requirements is lengthy and complex, and we are studying it closely. We need to be sure that the rule clarifies current law in a way that supports continued development of new and better medicines that patients need.”

Institute of Medicine: External Experts Should Vet Large Projects, Report Says

Before NIH launches any new large-scale projects, the Institutes should appoint a panel of external experts to assess the potential of proposed studies, according to a report by the Institute of Medicine of the National Academies.

The report describes for the first time how NIH and other federal agencies should select, fund, launch, and evaluate large, collaborative biomedical projects, and how their scientific staff should be trained and retained.

“A large-scale approach is relatively new in the life sciences, so there are very few precedents to follow or learn from when planning and launching a new project of this magnitude,” said Bruce Stillman, vice chairman of the committee that wrote the report and director of Cold Spring Harbor Laboratory. “With the recent completion of the Human Genome Project, it is now time to reflect and determine the best and most efficient ways to perform such endeavors.”

Biomedical research in the future is likely to involve larger teams of scientists working on complex problems that cannot be addressed by single researchers. Large projects might reduce the pool of money available for smaller studies. Because the process of appropriating federal funds is “both complex and treacherous,” the report said, NIH should establish guidelines supporting both types of projects.

The success of large, collaborative biomedical projects will depend on attracting high caliber staff, the report said. Recruiting might be difficult, because traditional career paths for scientists require them to build a reputation based on an individual publication record. To provide more incentives for scientists to work on large projects, universities could revise their policies on tenure and promotion to recognize the value of contributions made to collaborative research, the report said.

To increase the speed of discoveries and reduce the overall cost of future large-scale projects, the report recommends that academic scientists collaborate more frequently with pharmaceutical and biotechnology companies and nonprofit organizations.

One recent example of effective collaboration between the academic and industrial sectors is the Single Nucleotide Polymorphism Consortium—a public-private effort looking for DNA variations
Funding Opportunities:

Lustgarten Foundation Request for Proposals

Applications Receipt Date: Oct. 3

The Lustgarten Foundation for Pancreatic Cancer Research is funding one-year grants of up to $100,000 for research into the biology; diagnosis; treatment modalities, including active, palliative and supportive; and prevention of adenocarcinoma of the pancreas. National and international applications will be considered. Funding will commence January 2004.

Applications are available from the Web site at www.lustgartenfoundation.org or by contacting The Lustgarten Foundation, 1111 Stewart Ave., Bethpage, NY 11714, phone 516-803-2304, fax 516-803-2303.

RFAs Available

RFA CA-04-008: Community Clinical Oncology Program

Application Receipt Date: July 14

NCI Division of Cancer Prevention invites domestic institutions to apply to the CCOP, which 1) provides support for expanding the clinical research effort in the community setting; 2) stimulates quality care in the community through participation in protocol studies; 3) promotes the growth and development of a scientifically viable community cancer network able to work closely with NCI-supported clinical cooperative groups and cancer centers; 4) supports development of and community participation in cancer prevention and control intervention research, which includes chemoprevention, biomarkers and early detection, symptom management, quality of life, rehabilitation, and continuing care research; 5) involves primary care providers and other specialists in cancer prevention and control clinical trials; and 6) increases the involvement of minority and underserved populations in clinical research.


Inquiries: Lori Minasian, chief, Community Oncology and Prevention Trials Research Group, DCP, NCI Executive Plaza North-Rm 2017, 6130 Executive Blvd., MSC-7340, Bethesda, Md., 20892-7340; phone 301-496-8541; fax 301-496-8667; e-mail lm145a@nih.gov.

RFA OD-03-007: Human Subjects Research Enhancements Program

Application Receipt Date: July 11

The initiative provides short-term interim support for institutional activities that will strengthen oversight of human subjects research at institutions that receive NIH support for clinical research.

Letter To the Editor:

Prevention Research Requires Rigor And Collaboration

To the Editor:

That most of the May 30 issue of The Cancer Letter was dedicated to the subject of prevention is testament to its increasing emphasis among cancer researchers and physicians. Whether IEN is a useful endpoint for prevention strategies is a matter of healthy scientific debate and one of many prevention research areas that should be pursued. In fact, this year ASCO established a standing committee on cancer prevention to address the growing number of scientific and policy issues around this important topic.

For those who are at risk of developing cancer, prevention is of utmost importance. Not only is this a highly promising area of inquiry, but it is also one that requires rigor and collaboration across the cancer community to realize its potential. ASCO looks forward to working with AACR, NCI, FDA, industry, and the patient advocate community to design studies that will answer many of the questions the article raised.

Margaret Tempero
ASCO President

Bernard Levin
Chairman, ASCO Cancer Prevention Committee

among individuals in order to improve treatment of human disease, the report said.

Although research tools and data derived from large-scale projects should be widely available to scientists, NIH should develop guidelines that would allow researchers to preserve intellectual property rights, the report said. Also, because concerns have been raised in recent years about scientists’ willingness and ability to share information and research materials, NIH should provide funds to facilitate the dissemination of these tools.

Federal agencies should evaluate large-scale projects and have a plan to phase out funding when the goals have been achieved. In the vast majority of cases, the report adds, such projects should not entail establishing longer-term infrastructures such as institutes or centers at NIH.

A total of 16 Idea Development Awards were funded at the following institutions: Baylor College of Medicine; Temple University School of Medicine; University of California, San Diego; M.D. Anderson Cancer Center; University of Texas; Stanford University; Tulane University; University of Chicago; University of Arkansas for Medical Sciences; Fox Chase Cancer Center; Wright State University; Mount Sinai School of Medicine; Morehouse School of Medicine; and Pennsylvania State University. Milton S. Hershey Medical Center. . . . ROSWELL PARK Cancer Institute Division of Cancer Prevention and Population Sciences received grants totaling $1.6 million for tobacco and smoking related research. K. Michael Cummings, chairman, Department of Health Behaviors, received a grant of $800,000 for his project to expand public access to 20 million pages of previously secret documents from the Tobacco Institute. Andrew Hyland, Department of Cancer Prevention, Epidemiology & Biostatistics, received a grant of $550,524, to conduct three projects on recalcitrant smokers, harm reduction and the hardcore smoker, and the effect of product information on smoking behavior. The grants were funded by the American Alliance Foundation of Washington, DC. The Flight Attendant Medical Research Institute awarded a three-year, $343,591 grant to Martin Mahoney, chairman, clinical prevention, Division of Cancer Prevention and Population Sciences, on the effects of tobacco related public policy. . . . ROSWELL PARK made the following appointments to its Department of Cancer Genetics, said John Cowell, department chairman. Nicoletta Sacchi was appointed distinguished member. She was associate professor of molecular genetics, University of Milan, Italy, with a joint visiting faculty appointment at the Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins. Sacchi will participate in the Cancer Genetics Program and the Breast Cancer Translational Program at RPCI. Andrei Bakin, assistant member, was assistant research professor, Department of Medicine, Vanderbilt University School of Medicine. Irwin Gelman, associate member, was director of virology research and research associate professor, Department of Medicine, Division of Infectious Diseases, Mount Sinai School of Medicine. Keshav Singh, associate member, was assistant professor of oncology and environmental health, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University School of Medicine. . . . SCOTT WHITAKER, assistant secretary for legislation at HHS, was appointed chief of staff to HHS Secretary Tommy Thompson. . . . NCI DIRECTOR Andrew von Eschenbach discusses what it is like for a physician to become a patient, in an online book chapter. His comments are available at www.ConversationsInCare.com.
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