THE CANCER LETTER

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NCI Director Declines To Fund P-4 Breast Cancer Chemoprevention Trial

By Kirsten Boyd Goldberg

NCI Director John Niederhuber decided not to fund the P-4 STELLAR breast cancer prevention trial proposed by the National Surgical Adjuvant Breast and Bowel Project.

In a letter dated June 19, Leo Buscher Jr., the chief grants management officer at NCI, informed the cooperative group that Niederhuber "has determined, after receiving considerable community input—both scientific and public—and after much deliberation, that the numerous scientific concerns about the P-4 trial are sufficiently formidable that the NCI will not commit to the funding of this particular trial."

Niederhuber acted five days after a subcommittee of the National Cancer Advisory Board said it couldn't "offer strong endorsement" for funding the trial, which would randomize 12,800 healthy women at high risk of developing breast cancer to either letrozole or raloxifene for five years (The Cancer Letter, June 15).

The decision wasn't a surprise to proponents or opponents of the study. The trial passed all available NCI peer review, but since last fall, Niederhuber

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Panel Calls For New Office, Advisory Groups To Oversee NCI's Translational Research

By Kirsten Boyd Goldberg

An advisory group to NCI has recommended far-reaching changes to the way the institute supports translational research.

In a report to the National Cancer Advisory Board released June 15, the Translational Research Working Group recommended steps the institute should take to improve the coordination, management, and prioritization of translational research, including the establishment of new advisory committees and funding programs.

The changes would cost NCI $94 million over five years, the report estimated.

"NCI-supported translational research enterprise is not keeping pace with the enormous opportunities presented by advances in knowledge and technology over the past 40 years of cancer research," the report said. "Based on these opportunities, public expectations for significant advances in cancer prevention, treatment, and care are rising, yet resources devoted to cancer research have reached a plateau.

"Given this climate, the TRWG asked how NCI could best ensure

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NCI Director Instituted Unusual Multiple Reviews For P-4 Trial

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subjected it to unprecedented, additional examination that the study's supporters say appeared to be designed to kill it. Supporters also point out that Niederhuber's top-priority program, the $9 million NCI Community Cancer Centers, has not gone through formal peer review, and is being funded through a subcontract with SAIC, the contractor for NCI-Frederick.

After P-4 passed standard levels of review, Niederhuber sent it to the Clinical Trials Operating Committee, a group of NCI staff, which also voted to approve it. He then asked the NCI Executive Committee—which had previously approved the trial—to look at it for a second time.

After the Executive Committee voted 8-2 for approval, with Niederhuber and Deputy Director Anna Barker casting the two nay votes, the NCI director blocked the trial from proceeding and asked for further review by external advisors. Barker formed an ad hoc panel to meet in closed session to discuss the study (The Cancer Letter, March 2 and April 20).

Niederhuber said the extra review was needed because of the trial's cost over 10 to 13 years and questions about whether the results would be made irrelevant by trials of newer prevention agents. "Will anyone really care about the answer?" he said in an interview (The Cancer Letter, March 2).

The report of the P-4 Chemoprevention Trial Assessment Group was presented publicly on June 14 by a three-member subcommittee of the NCAB, but has not been posted on NCI's web site. The report provided a mixed review of the study, but the three NCAB members who presented it said they opposed going forward with the trial.

In May, Sen. Arlen Specter (R-Penn.) wrote a letter to Niederhuber seeking an explanation for the trial's delay (The Cancer Letter, May 25). Specter hasn't spoken publicly about Niederhuber's decision, a spokesman said.

The Pittsburgh-based NSABP said its investigators and participants in previous breast cancer prevention trials have sent about 2,000 letters to members of Congress and others to advocate for the trial.

The study, submitted as a grant application to NCI more than a year and a half ago, received strong support from the NCI Division of Cancer Prevention, which was prepared to fund the trial through its Community Clinical Oncology Program.

DCP Director Peter Greenwald was outspoken in his support of the trial, telling the NCAB last week that it should be "a top priority of NCI," because it is possible that letrozole could provide a substantial benefit over raloxifene in preventing breast cancer. Other approaches, such as finding biomarkers to identify women at higher risk than can be determined using current models, and then testing drugs in those women, will take "many, many more years" than the P-4 trial, he said.

Supporters and detractors of the trial offered conflicting estimates of its cost and duration. Niederhuber has said the study would cost "in excess of $100 million" and take a total of 10 to 13 years. NSABP officials said the study would cost NCI $54 million for the first five years, and could have an answer within seven years. Greenwald told the NCAB that "without knowing the result" of the study, any estimate of the cost of the trial beyond the first five years is suspect.

The sponsors of the drugs, Novartis and Eli Lilly, were providing the pills for free, and Novartis had agreed to provide an additional $30 million.

NSABP Chairman Norman Wolmark said the cooperative group is "exploring all other options" for possibly going forward without NCI funding.

"We were saddened and very concerned by Dr. Niederhuber's decision to cancel funding for NSABP protocol P-4," Wolmark said to The Cancer Letter. "This decision will have far-reaching and long-term consequences jeopardizing the feasibility of large-scale breast cancer prevention trials in the United States. It has taken many years to create the infrastructure necessary

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to carry out trials like P-4, and that infrastructure will be significantly degraded by this action. I very much doubt the cost to rebuild that infrastructure was factored into the decision to cancel P-4.

"We are perturbed by statements that have cast doubt regarding P-4's scientific integrity and validity," Wolmark said. "The seven NCI committees that approved this trial, including the NCI Executive Committee, would not have done so unless they were completely satisfied with P-4's scientific integrity and validity, and its importance in enhancing knowledge and understanding regarding breast cancer prevention. We appreciate the endorsement of P-4 by the seven NCI committees that approved this trial prior to the director's unprecedented intervention. We also appreciate the thousands of women who wrote letters in support of P-4 and believe, as we do, that a critically important public health opportunity has been lost.

"In the end, the real casualties in the cancellation of P-4 are the countless women at high risk for developing breast cancer, and the more than 33,000 women who selflessly participated in NSABP P-1 and P-2 breast cancer prevention trials to help advance knowledge and understanding regarding breast cancer prevention," Wolmark said. "The cancellation of P-4 eliminates the most significant avenue currently available for reducing the incidence of breast cancer, and undermines efforts to make the most productive use of the important information on breast cancer prevention that was gained from NSABP Protocols P-1 and P-2."

The National Breast Cancer Coalition, based in Washington, D.C., said it supported Niederhuber's decision. "I think it's a courageous decision," NBCC President Fran Visco said to The Cancer Letter. "We truly believe it's a step in the right direction toward figuring out how best to allocate funding for breast cancer research. Secondly, we don't have a good way of really assessing who is at risk for breast cancer and how to determine which individuals should be given drugs, if any."

Breast Cancer Action, an advocacy group based in San Francisco, also said it opposed the study. "We are concerned that pills to 'prevent' breast cancer will always result in disease substitution," said Barbara Brenner, executive director of the organization. "NCI Director Niederhuber has today put public health first, protecting many women from the potentially dangerous side-effects of powerful drugs. We applaud his decision."

Pat Halpin-Murphy, president and founder of the Pennsylvania Breast Cancer Coalition, said her group strongly opposed Niederhuber's decision.

"The concern of the Pennsylvania Breast Cancer Coalition is that is that a very scientifically solid prevention trial for high risk women that has been in the planning and approval stages for several years has been abruptly bought to an end, and those high risk women who want to have an option for preventing breast cancer are going to be very disappointed, because letrozole showed promise of a higher success rate of up to 70 percent in high risk women," she said. "High-risk women want to have an option. We are very disappointed and surprised, because this prevention trial was encouraged and supported and rated very highly by the NCI until the new director at the 23rd hour put a stop to it."

Halpin-Murphy, who works as government relations director for the American Federation of Teachers in Pennsylvania, said concerns about risk assessment shouldn't have prevented the trial from going ahead. "The Gail model has been widely accepted as a way of indicating a woman's risk level, and for those who would like to develop a more refined measure, we would encourage them to do that," she said. "We hope that ultimately there will be biomarkers that will be more definitive, but to stop a very promising prevention trial until they get better predictors, we think is short sighted."

NCI Letter to NSABP

Following is the text of NCI's letter to NSABP, referencing the grant applications 2 U10 CA035447-22 and 2 U10 CA069974-12. The letter was addressed to Joan Beyer Goldberg, CEO of the NSABP Foundation, and Allen DiPalma, director of the Office of Research at University of Pittsburgh:

The purpose of this letter is to inform you that the Director of the National Cancer Institute (NCI) has determined, after receiving considerable community input—both scientific and public—and after much deliberation, that the numerous scientific concerns about the P-4 trial are sufficiently formidable that the NCI will not commit to the funding of this particular trial, included in the grant applications referenced above.

This decision was made after very careful consideration of the facts presented by supporters and detractors of the study, along with input from members of the National Cancer Advisory Board (NCAB). This specific trial was weighted in the context of the field of chemoprevention and in context of the full body of cancer research. There is much that is already being studied with the classes of agents proposed for this

study, and those results will further our knowledge and understanding of these drugs and the mechanisms by which they work. While the P-4 study may provide another possible option for women at risk of breast cancer, the dangers of introducing these drugs, with their many known side-effects, outweighs their potential until we are better able to determine who will benefit from these interventions and what the longer term effect may be.

NCI is committed to working across the research community to address these concerns and to advance the field of cancer prevention. Like targeted treatment, targeted chemoprevention must rely on individual genomic and proteomic signatures to identify those patients for whom the risk-benefit ratio justifies using a chemopreventive drug. NCI will continue to have a strong commitment to cancer prevention and will continue to search for ways in which such patients can be provided highly personalized approaches to prevention that are appropriate for their level of risk, thus minimizing long term side-effects and ensuring good quality of life. We will utilize all aspects of molecular biology and genetics to improve individual cancer risk assessment through the development of new tools and new cancer prevention strategies to offer options that do not ask otherwise-healthy people to trade cancer risk for the increased risk of other serious health conditions.

Since the funding for P-4 will not continue with the award of the competitive renewals referenced above, all current work on preparations for the P-4 trial should end and any funds remaining for P-4 work in the current years of these grants should be listed as an unobligated balance when the FSRs are filed for 5 U10 CA35477-21 and 5 U10 CA69974-11 respectively.

Translational Research Needs Better Oversight, Report Says

(Continued from page 1)

that the most promising basic research concepts enter the developmental pathways and are advanced rapidly and efficiently either to translational success or to a productive failure that usefully informs further translational or discovery research."

The TRWG defined translational research as "research that transforms scientific discoveries arising in the lab, clinic, or population into new clinical tools and applications that reduce cancer incidence, morbidity, and mortality."

The working group found that NCI supports an estimated $1.33 billion in translational research, or 30 percent of the institute's $4.4 billion budget. The research is supported by a wide variety of programs managed through all NCI divisions, centers, and offices.

The group identified four "critical objectives" for a translational research enterprise:

—Improve coordination and collaboration, and instill a culture of active, goal-oriented management for both individual projects and the enterprise as a whole.

—Improve identification of the most promising early translational research opportunities across all disease sites, populations, and pathways to clinical goals through a transparent, inclusive process involving all relevant stakeholders and driven by: a) the strength of the scientific rationale, b) the technical feasibility of the development approach, c) the expected clinical or public health impact, and d) the risk that the opportunity would not be taken forward by industry.

—Tailor new and existing funding programs to facilitate early translational research progress and incentivize researcher participation.

—Enhance the operational efficiency and effectiveness of early translational research projects and the many supporting activities essential to the enterprise, including the participation of patients and advocacy groups.

"Implementing these changes will require a strong, committed effort by all stakeholders as well as a modest, focused financial investment," the report said. "But this investment of both time and money is well justified to ensure that the much larger ongoing national investment in early translational research achieves the goal of moving important discoveries more effectively toward successful human testing.

"By embracing these initiatives, NCI and the cancer early translational research community will enhance the nation's effectiveness and competitiveness in meeting the needs and opportunities of cancer research as it evolves into a global priority," the report said. "Perhaps more importantly, the NCI's commitment to these initiatives will also demonstrate a strong dedication to harnessing the advances in cancer biology achieved through the last 40 years of research progress for patient and public benefit."

More extensive oversight would require new advisory structures at NCI , the report said. The report recommended that NCI expand the membership of its new Clinical Trials Advisory Committee to include translational researchers, and rename the committee the Clinical and Translational Advisory Committee.

Second, NCI should form an internal Translational Research Operations Committee involving the

directors of all NCI divisions, centers, and offices with responsibility for translational research programs.

Third, NCI should establish a Translational Research Support Office within the new Coordinating Center for Clinical Trials and hire a director of this office who would have a "nationally recognized scientific reputation in translational research and experience managing organizations carrying out translational research," the report said. "The individual should also have experience with NCI operations, possibly through serving on NCI advisory committees."

Following is the report's list of proposed initiatives:

Coordinated Management:

—Establish a coordinated NCI-wide organizational approach to manage the diverse early translational research portfolio, reduce fragmentation and redundancy, and ensure that resources are focused on the most important and promising opportunities.

—Designate a specific portion of the NCI budget for early translational research to facilitate coordinated management, long-term planning, and prioritization among opportunities and approaches as well as to demonstrate NCI's commitment to translational research.

—Develop a set of award codes that accurately captures the nature and scope of the early translational research portfolio to enable a complete, shared understanding of NCI's total investment, help identify gaps and opportunities, and demonstrate the extent of translational activity to the public.

—Create a transparent, inclusive prioritization process to identify the most promising early translational research opportunities based on scientific quality, technical feasibility and expected clinical or public health impact.

Tailored Funding Programs:

—Modify guidelines for multi-project collaborative early translational research awards to focus research on advancing specific opportunities along a developmental pathway toward patient benefit, and to reward collaborative team science.

—Improve processes and mechanisms for review and funding of investigator-initiated early translational research to incentivize researchers to propose such studies.

—Establish a special funding program to advance a select number of especially promising early translational research opportunities identified through the newly created prioritization process.

—Establish a program for joint NCI/industry funding of collaborative early translational research projects that integrate the complementary strengths of both parties to pursue opportunities that are more attractive as a combined effort.

—Integrate access to GMP/GLP manufacturing and other preclinical development services more effectively with high-priority, milestone-driven early translational research projects to better address this often rate-limiting step in moving a product forward to early human testing.

Operational Effectiveness:

—Build a project management system involving staff both at NCI and at extramural institutions to facilitate coordination, communication, resource identification and access, and management of milestone-based progress for multi-disciplinary, early translational research projects.

—Coordinate core services essential for early translational research to reduce duplication and ensure that high quality services are readily accessible to all projects and investigators.

—Improve standardization, quality control and accessibility of annotated biospecimen repositories and their associated analytic methods to strengthen this key translational resource.

—Develop enhanced approaches for negotiation of intellectual property agreements and agent access to promote collaborations among industry, academia, NCI and foundations.

—Increase NCI interaction and collaboration with foundations and advocacy groups to capitalize upon their complementary skills and resources for advancing early translational research.

—Enhance training programs and career incentives to develop and maintain a committed early translational research workforce.

The TRWG was formed in June 2005 and included 62 members led by three co-chairmen: Ernest Hawk, director of the NCI Office of Centers, Training and Resources; Lynn Matrisian, the Ingram Distinguished Professor and Chair of Cancer Biology at Vanderbilt University; and William Nelson, professor of oncology, urology, pharmacology, medicine, and pathology at Johns Hopkins University and associate director of translational research at the Sidney Kimmel Comprehensive Cancer Center.

The report is available at http://www.cancer.gov/trwg/.

NCI Programs:

Community Cancer Centers Selected For Pilot Program

NCI announced it has funded a three-year pilot project intended to help bring state-of-the-art cancer care to patients in community hospitals in the U.S.

The NCI Community Cancer Centers Program would encourage collaboration among private-practice medical, surgical, and radiation oncologists, as well as with the 63 NCI-designated cancer centers, the institute said.

The pilot will begin at eight free-standing community hospitals and six other hospitals operated by health care systems. The sites will be funded for a collective total of $5 million per year. An internal NCI panel and an independent group of outside experts will set milestones, monitor progress, and evaluate success of the three-year pilot and then issue recommendations for a full-fledged program.

The NCCCP pilot sites will research ways to assist, educate, and better treat the needs of underserved populations, including elderly, rural, inner-city, and low-income patients, as well as racial and ethnic groups with unusually high cancer rates. The program will study how community hospitals nationwide could most effectively develop and implement a national database of voluntarily-provided electronic medical records accessible to cancer researchers. The sites will also study methods of expanding and standardizing the collection of blood and tissue specimens voluntarily obtained from patients for cancer research.

The program is being funded through a subcontract of SAIC, which holds the contract from NCI to operate the NCI-Frederick Research and Development Center in Frederick, Md.

NCI Director John Niederhuber advocated for the NCCCP when he served as acting director of the institute. The program was brought before external NCI advisory boards for comment, but didn't require approval, because the funding is through a subcontract.

"It is becoming clear that one of the greatest determinants of cancer mortality in the years ahead will be access to care," Niederhuber said. "This program will succeed if it can bring the benefits of our latest science to people in the communities where they live."

The hospitals, their locations, and their cancer centers are:

Billings Clinic, Billings, Mont. (Billings Clinic Cancer Center)

Hartford Hospital, Hartford, Conn. (Helen & Harry Gray Cancer Center)

St. Joseph's / Candler, Savannah, Ga. (Nancy N. and J.C. Lewis Cancer & Research Pavilion)

Our Lady of the Lake Regional Medical Center, Baton Rouge, La. (Our Lady of the Lake Cancer Center and Mary Bird Perkins Cancer Center)

Sanford USD Medical Center, Sioux Falls, S.D. (Sanford Cancer Center)

Spartanburg Regional Hospital, Spartanburg, S.C., (Gibbs Regional Cancer Center)

St. Joseph Hospital, Orange, Calif. (St. Joseph Hospital Cancer Center)

Christiana Hospital, Newark, Del. (Helen F. Graham Cancer Center at Christiana Care)

Ascension Health of St. Louis, Mo.

St. Vincent Indianapolis Hospital, Indianapolis, Ind. (St. Vincent Oncology Center)

Columbia St. Mary's, Milwaukee, Wis. (Columbia St. Mary's Cancer Center)

Brackenridge Hospital, Austin, Texas (Shivers Center)

Catholic Health Initiatives of Denver, Colo., will operate sites at:

Penrose-St. Francis Health Services, Colorado Springs, Colo. (Penrose Cancer Center)

St. Joseph Medical Center, Towson , Md. (St. Joseph Cancer Institute)

A coordinated regional program in Nebraska sponsored by Good Samaritan Hospital in Kearney (Good Samaritan Cancer Center); St. Elizabeth Regional Medical Center in Lincoln (St. Elizabeth Cancer Center); and St. Francis Medical Center in Grand Island (St. Francis Cancer Treatment Center).

Further information on the NCCCP program is available at http://ncccp.cancer.gov.

Bush Nominates Nancy Brinker Chief Of Protocol At State Dept.

Nancy Brinker, founder of the Susan G. Komen for the Cure, was nominated June 18 by President Bush as chief of protocol at the U.S. Department of State.

If confirmed by the Senate, Brinker will be responsible for overseeing the visits of chiefs of state, heads of government, and other international dignitaries who travel to the U.S. to meet with the President, Vice President or Secretary of State. She would accompany delegations representing the President at official ceremonies abroad.

"I am honored to serve our country in this important, public capacity," Brinker said in a statement.

"I was raised to always give back to the world, which is why I've dedicated my life to Susan G. Komen for the Cure and raising awareness about women's health issues on a global level. This position provides me the opportunity to serve at the ultimate level."

Brinker, a breast cancer survivor, served as ambassador to Hungary under President Bush. She has served on numerous boards, including NCI advisory boards, and has received many awards for her public service.

If confirmed, the Komen foundation said Brinker would continue her involvement with the organization in a private capacity.

HHS To Form Advisory Panel On Biodefense Science

HHS has formed the National Biodefense Science Board, a public health advisory panel concerned with chemical, biological, nuclear or radiological agents has been established.

The panel will advise the secretary of Health and Human Services on preventing, preparing for, and responding to release of such agents. The board was authorized by the Pandemic and All-Hazards Preparedness Act.

HHS plans to appoint 13 board members from among experts in science, public health, and medicine. Four would be from the pharmaceutical, biotechnology and device industries. Four would be from academic institutions. Of the remaining five, one must be from an organization representing health care consumers and one must be a practicing health care professional.

To submit a resume or curriculum vitae for board membership: nbsbnominations@hhs.gov. For inquiries: Susan Cibulsky: 202-0260-7000; nbsbquestions@hhs.gov. Additional information: http://www.hhs.gov/aspr/omsph/nbsb.

Funding Opportunities:

Lustgarten Offers Grants In Pancreatic Cancer Research

Letter of Intent due date: Aug. 3 on or before 5 p.m. ET. Application deadline: Aug. 20 5 p.m. ET.

The goal of the one-year grants that will be awarded in amounts up to $100,000 is to make rapid advances in pancreatic cancer through a combination of technology and ideas. Grants must focus on adnocarcinoma of the pancreas. Priority will be given to grants focusing on the following areas: 1. Pancreatic cancer stem cells, better known as tumor initiating cells; and 2. Familial pancreatic cancer. All other grants should fall in to the following categories: Screening for the early detection of pancreatic cancer; Novel therapies in pancreatic cancer; and Novel technologies for pancreatic cancer genetics. Application forms and the complete the RFP are available at www.lustgarten.org. Inquiries: The Lustgarten Foundation for Pancreatic Cancer: 1111 Stewart Ave., Bethpage, NY 11714, 516-803-2304.

NIH RFAs, PAs Available

RFA-CA-07-506: A Data Resource for Analyzing Blood and Marrow Transplants. U24. Letters of Intent Receipt Date: June 25. Application Receipt Date: July 25. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-CA-07-506.html. Inquiries: Roy Wu, 301-496-8866; wur@ctep.nci.nih.gov.

RFA-GM-08-005: Research on Interventions that Promote Research Careers. R01. Letters of Intent Receipt Date: Sept. 24. Application Submission/Receipt Date: Oct. 22. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-GM-08-005.ht. Inquiries: Shiva Singh, 301-594-3900; singhs@nigms.nih.gov.

PAR-07-384: Ruth L. Kirschstein National Research Service Awards for Individual Predoctoral Fellowship Training in Complementary and Alternative Medicine. F31. Application Receipt Date: April 13, Aug. 13, Dec. 13. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PAR-07-384.html. Inquiries: Nancy Pearson, 301-594-0519; pearsonn@mail.nih.gov.

PAS-07-381: Advancing Novel Science in Women's Health Research. R21. Application Submission/Receipt Date: Oct. 16; Oct. 16, 2008; Oct. 16, 2009 for new applications. Nov. 16 ; Nov. 16 2008; Nov. 16, 2009 for resubmission applications. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PAS-07-381.html. Inquiries: Anna Levy, 301-301 435 3860; levya@mail.nih.gov.

PAS-07-382: Advancing Novel Science in Women's Health Research. R03. http://www.grants.nih.gov/grants/guide/pa-files/PAS-07-382.html.

NOT-LM-07-001: Genotype and Phenotype Data Now Available from dbGaP Database; Request Process Involves New Procedures for Principal Investigators and Signing Officials. Inquiries: National Center for Biotechnology Information, National Library of Medicine, 301-496-2475; dbgap-help@ncbi.nlm.nih.gov.

NOT-CA-07-019: Request for Information: Development of Assays/In Vitro Devices for Use in Clinical Oncology. E-mail Response Due: July 25. Forms available at http://dctd.cancer.gov/ProgramPages/CDPRFI/CDPRFI_pub.pdf. Full text: http://www.grants.nih.gov/grants/guide/notice-files/NOT-CA-07-019.html. Inquiries: James Jacobson, 301-402-4185; jacobsonj@ctep.nci.nih.gov or J. Milburn Jessup, 301-435-9010; jessupj@mail.nih.gov.

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