

### NCI Faced Pressure From Congress, HHS, White House, On Mammography Statement

The National Cancer Advisory Board did not work in a political vacuum as it formulated the NCI recommendations on mammographic screening of women between the ages of 40 and 49.

In undisguised efforts to dictate the wording of the recommendation that was released last week, the Clinton Administration as well as members of Congress representing both parties exerted pressure on NCI Director Richard Klausner to ensure that the board's statement supported screening.

At one point during this back-room wrangling, Sen. Arlen Specter (R-PA) threatened to call for Klausner's resignation in the event the

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#### *In Brief*

#### **Cavenee Is President-Elect Of AACR; Coffey To Succeed Strong As President**

**DONALD COFFEY** will be named president of the American Association for Cancer Research for 1997-1998, at the AACR Annual Meeting in San Diego, April 14. Coffey, former president-elect of AACR, is professor of oncology, pharmacology, and molecular sciences, and the Catherine Iola and J. Smith Michael Distinguished Professor of Urology at Johns Hopkins Hospital. He has been a member of the AACR Board of Directors since 1993. . . . **WEBSTER CAVENEE**, director of the San Diego branch of the Ludwig Institute for Cancer Research, and head of the Laboratory of Tumor Biology and professor in the department of medicine at UC San Diego, will be named president-elect of AACR, and **Louise Strong** will become past president. Strong was the 1996-1997 AACR president, and is professor of experimental pediatrics, section chief of medical genetics, and geneticist in the department of experimental pediatrics at the University of Texas M.D. Anderson Cancer Center. . . .

**AACR MEMBERS** elected to the Board of Directors: **William Beck**, director of the University of Illinois at Chicago Cancer Center; **Michael Colvin**, director of the Duke Comprehensive Cancer Center; **Lynn Matrisian**, professor and vice-chair of the department of cell biology, associate professor in the department of obstetrics and gynecology, and associate director for education at Vanderbilt University Cancer Center; and **Joseph Simone**, medical director of the Huntsman Cancer Foundation.

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## NCAB Chairman Defended Klausner In Letter To Senator

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NCAB recommendation differed from one advocated by the Senator, sources said.

Specter, chairman of the Labor, HHS and Education Appropriations Subcommittee, said he never made the threat, and Klausner, in a recent press conference, said his conversations with the Senator were "private" and declined to discuss them.

However, the pressure from Specter prompted NCAB Chairman Barbara Rimer to defend Klausner's leadership and threaten to resign as board chairman if Klausner were forced to step down. A copy of Rimer's letter to the Senator was obtained by **The Cancer Letter**.

In addition to pressure from Capitol Hill, the White House and HHS officials urged NCI to make recommendations that would be identical to those released last month by the American Cancer Society.

The Administration wanted NCI to join ACS in its endorsement of annual mammograms starting at age 40. Despite the pressure, NCAB recommended mammography every one to two years for women in their forties who are at average risk of developing breast cancer (**The Cancer Letter**, April 4).

### Micromanagement By Congress?

NCAB members said the data support the



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board's recommendation.

"We did not make this recommendation because of political pressures," Rimer said at a press conference March 27.

"Certainly, there has been an intense amount of activity around this issue, but we stepped back and we looked at the science, and we filtered that science through our own judgment," she said.

The political pressure was unwarranted, said Louise Strong, president of the American Association for Cancer Research.

"I'm at a loss to understand why this issue engendered so much emotion," said Strong, chief of the genetics section and professor of experimental pediatrics at the University of Texas M.D. Anderson Cancer Center. "It's a mistake for Congress to get into micromanagement of this sort.

"This issue has gotten so blown out of proportion, that people who have common goals have become polarized on this issue," Strong said. "It can have an impact on other issues, such as the relationship between NCI and Congress, and the resulting availability of funding for cancer research.

"I would like to see this issue put behind us," Strong said. "We need to move on to other important issues."

### Senator Criticized Board's "Delay"

Last February, soon after the NCAB met to review the NIH consensus statement on screening mammography, members of Congress began sending letters urging the board to quickly develop a statement that would support screening for women between the ages of 40 and 49.

Some members of Congress, as well as several board members, wanted NCAB to formulate a statement at its Feb. 25 meeting, sources said.

However, unable to reach an agreement at the meeting, NCAB formed a subcommittee to study the issue and make a recommendations to the full board. At that time, Rimer said the board would need about two months to complete this work (**The Cancer Letter**, Feb. 28).

Board members received a letter signed by 39 women Members of Congress. "We believe the only real option is to give guidance to the women in this country," said the letter, dated Feb. 28. "We implore you to act quickly. Without definitive guidelines, the lives of too many women are at risk to permit further delay."

Following the NIH consensus panel's decision

not to recommend regular screening for younger women, the issue had become a personal concern for Specter. During the month of February, the Senator held four hearings that explored the details of the NIH consensus conference.

In a letter to Klausner dated March 5, Specter said he was “distressed” to hear about the “two-month delay” in NCI reaching a decision.

“During the intervening 60 days, thousands of women in the 40 to 49 age category might be screened which could result in the saving of many lives,” Specter wrote.

After receiving the letter, Klausner called the Senator to reiterate that the board needed time to complete its deliberations, sources said.

“The best protection from pressure is process,” Klausner said at a press conference March 27. “We got a tremendous amount of information and pressure from all sides, [including] from the scientific community, that this is an issue that people feel very strongly about.

“We did not waiver from the process we set up,” Klausner said. “Mr. Specter had an open public meeting, and made it very clear that he wanted an answer and he wanted an answer as quickly as possible.

“In my statement [at Specter’s hearing] I made it very clear that we had a process, that we all want to reach closure as soon as possible, but we will not do it any sooner than the board felt it needed to confer, to discuss, to evaluate information and reach agreement,” Klausner said.

During the phone conversation with Klausner, Specter said he would publicly call for the NCI Director’s resignation if the process didn’t move more quickly to endorse screening for women 40-49, sources said.

In a television interview March 26, Specter said he not threaten to call for Klausner’s resignation, but he did urge NCI to make a recommendation faster.

“I did not say Dr. Klausner ought to resign or to be replaced, but I did raise a question about whether they were using their funds properly,” Specter said in an interview with NBC Nightly News. “They are funded \$2.3 billion.”

Specter’s spokesman, John Ullyot, did not return a reporter’s telephone calls.

At the press conference, Klausner declined to comment on the phone conversation. “Private conversations are private conversations,” he said.

The pressure from Specter’s office prompted

NCAB Chairman Rimer to write a letter to Specter defending Klausner’s handling of the controversy.

“I am distressed by the maelstrom surrounding the mammography issue and the extent to which the important scientific questions have become politicized,” Rimer wrote in a letter dated March 11 to Specter. “I’d like to affirm the strong, unequivocal support of the National Cancer Advisory Board for Dr. Klausner as director of the National Cancer Institute.

“Dr. Klausner has revitalized the NCI and has infused new energy into every aspect of the NCI. We believe he has handled the mammography controversy in a very appropriate, responsible way. It is distressing to hear that his leadership is being questioned in Congress.

“I personally have such confidence in Dr. Klausner’s leadership that if he were to be asked to leave his position, I would resign immediately as chair of the National Cancer Advisory Board.

“The National Cancer Advisory Board is moving quickly to develop a statement about mammography....

“I hope you will allow Dr. Klausner to do his job and continue to do so.”

#### “We Knew Specter Was Disappointed”

Several NCAB members said Specter’s pressure had no bearing on their ultimate recommendations.

“The fact that we didn’t have a decision at the board meeting made Specter angry,” one board member said to **The Cancer Letter**. “Did it have an impact? No. We felt very strongly that we had to have closure on this.

“I don’t think anyone seriously thought about Specter,” the board member said. “It was the issue that was strangling us. The feeling was, let’s move on.”

“There was political pressure, but it was not the motivating force here,” said Barbara Gimbel, an NCAB member and a former member of the board of Memorial Sloan-Kettering Cancer Center. “We knew that Sen. Specter was disappointed that at the board meeting we didn’t come to agreement.

“The value of not coming to agreement then was that we were able to make more thoughtful recommendations,” Gimbel said.

NCAB member Ellen Stovall said Specter’s prodding had unnecessarily hastened the process.

“I would have preferred to have taken a few months to come up with more thoughtful

recommendations to help women with decision-making,” Stovall, executive director of the National Coalition for Cancer Survivorship, said at the March 27 press conference. “I feel that public pressure brought to bear to make us come out with this recommendation today.”

Stovall said Specter and others unduly politicized the mammography controversy.

“Where was this fervent interest in saving women’s lives during the health care reform debacle?” Stovall said to **The Cancer Letter**. “By enacting more responsible health care and insurance reforms, it is unlikely we would be having this intense level of debate over mammography.”

“The pressure, if any, was that our original time line was too long, and we should do it faster,” said Frederick Li, co-chairman of the NCAB subcommittee on mammography. “A lot of people seemed to be waiting for an NCI report, so we did what needed to be done.”

“There was an outcry from all different arenas,” said board member Zora Brown, president of Cancer Awareness Program Services, an organization based in Washington, D.C., that develops cancer awareness campaigns about reproductive cancers for African-American women. “There was lots of pressure on the board to do something.”

The NCAB took 30 days to weight the evidence and consider some exceedingly complicated issues. However, in Specter’s view, the board did not move fast enough.

“I am pleased that the record is now corrected that mammograms are warranted for women in their forties,” Specter said in a statement March 27. “I’m still perplexed about why it took so long to set the record straight.

“The Appropriations Subcommittee will be inquiring about this delay at a future hearing.”

### **Pressure To Sound Like ACS**

On March 23, after the American Cancer Society released its recommendation for annual screening mammograms, the pressure on NCI intensified further.

Now, the White House and HHS decided that the Institute’s recommendations should be identical to those of ACS, sources said. The pressure from the administration did not cease until the day before the NCAB held a press conference to release its statement, sources said.

“They wanted so badly for the NCI to sound

like ACS,” said a participant in the discussions who asked not to be identified by name. “They would have preferred the NCAB statement to have said annual mammography.”

Neither President Clinton nor HHS Secretary Donna Shalala requested changes in the statement, sources said. The pressure was exerted by mid-level officials, sources said.

“We really grappled with the question of whether to go to annual screening or every one to two years,” Rimer said. “As we looked at the trials, only two of them used a 12-month interval. In one of them, there was an increase in mortality. In the other, there was a decrease in mortality.

“The majority of the trials had intervals of 24 months,” Rimer said. “We really believe you cannot go beyond the evidence.”

Sources said that during the tense week, Klausner attempted to shield the NCAB from the pressure. In fact, several NCAB members said to **The Cancer Letter** that they were unaware of political pressure from HHS and the White House.

It was not until the night before the press conference—after it was too late to change the statement—that a small number of NCAB members were told about the pressure from the Administration.

“[Klausner] didn’t want us to be influenced,” a board member said. Had NCI changed the NCAB recommendation, at least one board member would have resigned, that board member said to **The Cancer Letter**.

Gimbel said she did not question whether Klausner would accept the board’s recommendation.

“Dr. Klausner had agreed to abide by the recommendations of the NCAB, whatever they turned out to be,” Gimbel said to **The Cancer Letter**. “He was part of the process all the way through.

“That did not happen in 1993,” Gimbel said.

In 1993, the NCAB voted 14-1 for the Institute to retain its previous screening guideline. Then-NCI Director Samuel Broder did not heed the board’s advice and decided to remove the recommendation for screening women 40-49.

### **A Consensus Emerges**

Initially, some board members doubted that the board or its subcommittee would be able to reach a consensus. “There were heated discussions,” Stovall said. “People were terribly upset.”

However, as discussions went on, it became clear that the majority on the board was in favor of



making specific recommendations for women in their forties, NCAB members said. And, just as the political interest in screening mammography peaked in Washington, the consensus was beginning to emerge.

The subcommittee co-chairmen, Robert Day, president of Fred Hutchinson Cancer Research Center, and Frederick Li, chief of the division of cancer epidemiology and control at Dana-Farber Cancer Institute, held different levels of conviction about the certainty of the scientific data. Day strongly favored screening for women in their forties, while Li seemed to take a more conservative view, sources said.

Li said he was determined to listen to all views. "Since screening is not my primary area of research, I was open to listening and learning," Li said to **The Cancer Letter**.

"There was a lot of back-and-forth," Li said. "People argued with conviction for their views.

"As we all came to understand our assignment, we were able to eventually come to a near-unanimous agreement," he said. "We wanted to do what's best for women who are perplexed by this controversy."

The assignment was to make a prudent public health recommendation, based on the scientific evidence, even though the evidence was not perfect, Li said.

"For me, it was a relatively novel experience to look at scientific data which always has some level of uncertainty, and use the data to make a recommendation to 10 million people," Li said. "It goes from a scientific judgment to a judgment regarding public policy.

"When I recognized the distinction, it was much easier to see other points of view," Li said.

"Any set of scientific results has a certain level of uncertainty attached to it, defined as a confidence interval," Li said. "No single study is perfect and settles the question forever.

"I think the board was faced with the situation of some level of scientific uncertainty, and feeling that for the women who needed a definitive recommendation, we ought to be able to help them."

Key to the NCAB's reaching an agreement was language in the document stating that the recommendations should be considered interim recommendations until more data are available, and that uncertainty is inevitable in science.

Li drafted the subcommittee's first position paper and distributed it to the subcommittee, Gimbel

said. After a two-hour conference call, the first draft was completed.

"Then we went back and forth on minutia," Gimbel said. "We wanted to avoid a rigid stamp."

After two more drafts, the statement was sent to the full board for comment.

The majority of the board favored screening for women 40-49, said Brown. "There were some who wanted to lean to pure science, and did not believe there was a statistical benefit," Brown said. "But we all know mammography does find cancer. Once we stopped trying to find that mammography is the cure for cancer, then we were able to agree.

"I, for one, would have liked to see a stronger statement that was consistent with ACS, to have screening annually," Brown said. "What we have is livable, as long as people know NCI does endorse screening for women in their 40s."

Brown said the discussions made her understand the importance of having a wide range of representation on the board. "There was a time that I felt inadequate for the board, but now I know that you have to have someone with a common-sense view," she said.

### **Statement's Order Was Reversed**

One major change from the subcommittee's draft was the order in which the recommendations were presented, a board member said. The subcommittee favored making its statement about uncertainty and risk assessment first, while the full board urged the presentation of the screening recommendations for women 40-49 first.

It was that switch that caused board member Kay Dickersin to cast the one dissenting vote against the statement, board members said. The statement passed on a vote of 17-1.

Dickersin could not be reached for comment.

Other board members said they valued hearing Dickersin's views and those of other board members who did not initially favor screening.

The result, board members said, was a balanced recommendation.

"The report is not an overwhelmingly positive endorsement of mammography," said Philip Schein, chairman and CEO, U.S. Bioscience Inc., of West Conshocken, PA. "The report is well-balanced and makes very clear that this represents an interim assessment, and physicians and women must recognize that there are both false positives and negatives with current mammographic technique."

"The process worked," said board member Ellen Sigal, president of Sigal Environmental Inc., of Washington, D.C. "The subcommittee did a good job. They did what was right for science and for women.

"It wasn't the political pressure," Sigal said. "We made a decision based on information."

"I was very comfortable with the statement, though in the beginning I would have made an even stronger recommendation," Gimbel said. "It does assist women, it is not too rigid for all women, and we defined high risk, which is very important.

"The next step is to get women to do it," Gimbel said.

### **Responsible Communication**

NCI, ACS, and other organizations need to provide more accurate and responsible public education about mammography, said Robert Smith, director of cancer detection science for the American Cancer Society.

"We face the new challenge of providing a more thorough message than simply: Mammography Saves Lives," Smith said. "We have to craft new materials that speak more clearly to the benefits and limitations of mammography."

"This challenge will take us beyond the 'sound-bite' educational messages that have been overly optimistic and somewhat misleading," Smith said. "We need to communicate the challenges we face with this disease and our disease control efforts, and what women and their doctors need to do and what they can expect. Today's solutions are effective, but they are imperfect, which is why continued research is so important."

However, Smith noted that long-term survival of breast cancer is significantly better for women whose tumors are found before they grow beyond one centimeter. "We have also not communicated the benefits of mammography well," he said.

The attention to "the mammography controversy" could ultimately have a positive effect, NCAB member Stovall said.

"One agreeable result of all this attention to mammography could be a heightened public awareness of science in general and cancer in particular," Stovall said. "Women need to be able to see the opportunity in the questions raised about mammography and insist on better information from which they can make more well-informed decisions about how to manage their health care."

## *The White House* **Clinton Designates April As Cancer Control Month**

President Clinton has declared the month of April 1997 as "Cancer Control Month."

The President issued a statement discussing the issues facing cancer research and policy, and urging Americans to unite toward controlling cancer.

The statement is as follows:

"In observing Cancer Control Month, we reaffirm our national commitment to fighting this deadly disease. Since the signing of the National Cancer Act in 1971, we as a Nation have made significant strides in combating many forms of cancer. In November 1996, the National Cancer Institute announced that the cancer death rate in the United States fell by nearly 3 percent between 1991 and 1995, the first sustained decline since national record-keeping began in the 1930s. The declines in lung, colorectal, and prostate cancer deaths in men, and breast and gynecologic cancer deaths in women, reflect the progress we have made in prevention, early detection, and treatment. However, we recognize how much work must still be done to control and eliminate this disease.

"Perhaps one of the most promising achievements of cancer research this past year is in our increased understanding of cancer genetics. We have learned that cancer is a disease of altered genes and altered gene function. Researchers are making great progress in identifying genes whose dysfunction leads to cancer. Our research into the relationship between genetics and cancer also is helping us to better understand the basis for many other diseases and will strengthen our ability to intervene against them. If we are to continue this remarkable progress, we must keep scientific research as a fundamental priority.

"Research has already taught us that smoking directly causes lung cancer and markedly increases a person's risk of developing cancers of the pancreas, esophagus, uterus, cervix, mouth, throat, and bladder. We know that many of the deaths from these cancers are preventable. Over the last several years, positive trends have emerged: Business, industry, and all levels of government have established smoke-free policies, and per-capita cigarette consumption has declined by 37 percent over the past two decades.

"Reasons for deep concern remain, however. More than 3,000 teenagers become regular smokers

each day in the United States. We must do all we can to help our children understand the consequences of smoking, and we must set a good example ourselves by not smoking. Last year, in an important step forward, the Food and Drug Administration proposed restrictions on the advertising, marketing, and sales of cigarettes to minors. In February of this year, I was proud to announce that the first part of those rules went into effect.

“We are also learning more about the relationship between diet and cancer risk, and we are gaining insight into the role of dietary supplements in reducing certain types of cancer. We know that by improving our diet—reducing fat and increasing the amount of fiber—we reduce our risk of cancer. The NCI, in collaboration with the food industry, sponsors the national 5-A-Day Program, which encourages Americans to eat five servings of fruit and vegetables each day.

“We are taking other important steps, as well. Federal agencies are working together to ensure that potentially active drugs move quickly from discovery to clinical use. To reduce the number of cancer deaths and new cases, and to help cancer patients survive longer and live better lives, several Federal agencies are working with State and local health departments to develop and implement national plans for breast and cervical cancer screening and to promote cancer prevention.

“I was pleased to announce last week that my Administration is launching a major public education campaign to make sure that every woman and every health care professional in America is aware of the NCI’s new recommendations that women between the ages of 40 and 49 should get a mammography examination for breast cancer every one or two years. The Medicare budget that I just submitted to the Congress will cover the expense of these annual exams, and we are urging State Medicaid directors to cover annual mammograms as well, with the assurance that the Federal Government will pay its matching share if they do so.

“As we commemorate this special month, I ask health care professionals, private industry, community groups, insurance companies, and all other interested organizations and individual citizens to unite to publicly reaffirm our Nation’s continuing commitment to controlling cancer. In 1938, the Congress of the United States passed a joint resolution requesting the President to issue an annual proclamation declaring April as Cancer Control

Month.

“Now, therefore, I, William J. Clinton, President of the United States of America, do hereby proclaim April 1997, as Cancer Control Month. I invite the Governors of the 50 States and the Commonwealth of Puerto Rico, the Mayor of the District of Columbia, and the appropriate officials of all other areas under the American flag to issue similar proclamations.”

### *Patient Advocacy*

## **Public Policy Should Prohibit Employer Use Of Genetic Tests**

The National Action Plan on Breast Cancer, in conjunction with the NIH-Department of Energy Working Group on the Ethical, Legal and Social Implications of human genome research, has released five recommendations for policy actions to prohibit discrimination based on genetic information.

The recommendations are the second set to be issued by the NABPC-ELSI group, and are designed to encourage policies that will prevent employers from using genetic information to deny jobs, health insurance, promotions, or other benefits.

The recommendations are as follows:

1. Employment organizations should be prohibited from using genetic information to affect the hiring of an individual or to affect the terms, conditions, privileges, benefits, or termination of employment unless the employment organization can prove this information is job related and consistent with business activity.

2. Employment organizations should be prohibited from requesting or requiring collection or disclosure of genetic information prior to a conditional offer of employment, and under all circumstance, employment organizations should be prohibited from requesting or requiring collection or disclosure of genetic information unless the employment organization can prove this information is job related and consistent with business necessity, or otherwise mandated by law. Written and informed consent should be required for each request, collection, or disclosure.

3. Employment organizations should be restricted from access to genetic information contained in medical records released by individuals as a condition of employment, in claims filed for reimbursement of health care costs, and other sources.

4. Employment organizations should be prohibited from releasing genetic information without prior written authorization of the individual. Written authorization should be required for each disclosure and include to whom the disclosure will be made.

5. Violators of these provisions should be subject to strong enforcement mechanisms, including private right of action.”

Several states are developing laws to address the NABPC-ELSI recommendations. On the federal level, the EEOC has adapted the Americans with Disabilities Act to cover employer discrimination based on genetic predisposition to disease.

In most states, employers are not prevented from requiring genetic testing of employees, or from gaining access to employee medical records.

A paper containing the group's recommendations was published in the March 21 issue of Science.

### Health Organizations **Organizations To Promote Skin Cancer Awareness**

The Cancer Research Institute and Cancer Care Inc., both of New York, have formed a program to raise public awareness the risks and dangers of skin cancer.

“The Melanoma Initiative” is geared toward identifying and funding promising research projects, developing patient and family support services, and creating an education program to increase public awareness about melanoma.

The initiative will support:

—A clinical trials program to support phase I/II trials to test novel immunotherapies for melanoma.

—A nationwide system of support to offer counseling and practical assistance, telephone support groups, educational seminars, a “buddy” program, guidance on medical services, and referrals to community resources and assistance.

—Advertisements to educate the public about the risks of melanoma, early detection and self examination, and available treatment options.

People magazine, as media partner in the initiative, has created a free booklet to be distributed on request to those who call the 800/813-HOPE, toll-free support line being established by the collaboration.

The program is being funded by an unrestricted educational grant from Schering-Plough Corp.

### Funding Opportunities **NCI Seeks Additional Center For PLCO Screening Trial**

In an attempt to expand the enrollment of minorities in the Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial, NCI plans to fund one additional screening center for the trial.

In a Request for Proposals, the Institute said it is seeking a center that can recruit up to 2,500 subjects and 2,500 controls, of which at least 60 percent are African-American, over the next two-and-a-half years.

The participants will be followed for at least 10 years. The trial was begun in 1992.

The text of the RFP follows:

#### **RFP: NO-CN-75022-70**

Title: **Prostate, Lung, Colorectal and Ovarian Cancer Screening (PLCO) Trial Expansion for Minority Enrollment**

Deadline: Approximately May 23

The NCI Division of Cancer Prevention and Control, Early Detection Branch, is expanding the PLCO Cancer Screening Trial and is interested in soliciting proposals from organizations for a new minority population focused screening center.

One additional screening center will be established to recruit no less than 2,500 subjects and 2,500 controls to the trial, of which at least 60 percent are African American. Female subjects will be screened for colorectal, lung, and ovarian cancers. Male subjects will be screened for colorectal, lung, and prostate cancer.

Screening will be annually for four years for prostate, lung, and ovarian cancers and only in years one and three for colorectal cancer. Subjects and controls will be followed for at least 10 years.

The PLCO Cancer Screening Trial was established in 1992 with ten screening centers, a Coordinating and Data Management Center, a steering Committee, and a Monitoring and Advisory Panel. The protocol is established.

Inquiries: Erin Lange, Contracting Officer, NCI, Research Contracts Branch, PCCS, Executive Plaza South, Rm. 635 MSC 7226, 6120 Executive Blvd., Rockville, MD 20852, tel: 301/435-3828, fax: 301/402-8579, email: Langee@rcb.nci.nih.gov.