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Senate To NCI: Return To Old Guidelines, Stop "Mixed Messages" On Mammography

The controversy over the NIH consensus statement on mammography screening for women 40-49 years old moved from the conference auditorium in Bethesda to the US Senate chambers last week.

On Feb. 4, the Senate passed a resolution urging the National Cancer Advisory Board to consider recommending mammography screening for women aged 40-49, or to "direct the public to consider guidelines issued by other organizations."

The non-binding "sense of the Senate" resolution, passed by a 98-0 vote, urged NCI to conduct additional research on breast cancer screening

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In Brief

Loberg Resigns From Bristol-Myers Squibb; Bloomfield Heads Cancer Center At Ohio State

RICK WINNINGHAM was named president of US Oncology and Immunology at Bristol-Myers Squibb, the company said. Winningham, currently vice president for Southeast Asia and general manager of the BMS Indonesia business, will replace **Michael Loberg.** A company spokesman said Loberg resigned from the company "by mutual agreement." The changes occurred last week, and the official announcement was made Feb. 10. . . . **CLARA BLOOMFIELD** was named director of the Comprehensive Cancer Center at Ohio State University College of Medicine and co-director of the James Cancer Hospital and Research Institute. She also will be the director of the *Division of Hematology* and Oncology at the Department of Internal Medicine and will assume the William G. Pace III endowed chair in cancer research. Bloomfield is chief of the division of oncology at the State University of New York at Buffalo and chairman of the Division of Medicine at Roswell Park Cancer Institute. . . . **MICHAEL CALIGURI** will serve as co-director for the Division of Hematology and Oncology and associate director, clinical research, at Ohio State Comprehensive Cancer Center. Caliguiri will assume the John Marakas chair in cancer research. Caliguiri is an associate professor at Roswell Park. . . . **ALBERT DE LA CHAPELLE** was named director of the human cancer genetics program at Ohio State. De la Chapelle will assume the Leonard and Charlotte Immke chair at the Department of Medical Microbiology and Immunology. He is former chairman of Medical Genetics at the University of Helsinki and physician-in-chief for clinical genetics at Helsinki University Hospital.

Consensus Statement, Process Criticized In Senate Hearing

(Continued from page 1)
in this age group. The resolution was sponsored by Sen. Olympia Snowe (R-ME).

At a hearing the day after the vote, three Senators criticized the consensus statement, and by association, NCI and NIH, for sending a "mixed message" to women.

NCI Director Richard Klausner, a witness at the Senate hearing, deflected criticism by pointing out that the independent consensus panel appointed by NIH was not an "NCI panel," as members of Congress and some press accounts have stated.

NCI will discuss with the NCAB how to provide "accurate, current, balanced and user-friendly" information about mammography to the public, Klausner said.

"In general, a woman in her forties has a 1 in 66 chance of being diagnosed with breast cancer and about a 1 in 190 chance of dying of breast cancer that develops in that decade," Klausner said. "A 15 percent reduction [expected from mammography screening] would lower these odds of dying to about 1 in 220.

"This year, over 30,000 women in their forties will be diagnosed with breast cancer and a 15 percent reduction in mortality would mean over 1,600 lives saved," Klausner said.

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The hearing, called by Sen. Arlen Specter (R-PA), chairman of the Labor, HHS, and Education Appropriations Subcommittee, quickly shifted focus from mammography screening guidelines to funding for breast cancer research.

Specter said the subcommittee would try to provide NIH with more research funding for fiscal year 1998 than the Administration requested. "We have $1.06 trillion in our federal budget and we have not done an accurate job of assessing priorities," Specter said. "And there isn't a higher priority than breast cancer."

Criticism of Consensus Process

In their opening statements, Sens. Specter, Tom Harkin (D-IA) and Kay Bailey Hutchinson (R-TX) leveled criticism at the consensus development process:

- "If there wasn't enough evidence to prove that women in their 40s would benefit from screening, was there evidence to conclude that women in their 40s would not benefit from screening?" Specter asked. "It seems to me we are allowing the burden of proof issue to dominate. I have a fixed opinion on this issue."
- "The findings of the NCI panel in some ways are disturbing to me, but in other ways, I understand that women have to make their own decisions," Harkin said. "I hope this NCI finding is not sending some erroneous signal out there that if you are below age 50 you don't have to worry. It's not what it said, it's the echo of what it said, how it ripples through society."
- "These are not issues that should be raised with a mixed message," said Hutchinson. "Help us get a clear message, tell us what the risks are, tell us what the advantages are. There is no question that the advantages outweigh the risks."

NIH officials are considering making changes for future Consensus Development Conferences, said Klausner at the hearing. "We have been discussing the process by which a draft report is released so quickly after a very complex conference," he said.

William Harlan, NIH associate director for disease prevention, told the subcommittee that the draft report was released to allow for public comment.

"The panel intended to take that comment into consideration as it comes to a final report," Harlan said. "We have been doing this for about 20 years

and it has always worked reasonably well. It has given the public and other people outside of the conference a chance to comment on the report."

The final report of the consensus panel is expected to be completed in about six weeks, Harlan said.

"Aren't You Saying They're Wrong?"

In the one confrontational exchange, Specter prodded Klausner to give a yes-or-no answer to the question of whether the consensus report was "wrong."

SPECTER: Dr. Klausner, in your statement you say, "It is my opinion that the draft report of the panel overly minimizes the benefits and overly emphasizes the risks for this population." Aren't you *pretty flatly saying they're wrong?*

KLAUSNER: I'm saying that the balance of the data and the evidence they presented, the tone of the report, in my opinion, was not reflective of the balance of evidence we now have, largely because I thought it minimized the evidence that there is benefit, and it overemphasized certain risks such as radiation risks, which as I said is a quite theoretical one.

SPECTER: Isn't that an elongated way of saying, again, they're wrong?

KLAUSNER: I do think there is a difference between evidence and the verdict you reach. We look at multiple pieces of evidence and we weigh them in order to reach a conclusion. I felt the conclusion was very defensive, that women need to be informed to make a decision. But in order to be informed, to make an informed and educated decision, we have to be very clear about whether there are pros—and I believe there are—and what are the limitations, and there are limitations. Or else, we can't expect women, with the support of their physicians, with the support of us, to be able to make that sort of informed decision.

SPECTER: Dr. Klausner, either I hear you saying for the third time that they're wrong, or I hear you saying something, candidly, which is unintelligible. The women of America in the age category of 40 to 49 need to know in unequivocal terms, whether a mammogram would be helpful to them in detecting breast cancer. Yes or no?

KLAUSNER: And, as I said, I hope I have been trying to be very clear, and that is, that the evidence is, as far as I can read, the evidence is, is that there is a statistically significant benefit in terms of reduction of mortality over long periods of time from initiating screening at some time in your forties. I think I have been very clear with that. And, as I said, I disagree with that aspect of the report of the panel.

SPECTER: I take that as a yes.

"Fund The Research to Find The Cure"

Breast cancer activists took differing positions on the consensus report.

Speaking in support of the consensus report, Fran Visco, president of the National Breast Cancer Coalition, told the subcommittee that the controversy over screening has been excessive.

"We are acting as though this issue—whether to recommend population screening of women 40-49—is the most important question in breast cancer," Visco said. "Let's save our outrage for the fact that we don't know how to prevent this disease, how to cure it, how to detect it truly early, or what to do for an individual woman once we do find it.

"Let's save our outrage, our resources, our energy, our time, for the 44,000 women who die each year," Visco said. "For the tens of thousands of women who have no access to health care.

"Rather than worrying about confusing women, let's devote our resources to designing mechanisms to empower women to understand the message: If you are under 50, there are certain things you should know about mammograms, get the information and discuss it with your health professional," Visco said. "Let's fund the research that will find the cure, prevention, early detection."

Visco said NBCC would request $650 million in funding for breast cancer research in the NIH budget and $210 million for the Department of Defense breast cancer research program. In FY97, NCI is estimated to spend about $419 million and DOD will spend $150 million on breast cancer research.

"Clear Guidelines Send Public Health Message"

Susan Braun, president and CEO of the Susan G. Komen Breast Cancer Foundation, said the foundation is considering changing its guidelines to recommend annual screening mammograms for women aged 40-49, instead of the current recommendation of screening every one to two years in that age group.

"Clear guidelines reflective of all available data,

properly weighed, send a strong public health message: that mammograms should be considered an essential element in the annual health and medical routines of women," Braun said.

"Unclear guidelines, or a statement that inappropriately sends the message that mammography is of equivocal value, can undermine public health policy by creating confusion, undue concern, and avoidance excuses for disinclined individuals, healthcare professionals and—perhaps most critically—healthcare insurers," Braun said.

Diana Rowden, chairman of the board of the Komen Foundation, told the subcommittee she was diagnosed with breast cancer at age 38, after having a screening mammogram. The cancer had not spread to the lymph nodes, she said.

"Had the cancer spread to my nodes, I would have had chemotherapy, which would have meant prolonged recovery and significantly higher cost for my treatment," Rowden said. "I urge the government to change its guidelines to include mammography screening women in their 40s."

Also testifying in opposition to the consensus report were Marilyn Leitch, of the American Cancer Society, and Barbara Monsees, chief of breast imaging at the Mallinckrodt Institute of Radiology at the Washington University School of Medicine, St. Louis, MO.

A member of the consensus panel, David Hoel, professor and chairman of the Department of Biometry and Epidemiology, at the Medical University of South Carolina, testified that the panel was restricted to answering the five specific questions posed by NIH.

The questions are included in the draft consensus statement, available on the World Wide Web at http://consensus.nih.gov.

Bill Would Require Screening Studies

In another development related to mammography screening, Snowe introduced a bill that would require NCI to "conduct adequately designed studies to determine the benefit of screening women ages 40-49 through mammography and other emerging technologies."

The bill, S90, also would require NCI to reissue the mammography guideline that was rescinded in 1993.

It would also require NCI to "direct the public to consider guidelines issued by other organizations."

NIH Panel Member Resigns Over "One-Sided" Document

A member of the NIH Consensus Development Panel on Breast Cancer Screening for Women Ages 40-49 has resigned, calling the panel's document "one-sided" and "unacceptable."

Jeanne Petrek, a breast cancer surgeon at Memorial Sloan-Kettering Cancer Center, resigned from the panel six days after the panel issued its draft statement. Petrek said she quit because she did not want her name associated with the panel's report.

In a letter dated Feb. 3 to John Ferguson, director of the NIH Office of Medical Applications of Research, which organized the panel, Petrek said the consensus statement was not balanced and, despite her suggestions, *the document had not* improved from its first draft.

Petrek said the document did not make a clear distinction between population screening versus the value of mammography for women who may have risk factors for breast cancer.

"I agree that randomized clinical trials do not provide evidence that mammographic screening should start in all American women beginning at age 40," Petrek wrote. "However, I yet believe that mammographic screening is advisable for many women 40 to 50 years of age, depending upon clinical factors and the woman's informed decision.

"This belief is primarily based on the small, but significant, reduction in breast cancer deaths found in the meta-analysis of the RCTs and the improvements in mammography during the 15 years since even the most recent trial.

"The draft would indicate that the majority of the panelists believe that screening in the 40s is without value," Petrek wrote. "The different perspectives on the value of screening in the 40s apparently cannot be separated from what individual panelists bring to the consensus document. This is apparent from the current one-sided draft of the 'consensus' document.

"The draft diminishes the survival benefit," Petrek continued. "It overemphasizes the risks, while making no attempt at a balanced presentation of risks versus benefits.

"The draft has not appreciably changed or improved since its inception, despite changes that I have recommended and despite my conversations with panel members on these issues," Petrek wrote.

"The document is unacceptable to me and I cannot have my name associated with it."

Provide Informed Consent, Not Generalizations: AACR

The American Association for Cancer Research said women should be provided a clear statement of their individual risks for breast cancer and the potential benefits of mammography screening, rather than a generalization about the age at which mammography should begin.

"The AACR does not believe that a single all-inclusive yes or no recommendation for mammography screening was intended to be generated by the Consensus Development Conference, nor would a single recommendation be in the best interest of women who fall into the 40-49 age group," the association said in a statement dated Feb. 5.

"We are strongly in favor of clearly defining the risks and benefits for each patient, rather than generalizing about specific ages at which women should seek mammograms," AACR said. "It is especially critical in the informed consent process that each patient understand her personal risk factors for breast cancer, the risks of the mammogram itself, and the potential for false negatives and positives as well as the potential benefits of the procedure."

The Philadelphia-based association, with a membership of 13,000 cancer researchers, called for "meticulous scientific analysis" of mammography screening studies before the final release of screening recommendations.

"Any recommendations...must give careful consideration to the issue of differential risks within this age group, since younger women's mammograms are more difficult to read and younger women generally tend to develop more aggressive cancers," the AACR said.

The association criticized as "premature" the release of the NIH consensus report.

"Any process in which scientists are charged with reviewing an evolving body of scientific data and making recommendations that may have a far-reaching effect on policy decisions, public perception, insurance coverage, and in this case, breast cancer mortality, must involve rigor in terms of scientific review, the evaluation of the report, and the appropriate process for communication," AACR said. "It is unacceptable to announce findings and recommendations to the press before appropriate members of the scientific community, health care providers, consumers, and other interested parties have had an opportunity for review and comment.

"The premature release of controversial recommendations based on inconsistent data can only serve to slow scientific progress and create additional confusion and insecurity both in this group of women and the general public," the statement said.

"We recommend that critical research issues such as quality assurance in the interpretation of mammograms, breast cancer risk factors, and the overall economic impact of early detection in this population become the focus of the recommendations from this Consensus Development Conference," the statement concluded. "The goal of this process should be to provide a rational and understandable basis for patients, physicians, hospitals, clinics, and public health departments that offer mammography on which to weigh the benefits and risks in each specific case so that the individual patient may make a personal choice about mammography based on truly informed consent."

Federal Research Funding

Clinton Budget For NIH Called "Paltry" In Senate

The Clinton Administration last week submitted a budget proposal that includes a 2.6 percent increase for NIH in fiscal 1998.

The proposed increase is a third lower than the increase of 3.9 percent originally proposed by the President for fiscal 1997.

According to NIH projections, the rate of inflation in biomedical research will be around 3 percent in 1997. This could mean that in real terms the Administration's proposal would bring about a decline in NIH funding next year.

Several Capitol Hill observers said the President's less than generous proposal could motivate Congressional supporters to increase the NIH budget. Last year, Congress boosted the NIH budget from the 3.9 percent increase proposed by the President to a 6.9 percent increase.

The current appropriations proposal comes at a time when the Republican Congress has clearly elevated research funding into a major political

issue, observers said. Setting the stage for battles to come, on the day of the announcement of the President's budget, Sen. Connie Mack (R-FL) described the proposed NIH funding as "paltry" and "unacceptable."

"The President's budget proposal calls into question the Administration's true commitment to the role medical research plays in improving the quality of life for men and women in America and all over the world," Mack said. "I am extremely disappointed with this funding request."

Mack, a cancer survivor and co-founder of the Senate Cancer Coalition, recently introduced a sense of the Senate resolution that calls for doubling the NIH budget over the next five years.

Under the President's 1998 proposal, the NIH budget would increase by $337 million, to $13.071 billion.

The NCI budget, excluding AIDS research funding, would increase by $61 million to $2.217 billion. This translates into a 2.75 percent boost over the appropriation enacted for the current year.

Last year, the President proposed a 1.73 percent increase for NCI. However, by the time the time the bill was enacted, NCI's increase was beefed up to 6 percent (**The Cancer Letter**, March 8 and Oct. 4, 1996).

Includes Funding For ASSIST

The Administration's proposal for NCI includes language mandating a one-year extension of funding for the American Stop Smoking Intervention Study (ASSIST).

Earlier this year, NCI said it would extend funding for ASSIST through the end of fiscal 1999 (**The Cancer Letter**, Jan. 17).

"Between now and then, NCI will be working with its departmental and external partners to determine the most effective way to support and manage future tobacco prevention efforts as we move beyond the research phase of ASSIST and transition to the essential task of supporting disseminated tobacco prevention and control programs in public health," the budget proposal states.

The proposal also includes a $90 million request for construction of the NIH Clinical Center. This matches the current appropriation.

According to the administration proposal, the center will require $90 million in fiscal 1999 and another $40 million in fiscal 2000.

Action Plan On Breast Cancer

Committee Tells Shalala: Return $14 Million To NCI

HHS Secretary Donna Shalala wanted to hear it for herself: Did the Steering Committee of the National Action Plan on Breast Cancer really intend to return to NCI the money Congress had earmarked for the plan?

As the Secretary polled the plan's steering committee earlier this week, one after another, the committee members said that the answer was still Yes.

Now, presumably, Shalala will face the onerous task of trying to convince Sen. Arlen Specter (R-PA), a key supporter of the plan administered by the PHS Office on Women's Health, to withdraw the congressional mandate that takes money from NCI.

During last year's appropriations process, Specter, chairman of the Labor, HHS and Education Appropriations Subcommittee, disregarded the arguments by the National Breast Cancer Coalition, the founding constituency of the Action Plan, that $4 million would be more than enough to finance the plan's operations.

At the time, Susan Blumenthal, head of the PHS Office of Women's Health and the administrator of the Action Plan, insisted on broadening the plan's mandate to include new areas of study as well as to undertake new "cross-cutting" initiatives in breast cancer (**The Cancer Letter**, Oct. 24, 1996).

After Congress mandated a $14.75 million earmark of NCI funds to finance the Action Plan, the plan's steering committee voted not to exercise the earmark.

The committee renounced claim to $14 million, allowing Blumenthal's office to use only $750,000, enough to cover staff salaries (**The Cancer Letter**, Nov. 15, 1996).

"When your recommendations were proposed to me, I wanted to come and listen to the steering committee myself to see what was the underlying discussion that went on," Shalala said to the Steering Committee Feb. 10. "If your recommendations are different than what Congress suggested to us, I need to go talk to Sen. Specter.

"I want to hear from all of you first, before I make final decisions. And then, I have indicated to

Sen. Specter that I will come up and talk to him."

One by one, committee members said the Action Plan was intended as a project of limited duration rather than a growing bureaucracy that would duplicate the work of other government agencies.

Only one member of the committee suggested that the committee may need to consider undertaking new initiatives.

"I feel that we have started a process that has not been finished," said Col. Dorris Browne, director of prevention and standards at the office of the Assistant Secretary of Defense. "There are still areas that we have not addressed. There is a large segment of the population that has not been looked at—the minority populations. I think we really need to address that."

Though Shalala asked the committee to decide by the end of the day how long it wants to remain in operation and whether it wants to consider adding new areas of study, the committee decided to address these issues at a later date.

Committee members were not enthusiastic about another of Shalala's suggestions, conducting a conference at NIH to assess the progress in breast cancer.

"Maybe we should bring everybody in again and have another large meeting and talk about where we have been and talk about where we might go," Shalala suggested. "One possibility is that we go back to NIH and have a thoughtful discussion on the general issue."

The committee took no position on Shalala's suggestion, and several key members said such a conference would not be useful.

At the meeting, Blumenthal reluctantly accepted the committee's decision to limit the activities of the Action Plan.

"From my own perspective, there are many things to do, and many other issues to address," she said. "But this is totally up to what everyone wants to do."

Now, observers question whether Specter would agree to annul the earmark. At a hearing on the NIH consensus statement on mammographic screening for women in their forties, Specter said he would like to know how eliminating the earmark would benefit breast cancer research at NCI.

"What is the impact when [NCI has] a [breast cancer] research budget of $419.6 million?" Specter asked. "I would not like to sacrifice [the priorities of the Action Plan] unless we know those marginal dollars really mean something significant."

Specter suggested than an overall increase in funding for breast cancer research may provide a way out of the controversy. "Since this Action Plan has these important items, I don't want to see them eliminated," Specter said.

"If it's more money for research, let us know. Let us see what we can do."

Funding Opportunities

FDA To Fund Studies Of Adverse Drug Effects

The FDA Center for Drug Evaluation and Research announced the availability of $1.4 million in fiscal year 1997 funds for cooperative agreements to study adverse effects of marketed drugs, biologics, and devices.

FDA expects to make four to six awards in the range of $250,000 to $350,000 for direct and indirect costs. The purpose of these agreements is to conduct drug, biologic, and device safety analysis for public health benefit; respond expeditiously to urgent public safety concerns; provide a mechanism for collaborative pharmaco-epidemiological research designed to test hypotheses, particularly those arising from suspected adverse reactions reported to FDA; and enable rapid access to multiple data sources to ensure public safety when necessary.

Application receipt date is March 21.

Inquiries: Robert Robins, Grants Management Officer, Division of Contracts and Procurement Management (HFA-520), FDA, Park Bldg Rm 3-40, 5600 Fishers Ln., Rockville, MD 20857, tel: 301/443-6170.

RFAs Available

RFA CA-97-008

Title: **Clinical Oncology Research Career Development Program**

Letter of Intent Receipt Date: March 5

Application Receipt Date: April 29

The NCI Cancer Training Branch announces the reissuance of the Institutional Physician Scientist Award (K12) program. The purpose of this program award is to increase the number of clinical oncologists who can: 1) interact and coordinate

clinical research activities with basic research scientists in order to expedite the translation of basic research information into patient-oriented research; 2) perform independent clinical research that develops and tests rational scientific hypotheses based on fundamental and clinical research findings for improving the medical care of patients; and 3) design and test innovative clinical protocols and manage all phases of clinical trial research.

There will be approximately 10 awards made at a total cost level of $3.6 million per year.

The maximum direct costs available per award for the first year support of the program is $350,000.

Inquiries: Vincent Cairoli, Division of Cancer Treatment, Diagnosis and Centers, NCI, 6130 Executive Blvd Rm 520 MSC 7390, Bethesda, MD 20892-7405, tel: 301/496-8580, fax: 301/402-4472, email: C14Z@NIH.GOV

RFA CA-97-003
Title: **Mentored Career Development Award**
Letter of Intent Receipt Date: March 6
Application Receipt Date: May 8

The Comprehensive Minority Biomedical Program, NCI Division of Extramural Activities, invites underrepresented minority research scientists who have been the recipient of an NIH Research Supplement for Underrepresented Minority Individuals in Postdoctoral Training (MIPT) or a Minority Investigator Supplement (MIS), funded by the NCI, who need an extended period of sponsored research as a way to gain scientific expertise while bridging the transition from a mentored research environment to an independent research/academic career to submit applications.

This award offers opportunities for a mentored peer review experience in cancer research which will enhance the candidates knowledge and understanding of the peer review process with the intended purpose of developing skills with the expectation that the candidate will submit a grant application for nontargeted mechanisms (R29, R01).

This award is aimed at fostering the cancer research careers of outstanding, junior minority scientists who (a) have been the recipient of an NIH Research Supplements for Underrepresented Minorities award, funded by the NCI; (b) are located at a majority institution; and are committed to developing and sustaining academic research programs. This award is a novel mechanism which is intended to support underrepresented minority scientists and enhance the likelihood of success for junior underrepesented minority investigators who have committed to basic and clinical research careers in cancer.

Support for this program will be through the NIH Mentored Research Scientist Development Award (K01).

The estimated total costs available for the first year support of this program is $500,000. There will be approximately five new awards made in response to this solicitation.

Inquiries: Sanya Springfield, Comprehensive Minority Biomedical Program, NCI, 6130 Executive Blvd Rm 620, Bethesda, MD 20892-7405, tel: 301/496-7344, fax: 301/402-4551, *email:* springfs@dea.nci.nih.gov

Program Announcement

PAR-97-031
Title: **Minorities In Medical Oncology**
Application Receipt Dates: June 1, Oct. 1, Feb. 1

The Comprehensive Minority Biomedical Program, NCI Division of Extramural Activities, announces the availability of minority medical oncology awards.

These awards are intended to encourage recently trained underrepresented minority clinicians to acquire research experience in medical oncology, and increase representation of minorities in medical oncology.

These awards will provide the opportunity for recent, clinically trained underrepresented minority physicians and D.O.s to gain sufficient research expertise to become medical oncologists with experience in biomedical research.

Support for this program will be through the NIH Mentored Clinical Scientist Development Award (K08).

Inquiries: Sanya Springfield, Comprehensive Minority Biomedical Program, NCI, 6130 Executive Blvd Rm 620, Bethesda, MD 20892-7405, tel: 301/496-7344, fax: 301/402-4551, email: springfs@dea.nci.nih.gov

The Cancer Letter welcomes submissions of news items and Letters to the Editors. Material may be sent by email to: kirsten@www.cancerletter.com. See box on page 2 for regular mailing address.