THE CANCER LETTER

Vol. 20 No. 20
May 20, 1994

Price $225 Per Year US, Canada
$250 Per Year Elsewhere

P.O. Box 15189 Washington, D.C. 20003 Telephone 202-543-7665

News Organizations Protest Invitation-Only Press Conferences, Exclusion Of Reporters

In recent weeks, NIH Director Harold Varmus has held two press conferences which excluded news organizations with an established track record of coverage of NIH.

Several of those news organizations said they intended to file official protests to NIH and HHS officials. Another news organization, the Bethesda Gazette, alleged that Varmus had violated open meetings law by holding a dinner meeting with six citizens, three of whom served on an NIH advisory committee.

The Cancer Letter is drafting a protest over being excluded from a

(Continued to page 2)

In Brief

Mayo Director Kovach Moves To City Of Hope; Seattle Institutions Win Gene Therapy Grant

JOHN KOVACH, director of the Mayo Clinic Comprehensive Cancer Center and chairman of the Mayo Clinic Dept. of Oncology, has been appointed executive vice president, medical and scientific affairs, of the City of Hope National Medical Center and Beckman Research Institute. He will assume the position June 1. Kovach has been with Mayo Clinic since 1976. He is vice president and president-elect of the Association of American Cancer Institutes. . . . **THREE SEATTLE** medical institutions have received a $3.75 million NIH grant to establish a new core center for gene therapy at the Univ. of Washington Medical Center. The program combines the efforts of researchers at Children's Hospital and Medical Center, Fred Hutchinson Cancer Research Center, and UWMC to develop gene therapy for hereditary diseases such as cystic fibrosis, immune system disorders and blood clotting factor deficiencies. Program directors are **Dusty Miller**, of Fred Hutchinson; **Bonnie Ramsey**, of Children's and UW; and **Arnold Smith**, of UW. . . . **M.D. ANDERSON** Cancer Center has named two specialists to newly created professorships. **Christopher Logothetis**, chairman of the Dept. of Genitourinary Medical Oncology, was named to the Bessie McGoldrick Professorship in Clinical Oncology. **Mark Schusterman**, chairman of the Dept. of Reconstructive and Plastic Surgery, was named to the Charles M. McBride Professorship in Surgical Oncology. . . . **AMERICAN CANCER** Society reviewed 3,446 grants in fiscal 1993 and funded 847 of them for a total of $95.8 million. The number of new and renewal grant applications increased 3% from the previous year, while funded applications increased by 4%, according to a report.

'We Don't Like To Think Of Them As Press Conferences'

(Continued from page 1)

press conference May 4, where NIH officials released a plan for restructuring of the NIH intramural program.

"It never occurred to me that it would be of interest," said Anne Thomas, NIH acting associate director for communications.

Confirming that the meeting was by invitation-only, Thomas said the number of invitations issued was dictated by the size of Varmus's conference room, which seats 12.

"In the past, we have always put out press notices extremely broadly, and that meant we couldn't have a good discussion, because there are people who don't know what a Board of Scientific Counselors is, or there are people who assume it is a big news announcement," Thomas said.

"We don't even like to think of them as press conferences," she said. "These were informal briefings."

Controlling News Flow

As a result, the cancer community had to learn about the 69-page report of an external advisory committee from a brief story in the back pages of The New York Times.

NCI has the largest intramural research program at NIH and is the leading user of the Clinical Center.

"The general rule is that when government agencies decide to hold press conferences, they cannot exclude legitimate news media," said Jane Kirtley, executive director of Reporters Committee for Freedom of the Press. "They could have moved [the news conference] to a larger room."

Varmus did not respond to a request for an interview with **The Cancer Letter**.

The failure by NIH to notify news organizations in an equitable manner forms a pattern that suggests attempts to control the flow of news from NIH and insensitivity to requirements that federal officials conduct government meetings in the open.

On April 12, a day before NIH and NCI officials were to face the Oversight and Investigations Subcommittee of the House Committee on Energy and Commerce, Varmus held a similar invitation-only press conference which appears to have infuriated virtually every party involved:

- The news organizations that were not notified, including **The Cancer Letter,** were later shocked to learn they had been excluded.
- Reporters chosen by NIH were puzzled by the ground rules of the press conference, which initially prohibited taping and even using the materials presented. Several reporters said they would not have attended the meeting had the ground rules been laid out. At least one reporter walked out, and at least one other broke the embargo.
- The Oversight and Investigations Subcommittee received no notice of the meeting. "We were concerned to learn about the meeting from a reporter rather than HHS," a staff member said to **The Cancer Letter**. "We were told that we would have to get permission from the NIH director for our staff to be present," the staff member said. "In the previous administration, we were invited and staff were present at similar meetings."

"Please Keep Your Distance"

Two weeks later, on April 27, Varmus had another run-in with the press.

In a Bethesda restaurant, Varmus met with six citizens opposed to incineration of medical waste on the NIH campus, the Bethesda Gazette reported. Three of the six were members of the NIH Neighbor Council, an advisory group convened by NIH two years ago.

A Gazette reporter approached the group's table at the El Caribe restaurant.

According to a story in the May 4 issue, the reporter, Myra Mensh Patner, said she wished to cover the meeting. Varmus refused. "Please keep your distance," he said.

Under the Federal Advisory Committee Act, meetings of government advisory committees are open

THE CANCER LETTER

Editors: **Kirsten Boyd Goldberg**
Paul Goldberg
Founder & Contributing Editor: **Jerry D. Boyd**

P.O. Box 15189, Washington, D.C. 20003
Tel. (202) 543-7665 Fax: (202) 543-6879

Subscription $225 per year North America, $250 elsewhere. ISSN 0096-3917. Published 48 times a year by The Cancer Letter Inc., also publisher of The Clinical Cancer Letter.

to the public. Federal regulations require that the date, time and place of meetings of advisory committees be posted in the Federal Register. The Gazette filed a protest with NIH and HHS.

Thomas declined to discuss the incident with **The Cancer Letter**.

"Invariably, You Miss Somebody..."

Some government institutions, including Congress, the White House and the Department of Defense allot space by credentialling reporters. NIH has no credentialling program.

"Case law suggests that if space is limited, it is possible to provide some methodology of alloting space, but it cannot be done in a discriminatory manner," said Kirtley of the Reporters Committee. "It should be done either by lot or on a first-come, first-serve basis."

NIH's Thomas declined to provide to **The Cancer Letter** the list of reporters who were selected by NIH to cover its press conference on the intramural program. **The Cancer Letter** is filing a request to obtain the list under the Freedom of Information Act.

However, Thomas described the criteria used for selection of news organizations:

"We sat down with [NIH News Branch chief] Marc Stern, who has a list of about 60 reporters and we picked out 27 people who might be interested," Thomas said. "We didn't want to put something on the [wire service] day book, because it was a briefing for people who were really interested."

Stern's "quick fax" list was put together within the past few weeks, Thomas said. **The Cancer Letter** was not on the list, she said.

"We went through this list and said yes, no, yes," Thomas said. "I also forgot to invite The Journal of the National Cancer Institute.

"Invariably, you miss somebody," she said.

"I Realized The Oversight"

Thomas said she became aware of her faux pas after Paul Marks, president of Memorial-Sloan Kettering Cancer Center and co-chairman of the advisory committee that issued the report on the intramural program, mentioned a news story that had previously appeared in **The Cancer Letter**.

Said Thomas: "I realized [the oversight] when we got in the room and Paul Marks said, 'Have you seen the stories in **The Cancer Letter**?' I don't get **The Cancer Letter**. I really apologize."

Editorial

Cozy News Conferences At NIH Achieve Ambiance By Exclusion

It appears that Harold Varmus is having serious difficulties with his transition from running graduate seminars at the Univ. of California at San Francisco to discharging his duties as the Director of the National Institutes of Health.

At a time when the Cancer Program and clinical research are confronting a crisis of trust, the NIH Director has chosen to demonstrate his contempt for federal laws that mandate that meetings be conducted in the open.

In recent weeks, **The Cancer Letter** as well as other news organizations have been denied their lawful rights of access to news events at NIH.

Why is this happening? If we are to believe the official explanation, in one case, reporters were denied access to a news event because a conference room chosen by Varmus seated only 12 reporters.

"We don't even like to think of them as press conferences," an NIH spokesman Ann Thomas explained.

Apparently, NIH is achieving ambiance through exclusion. Press notices used to be sent out broadly, but that caused frustration at NIH.

"We couldn't have a good discussion," Thomas said. "Because there are people who don't know what a Board of Scientific Counselors is."

This is a nonsensical explanation for unacceptable actions. After two decades of covering NIH, **The Cancer Letter** has more than a vague idea of the function of the Boards of Scientific Counselors. Also, we happen to know that NIH has some very large meeting rooms.

Since the principles at stake are worth fighting for, ultimately, Varmus and his staff will have to confront hard questions from **The Cancer Letter** and other news organizations. For now, NIH officials are dodging those questions. Varmus did not respond to our request for an interview. His staff, too, declined to provide the list of news organizations NIH deems worthy of attending its news events.

Sadly, it appears that Varmus personally is the cause of the problems between NIH and the press.

Consider the scene at Bethesda's El Caribe restaurant on April 27: the NIH Director was caught by a reporter in the midst of a meeting with members of an advisory committee. When the reporter asked

to cover the meeting, Varmus responded with a warning: "Please keep your distance."

Even if the conversation was exclusively about the weather, a responsible public servant would have invited the reporter to pull up a chair, lest there be any appearance that an illegal meeting was taking place.

Varmus's attitude to the press appears to range from hostile to patronizing. "I know you guys want stories," he said at a background press briefing the day before a hearing of the House Oversight and Investigations Subcommittee. (Ironically, the subject of the hearing was failure by NCI and a cooperative group to disclose fraud in clinical trials.)

"One story that would make me uncomfortable is the story that says, 'In a surprise move, the NIH today held a press conference to try to fend off the adverse effects of the hearing,'" Varmus instructed reporters. "Because that is not what we are here to do. We are trying to provide information about the hearing, because I think the hearing is going to be rapid-fire, confusing episodes."

The Cancer Letter was improperly—albeit mercifully—not invited to that briefing. But, for the record, we submit our response:

Many of us in the press have the intelligence to follow rapid-fire exchanges. More importantly, every news organization struck from the NIH A-list can readily discern a public servant's contempt for the principles of openness in government.

Force Stronger Peer Review, Cut Weaker Intramural Labs, Advisors Urge NIH In Report

NIH should conduct more stringent peer review and eliminate weaker laboratories in a revitalization of its intramural research program, a committee advising the NIH director said in a report.

The $1.2 billion intramural research program is suffering from uneven quality and productivity across NIH's various institutes as a result of a fragmented structure that the committee called "Balkanization."

"Unless addressed, problems identified in this report—and several previous reports—may destine the NIH [intramural program] to a mediocre future," the committee wrote.

NIH Director Harold Varmus commissioned the report in response to a House Appropriations Committee directive in the FY94 budget. The House asked NIH to "review carefully the role, size, and cost of the intramural program" and its relationship to the extramural research program.

The report of the External Advisory Committee was released at a news conference May 4. The NIH Director's Advisory Committee is scheduled to review the report at its next meeting June 2.

NIH decided to release the report, marked "draft," early because copies are being distributed widely among the institutes' staff, an NIH spokesman said to **The Cancer Letter**.

"Rigorous Standards" Needed

"The most important recommendations were developing systems which can provide overview for the entire NIH intramural research program with the same rigorous standards, taking into account the different missions of each institute," Paul Marks, co-chairman of the committee, said to **The Cancer Letter**.

"We did not rigorously attempt to evaluate the quality of individual programs," said Marks, president of Memorial Sloan-Kettering Cancer Center. "We were more concerned with the issue of how you assure quality."

The NIH budget is under increasing pressure due to a number of factors, the report said. These forces include rapidly expanding opportunities to increase basic biomedical knowledge and enhanced capabilities for translating basic knowledge into clinical application.

However, costs of biomedical research are rising and opportunities for expanding the federal budget for biomedical research are diminishing, the report said.

"These forces are leading to a new reality in the extramural research community," the report said. "Research judged to be 'good,' 'very good,' or even 'excellent' is no longer funded. Funding of new grants is at an all-time low of about 15 percent of submitted proposals."

The intramural program has its own set of problems, the committee said.

"Over the past decade, the [intramural research program] has experienced problems with recruitment and retention of senior scientists, expansion of a postdoctoral training program of uncertain and uneven quality, cumbersome administrative

requirements, inadequately funded congressional and administrative mandates, and a deteriorating facility infrastructure, in particular the Clinical Center."

Balkanization Of Intramural Research

The intramural program is fragmented among the various NIH institutes, centers and divisions, each with its own mission and mandate from Congress, the report said. These differences contribute to vital and diverse research, but have led to "an administrative structure that in the present environment of constrained resources frequently hinders effective management" of the intramural research program, according to the report.

"This Balkanization of the [intramural research program] has contributed to unevenness in quality, quality control, and productivity," the report said.

NIH in the past has ignored recommendations of at least three previous advisory committees for improving the intramural program, the report said.

"This may be attributed in part to systemic problems that transcend NIH and require major administrative or legislative remedies and in part to resistance to change within a large institution," the committee wrote.

Gail Cassell, professor and chairman of the Dept. of Microbiology at Univ. of Alabama at Birmingham, was co-chairman of the committee. Other members of the committee were Michael Brown, Gerald Fischback, Elizabeth Neufeld, Arthur Rubenstein, Kenneth Shine, Maxine Singer, James Wyche, and Roy Vagelos.

New, Smaller Inpatient Hospital

As was expected, the report called for building a new, 250-bed hospital to replace the 450-bed NIH Clinical Center (**The Cancer Letter**, April 15).

A study by an independent engineering firm and a 1991 report by the U.S. Army Corps of Engineers found the 40-year-old Clinical Center has deteriorated to such an extent that the safety of those who use the facility is threatened, the committee said.

"The question is not whether [the Clinical Center] should be renewed, but what is the most appropriate plan for renewal of the facilities that would meet the needs of the intramural research program and be as timely and affordable as possible," the report said.

Total replacement of the Clinical Center complex is "neither necessary nor desirable," the committee said. Instead, the renovation should done in phases.

First, NIH should build the new inpatient facility close to the existing Clinical Center. Plans for construction should proceed "as promptly as possible," the report said.

Second, NIH should determine which laboratories will be housed adjacent to the new hospital, and make plans for new construction or renovation of old Clinical Center laboratories, the committee said.

Third, a long-range plan should be developed for upgrading and maintaining the laboratories and ambulatory care space that would remain in the existing Clinical Center, the committee said.

"The committee was concerned by the failure of NIH to maintain the physical plant of the Clinical Center," the report said. "In part, this may reflect a lack of funds, but it also may reflect misplaced priorities or a lack of commitment to improving the physical infrastructure on the part of leadership."

Once a new Clinical Center is built, only clinical research protocols deemed "very good to outstanding" should be supported by the intramural research program, the committee said.

The committee did not attempt to review the quality of the clinical research conducted at the Clinical Center, but asked the institutes to prioritize their active protocols.

According to the report, NCI's Div. of Cancer Treatment, the largest user of the Clinical Center, ranked 50 percent of its protocols "good" or "the very best." DCT said 35 percent of its protocols are "of average importance," and 15 percent represent "poor or obsolete ideas."

Summary Of Recommendations

The report's executive summary listed the following as the committee's primary recommendations:

1. To improve the processes by which senior scientists and scientific directors are reviewed, the External Advisory Committee recommends that a standing advisory committee to the Deputy Director for Intramural Research be formed composed mainly of the chairs of the external boards of scientific counselors of each institute, center, and division.

This committee should be charged to provide ongoing review of the processes of quality control across NIH. The committee should be chaired by the Deputy Director for Intramural Research.

2. Further, to improve quality review, the committee recommends that the selection and

appointment process be altered for the boards of scientific counselors to assure expert, arms-length membership; that the process by which boards of scientific counselors review the programs of intramural scientists be more explicit; and that the criteria used to evaluate scientific directors be made more rigorous.

3. To ensure a strong tenure system that provides the intramural research program with creative and productive scientists, an NIH-wide Tenure Committee, advisory to the Deputy Director for Intramural Research, and composed of 12 to 16 tenured scientists serving staggered terms, should be established to review and recommend for approval (or rejection) all potential appointments to tenure and tenure-track positions.

Recommendations for appointments to tenure or tenure track should be made by each institute, center, and division through its existing processes, then forwarded to the Tenure Committee with all appropriate documentary support. Once the NIH Tenure Committee is in place it should no longer be necessary for the NIH Board of Scientific Directors to review or approve tenure decisions.

4. To improve the intramural training program, the independence and career development of trainees should be emphasized.

Trainees should be encouraged to seek positions outside NIH following a two- to four-year program so as to continuously provide space and resources for recruitment of new trainees.

5. To provide ethnic diversity in the intramural training programs, there should be better linkage with NIH-funded extramural programs, including the NIH Minority Access to Research Careers and Minority Biomedical Research Support undergraduate programs, and with the Short-Term Training Program for physicians.

The intramural program also should increase the number of physician scientists from under-represented minority groups by increasing research experiences for minority medical students.

6. An annual, prospective planning process should be conducted by each institute, center and division to determine the allocation of resources to the intramural and extramural programs.

The process should be outlined in a written document and reviewed, approved, and monitored by the NIH Director and the Advisory Committee to the Director. Extensive consultation with the extramural research community should be part of this [process. The overall NIH scientific mission should be assessed and allocation decisions made on the basis of scientific excellence and opportunity.

The total intramural research program budget for institutes, centers and divisions should not exceed the current rate of 11.3 percent of the total NIH budget. This percentage should be reviewed and appropriately adjusted through the prospective planning process, following full implementation of the recommendations which emerge from the quality review of the intramural program as outlined in recommendation number 1.

It is anticipated that implementation of this process of quality assurance may require three to four years.

7. The procedures for procurement and staff travel should be streamlined and improved, as should the procedures for appointment of technical as well as scientific staff as part of the process of "reinventing government."

NIH could serve as a model for developing and testing novel procedures to make the procurement process efficient and responsive to research needs, while simultaneously ensuring the integrity of federal expenditures.

8. To ensure that the NIH intramural program is fulfilling its mandate to facilitate technology transfer, NIH should broadly communicate in a clear and precise manner the scope, purpose, definition, and process of implementing and monitoring Cooperative Research and Development Agreements (CRADAs).

9. There is a need for renewal of the Clinical Center.

There should be a phased program starting with a 250-bed Clinical Center Hospital and followed by a modular approach to construction and renovation of research laboratories. Funds recovered from phasing out weaker intramural research programs should be used to the extent possible to fund renewal of the Clinical Center.

However, recognizing the likelihood that these funds will not be adequate to meet the costs of renewal of the Clinical Center, the committee recommends that additional funds be allocated by Congress for this purpose.

Funds must not be diverted from the extramural program to the intramural program for renewal of the Clinical Center.

10. If, on renewal of the Clinical Center, inpatient nursing units and laboratory research space become available in excess of the needs of the ongoing programs of the Clinical Center, then establishing priority for the use of such space should be the discretion of the NIH Director, with the understanding that priority should be given to programs currently housed off the Bethesda campus (both clinical facilities and research laboratories). Such consolidation of NIH intramural programs should facilitate quality control and could reduce costs.

11. Recognizing that it is not within the authority of the Director of NIH to change the current classification of the intramural research program as an administrative expense, the committee strongly believes that it should not be classified in this manner.

Such a classification leads to budgetary procedures which are not rationally related to the scientific process and which do not support the goal of achieving the highest quality and productivity of the intramural research program.

NCI To Recompete NSABP In 1995, Chabner Tells Senate

NCI will require recompetition of the National Surgical Adjuvant Breast & Bowel Project in early to mid-1995, an Institute official said at a Senate hearing last week.

The Univ. of Pittsburgh will have to compete with other institutions next year for the funds to support the NSABP headquarters, Bruce Chabner, director of the Div. of Cancer Treatment, said to the Senate Cancer Coalition.

The cooperative agreement was not due to expire until 1997. Because so many changes have to be made in the group's administration and procedures, it is only fair to let other institutions submit applications for the funds, Chabner said to **The Cancer Letter**.

After forcing Bernard Fisher to step down as principal investigator of the cooperative group in March, NCI required the group to make plans to elect new leaders. The new leadership is subject to NCI approval, according to a March 29 letter from NCI to the Univ. of Pittsburgh (**The Cancer Letter**, April 8).

"When the leadership of the group changes, they will have to recompete," Chabner said at the May 11 hearing. "We will issue a [Request for Applications] indicating the availability of funds to support breast and bowel cancer research."

The NSABP is scheduled to hold a group meeting in June, at which the election of new leaders is expected. Ronald Herberman is the interim prinicipal investigator and Donald Trump is the interim executive officer of the group.

Sen. Diane Feinstein (D-CA) and Sen. Connie Mack (R-FL), co-chairmen of the Senate Cancer Coalition, called the hearing to look into allegations that the dangers of tamoxifen were not readily disclosed to women entering the Breast Cancer Prevention Trial.

NSABP three years ago won the grant to conduct the trial. The group's proposal was $100 million cheaper than the closest competitor, the Univ. of Wisconsin, Chabner said.

Leslie Ford, acting deputy director of the NCI Div. of Cancer Prevention & Control, defended the prevention trial and said NCI wants to reopen the study as quickly as possible.

At the hearing, Chabner describe the events of the past two months as "wrenching." Placing NSABP on suspension and halting accrual to its studies was "a major step," he said.

"This was the leading breast cancer research group in the world," Chabner said. "It is not something you do lightly. We felt we had no alternative because of the lack of compliance" with NCI rules for auditing institutions involved in cooperative group studies.

"We asked for the leading figure in cancer research to step down," Chabner said. That action was the direct result of an NCI staff visit to NSABP headquarters in Pittsburgh.

"What we found when we went to NSABP headquarters in March was that NSABP had suspended auditing nine months before," Chabner said. "They had lost their main auditing staff person and were overwhelmed by the prevention trial. They threw up their hands and said, 'We can't handle this.'"

NSABP statistician Joseph Constantino testified that Fisher's office was responsible for the program of auditing the group's member institutions.

NCI should spend more on auditing clinical trials, Chabner said at the hearing.

"We don't spend nearly as much as drug companies spend to audit trials," he said. "I think there is room to expand that. It will do two things: It will take money away from research, and it will discourage some people from participating."

Letter to the Editor:

Screening Revisited. Again.

The following is the edited text of a letter sent to Sen. Barbara Boxer (D-CA) and Rep. Patricia Schroeder (D-CO).

Dear Sen. Boxer and Rep. Schroeder:

I read with disappointment, and some concern, Dr. Susan Love's letter to you concerning breast cancer screening for women ages 40 to 49, as it was published in **The Cancer Letter** April 15. Unfortunately, Dr. Love's analysis is incorrect and her statements not supported by facts.

The majority of the trials have, in fact, shown a decrease in mortality for women under 50.

Since the trials were not designed to evaluate women of 40 to 49 separately, they are not large enough to permit the benefits to achieve statistical significance. This is a matter of basic statistics and mathematics,

This fact was confirmed at the International Union Against Cancer meeting last October and reaffirmed last month at a meeting cosponsored by the American Cancer Society and NCI. Both meetings concluded, with unanimous agreement, that the trials were not of sufficient size to be expected to provide statistically significant results for evaluating women ages 40 to 49 as a separate group.

Dr. Love has fallen into the statistical trap. She has merely looked at the end results of the trials without understanding how those trials were performed, and without understanding what legitimate conclusions can be drawn from them.

Dr. Love has buttressed her conclusions by suggesting "facts" that are incorrect. She has reiterated the suggestion that women under 50 have dense breast tissue, and those over 50 have fatty tissues, preventing mammographic screening from being effective in younger women and permitting it to work in "older" women. This is simply not true.

There is no dramatic change that takes place on mammograms at age 50 or even at menopause. The dense tissues that are more common in younger women do not suddenly melt away.

Dr. Love is incorrect in stating that "every study" has shown that mammography screening in women over 50 works well. In fact, some of the studies have not shown a benefit for these women, but the aggregate has shown a trend that many have accepted. Dr. Love has ignored the fact that many experts have accepted the trend that is apparent for women aged 40 to 49, with the knowledge that the numbers cannot be significant.

Dr. Love has further confused the data by suggesting that for every 1,000 mammograms there will be 700 procedures. In reality, for a woman being screened for the first time, the need for an additional evaluation is about 7 percent. This drops to 1 to 2 percent after the first screen. Dr. Love seems to forget that the same argument ["unnecessary interventions"] could be made in opposition to clinical breast examination and breast self-examination. If she were consistent in her logic, she would have to advise against any form of breast evaluation until age 50.

Dr. Love has used the analyses and the advice of others and has not, herself, returned to the studies to better understand their significance. This is clear in her statement that the results of screening have not changed with technology "whether a study was done in the 1950's or more recently..." There were no screening studies performed in the 1950's.

Mammography screening is not the ultimate answer, but it offers the best hope at the present time for reducing the number of deaths for women beginning at age 40. "Society" may decide that screening is too expensive (there are ways to lower its costs), but women should not be denied the right to determine how resources are allocated by incorrectly suggesting that science shows no benefit of screening mammography.

It was scientifically incorrect for NCI to break the data from the screening trials into sub-groups to make clinical recommendations. Having done so, they were well aware that the power of the data to "prove" a benefit was lost.

By eliminating the power of the randomized, controlled trials, they cannot ignore data from other screening efforts which provide ample evidence that mammography is as effective among women ages 40 to 49 as it is among women 50 to 59.

When the design and execution of the randomized, controlled trials is understood, and all the available data on screening are reviewed, the preponderance of evidence suggests that screening women ages 40 to 49 on an annual basis, using two-view mammography and clinical breast examination, can reduce breast cancer mortality by 25 to 30 percent.

Daniel Kopans
Harvard Medical School