

THE

# CANCER LETTER

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## NIH Closes Meeting Of BSC Chairmen, Violation Of Open Meetings Law Alleged

In an action that raises questions of compliance with federal law, NIH officials earlier this week attempted to hold a closed meeting of a panel that consisted of chairmen of the 23 NIH Boards of Scientific Counselors.

However, after reporters from *The Cancer Letter* challenged the rationale for closing the meeting, NIH officials did an about-face and declared that a portion of the meeting would be open.

An hour and forty minutes into the session, the reporters were asked to leave to allow for discussion of personnel, generally a valid reason for  
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### In Brief

#### Kamen Named ACS Professor; Bordon Moves To Univ. Of Maryland As Center Director

**BARTON KAMEN**, professor of pediatrics and pharmacology at Univ. of Texas Southwestern Medical Center, has received an American Cancer Society Clinical Research Professorship. The professorship provides \$60,000 per year and the requirement not to assume academic chairmanships or other positions that would limit his ability to treat patients and conduct research. Kamen is one of seven ACS Clinical Research Professors nationwide and the only pediatrician. . . . **ERNEST BORDEN** has been named director of the Univ. of Maryland Cancer Center. Borden served as director of the Medical College of Wisconsin Cancer Center in Milwaukee since 1990. Prior to that, he spent more than 17 years at the Univ. of Wisconsin Comprehensive Cancer Center in Madison. His major research interests are tumor immunology and biologic response modifiers. Borden will recruit 18 new clinical and research faculty over the next four years, said Stephen Schimpff, executive vice president of the Univ. of Maryland Medical System. . . . **JANYCE HEDETNIEMI** was named the first director of a new NIH Office of Community Liaison. Last year, she organized HHS Secretary Donna Shalala's national meeting on breast cancer. The new office will maintain communication between NIH and its neighbors in Bethesda on issues such as disposal of medical waste and the development of an NIH campus master plan. . . . **CORRECTION:** Of the two dozen tumors reported in sharks, most are not cartilage tumors, as reported in last week's issue. Three tumors—two in the literature and one in the Registry of Tumors in Lower Animals—are cartilage tumors, said John Harshbarger, director of the registry. Other tumors reported have included blood cell, brain, skin, kidney, and several other types of cancers.

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## NIH Meeting Changes From Closed To Open And Back

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closing a portion of a meeting. The reporters complied, but subsequent interviews with participants revealed that no confidential matters were discussed.

The Aug. 1 meeting where board chairmen were invited to offer advice on the overhaul of the NIH intramural program was not announced in the Federal Register. The Federal Advisory Committee Act requires that notice of advisory committee meetings be published at least 15 days in advance.

"The case law is clear: the question of closing the meeting to the public should not have arisen in the first place," said Maxwell Chibundu, professor of law at the Univ. of Maryland. "As long as they provide advice or any kind of policy guidance to an executive branch agency, they are a de facto advisory committee, and should comply with the requirements of the Federal Advisory Committee Act. If they have not filed a charter, they may be acting illegally."

Jay Ward Brown, an attorney with Ross, Dixon and Masback, a Washington law firm that offers First Amendment counsel to the media, said inconsistency may have put NIH in violation of the open meetings law.

"Saying that a meeting is closed, and then at the meeting itself announcing that a part of the meeting would be open certainly contradicts the spirit and intent of the notice requirement, because it effectively prevents public presence at the meeting," Brown said. "The fact that, when aggressively challenged, the NIH officials changed their mind indicates that they have serious questions as to whether they were subject to the Federal Advisory Committee Act."

### THE CANCER LETTER

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NIH Deputy Director for Intramural Research Michael Gottesman ultimately closed the meeting, saying that he wanted to invite a more detailed discussion that would include examples of personal matters involving intramural scientists. However, participants said no matters involving individuals were discussed.

"I did not hear anything that was sensitive or proprietary," said a participant who asked not to be identified by name. "There were no discussions of individual investigators at all. It wasn't that interesting a meeting."

"The closed part seemed to be a continuation of the open part," said another participant. "There did not seem to be any discussion of individuals."

"I don't think there was anything that focused on personalities," said a third participant contacted by **The Cancer Letter**. "I could see no reason why you were excluded."

After the reporters were expelled, the group continued to plough through the agenda, participants said.

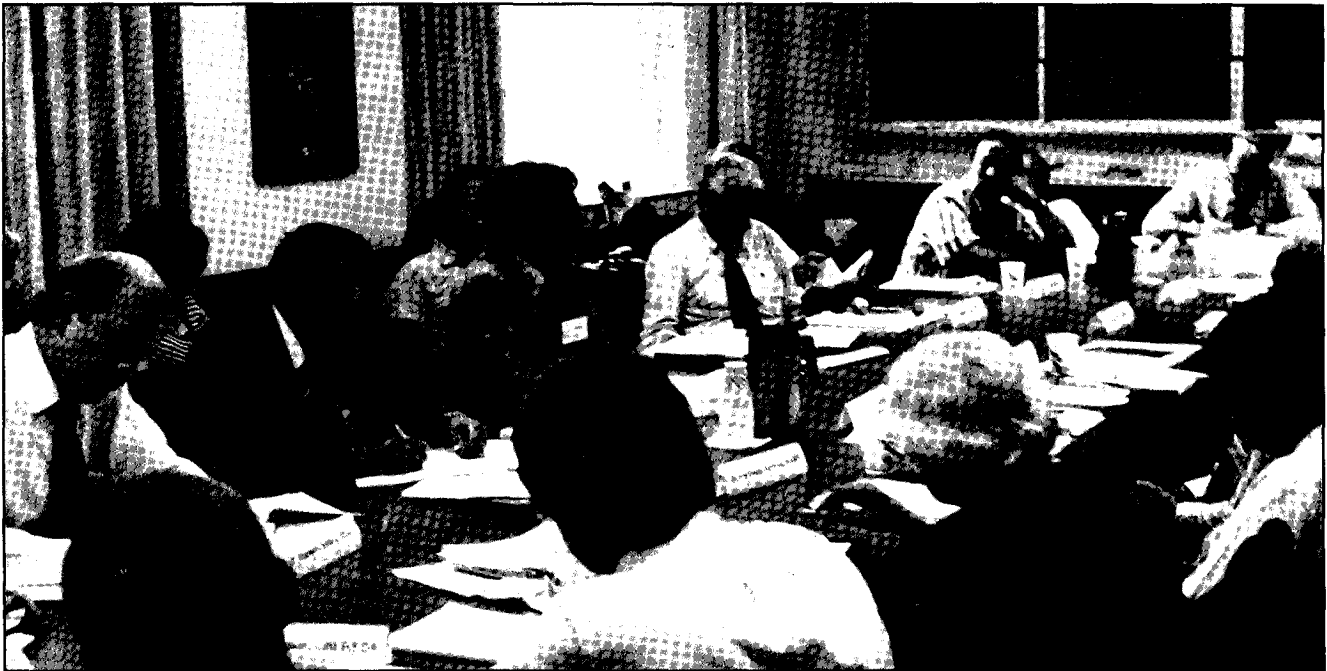
"When they closed the meeting, apparently for the reason of personal privacy, and then did not discuss issues of personal privacy, that brought their actions and their commitment to open government into question," Rebecca Daugherty, an attorney with the Reporters Committee for Freedom of the Press, said to **The Cancer Letter**.

"It looks to me that the agency has violated the Federal Advisory Committee Act, and they ought to be thinking of ways to make contact with the outside public," Daugherty said.

Several NIH scientists said to **The Cancer Letter** that it would have been improper for BSC chairmen to discuss individual scientists since such a discussion would have been held outside the format of site visits and peer review. "It would have been absurd for them to discuss individual scientists in the context of a policy discussion," a senior NIH official said to **The Cancer Letter**.

The BSCs, made up of scientists from academia and industry, advise the scientific directors of the institutes on research directions for the intramural and extramural research programs.

The Federal Advisory Committee Act of 1972 requires that all meetings of advisory committees be held in the open and announced in the Federal Register. Meetings may be closed for reasons that include national security, personal privacy in matters



**Circumventing the law? Gottesman, Varmus meet with BSC chairmen.** Photo by Paul Goldberg

involving individuals, and confidential business information. However, notice must be published even for closed meetings.

The Aug. 1 meeting was convened to discuss implementation of administrative changes in the NIH intramural program. These changes were suggested in a report issued last May by the External Advisory Committee to the NIH Director.

The report's recommendations included revamping the hiring and review of scientists, the advisory functions of the BSCs, and the selection of BSC members.

The report directed NIH to meet regularly with BSC chairmen in the process of implementing the changes (see story on page 5).

#### **NIH Rationale Disputed**

After learning that a meeting of BSC chairmen was about to take place, **The Cancer Letter** notified Gottesman's office that it intended to cover the meeting.

On the morning of the meeting, in a telephone call, NIH associate director for communications Anne Thomas said the meeting would be closed. Thomas cited an opinion of the NIH counsel that the open meetings law did not apply because the BSC chairmen "did not constitute a standing advisory committee and any advice they give us will come from them as individuals."

Subsequently, NIH officials argued that the

scientists invited to the session would meet once a year and that personal matters involving intramural scientists would be discussed.

**The Cancer Letter**, following advice from counsel, chose to challenge this rationale for closing the meeting.

"As NIH restructures its \$1.2 billion intramural research program, the change will affect every employee, every grantee—and the entire enterprise of biomedical research," said Kirsten Goldberg, editor of **The Cancer Letter**. "We believe that these policy decisions should not be made behind closed doors and that confidential matters, when they arise, can be considered in the format used by all NIH advisory boards.

"We contend that the individuals invited by Dr. Gottesman Aug. 1 constituted a de facto advisory committee, especially since their meeting was called as a result of an explicit recommendation of the External Advisory Committee report on the intramural program," Goldberg said.

#### **From Closed to Open to Closed**

After two reporters from **The Cancer Letter** arrived to cover the meeting, a staff member in Gottesman's office informed them that the meeting would be closed, telephoned Thomas and instructed reporters to await her arrival. The reporters declined to wait and followed several BSC chairmen into the conference room.

In the conference room, the following exchange ensued:

**Gottesman:** This is not an open meeting, but I'd be happy to talk to you afterwards. There is going to be a lot of discussion of individual scientists in the various institutes.

**The Cancer Letter:** It is our understanding that this meeting is about policy implementation.

**Gottesman:** There will be some policy, but it will be illustrated with very specific examples. This is an occasion for the chairs to come to me and talk about what's going on in their individual programs.

**CL:** Do you plan to meet with this group again?

**Gottesman:** We will be meeting again on occasion, probably on a yearly basis.

**CL:** So in effect this constitutes an advisory committee.

**Gottesman:** No, it's not an official advisory committee. It's a group of people who will not be meeting certainly more than once a year. It's not an official advisory committee.

**CL:** There is such a thing as a utilized advisory committee, and there is case law—

**Gottesman (interrupting):** You are welcome to stay for the initial discussion, but then we'll get down to brass tacks. Okay? And I'll be happy to talk to you after the meeting.

Opening the meeting, Gottesman told the BSC chairmen why they were called to Bethesda:

"First of all, you are not a committee, a standing committee, you are a group of people who come representing the institutes, to come and individually give your advice and voice your concern or complaints or any positive information you have about what is going on, with the Boards and the institutes that you review," Gottesman said.

"The first part of this meeting will be an open discussion of some points of information for you, and then I hope for the remainder of the day to get into very detailed about the way in which individual Boards review their programs, the problems they come across, and any suggestions that you might have individually as to how we can make improvements," Gottesman said.

Gottesman and the BSC chairmen discussed tenure review procedures, salary and promotion issues, for the next hour and a half. NIH Director Harold Varmus and Deputy Director Ruth Kirschstein attended part of the open session (see story on page 5).

Following a discussion of the whether BSCs

should be allowed to review the letters of recommendation for tenure candidates, Gottesman called a coffee break. At that point, he said, the meeting would be closed to the public.

"You are the only press here, so you got quite a scoop," Gottesman said to a reporter during the break.

"If we'd had more time before the meeting, perhaps we could have come to some understanding," said Thomas as she followed the reporters out of the conference room.

#### Advisory Committee By Any Other Name...

In an interview with **The Cancer Letter** following the meeting, Gottesman offered another explanation for the decision not to announce the meeting: President Clinton last year ordered all federal agencies to cut the number of advisory committees, thereby preventing NIH from officially chartering the group.

"We are under a mandate to reduce the number of our standing advisory committees," Gottesman said. "The point you made about the informational aspects was a good one. We will try to format something like that in the future. This administration has been open."

When the BSC chairmen meet again, probably in January, "it will be mostly a discussion of how the implementation is going and there will be a lot of specific, confidential information," Gottesman said.

"The mandate to reduce the number of advisory committees does not mean that you can call it something else," said Daugherty of the Reporters Committee. "Changing the name is not going to work. If it acts like an advisory committee, it is an advisory committee."

The Federal Advisory Committee Act defines the term "advisory committee" as "any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof which is (A) established by statute or reorganization plan, or (B) established or utilized by the President, or (C) established or utilized by one or more agencies, in the interest of obtaining advice or recommendations for the President or one or more agencies or officers of the Federal government..."

Earlier this spring, **The Cancer Letter** filed a protest with HHS Secretary Donna Shalala over being excluded from two NIH-sponsored news events (**The Cancer Letter**, May 20).

## Advice To Intramural Program: Set Up An Advisory Committee

*In its report last April to NIH Director Harold Varmus, the External Advisory Committee of the NIH Director's Advisory Committee specifically recommended that NIH establish an "External Advisory Committee to the Intramural Research Program" made up the chairmen of the Boards of Scientific Counselors.*

*The committee was chaired by Paul Marks, president of Memorial Sloan-Kettering Cancer Center, and Gail Cassell, chairman of microbiology at Univ. of Alabama at Birmingham.*

*An excerpt from the report follows:*

"The committee should have its first meeting within three months of the acceptance date of this report. At the meeting the [Deputy Director for Intramural Research] should explain the new ground rules for the review process, stressing the need for stringent quality control and the necessity to free up resources for new recruitment.

"The government mandate to reduce the number of personnel at rank GS-14 or above should be thoroughly analyzed in terms of the implications for retention of senior scientists and recruitment of young and established scientists."

The BSC chairmen and Gottesman "should draft written guidelines for the BSC members and chairpersons outlining duties and responsibilities. These guidelines should stress the crucial role of the BSCs in determining the future of the NIH intramural research program.

"Thereafter, the External Advisory Committee to the Intramural Research Program should meet at least annually and more often as needed. At each meeting the chairperson of each BSC should make a brief oral report of the state of the institute, outlining its significant accomplishments, and highlighting any weaknesses that have been found. These meetings should help to maintain uniform standards among the institutes."

## New Tenure Program Begins, More Positions To Open In Fall

NIH has begun a new process for appointing scientists to tenured and tenure track positions in the \$1.2 billion intramural program.

The process will make NIH positions more open to young scientists working in academia and to women and minorities, NIH Director Harold Varmus said to a group of advisors this week.

"There has been the perception that NIH positions are appealing but are walled off to anyone outside NIH," Varmus said. "We are going to change that. We need to make it clear to the academic community that these jobs are competitive."

About 20 to 30 tenure track positions may be open for recruitment this fall when the NIH hiring freeze "begins to thaw," Michael Gottesman, NIH deputy director for intramural research, said to the chairmen of the 23 Boards of Scientific Counselors.

The new tenure program establishes more formal and rigorous review of intramural scientists, Gottesman said. Candidates recommended for tenure by their institute's director and scientific director will also be reviewed by the BSCs.

The more rigorous review of tenure-track

scientists, equivalent to university assistant professors, moves NIH closer to a university-like system for allocating laboratory space and funding, sources said to **The Cancer Letter**.

### Abolishing "Fiefdoms"

The new tenure program implements one recommendation of the report on the intramural program issued earlier this year by an advisory group to NIH Director Harold Varmus. Last May, the advisory group encouraged NIH to do away with the system of "fiefdoms" created when young scientists work for many years under the direct supervision of a laboratory or branch chief.

"NIH would be better served if laboratories and branches contained a larger proportion of independent scientists either tenured or on the tenure track, analogous to the best departments within universities," wrote the committee, chaired by Paul Marks, president of Memorial Sloan-Kettering Cancer Center, and Gail Cassell, chairman of microbiology at Univ. of Alabama at Birmingham.

A more formal search process will better open the tenure program to young scientists outside NIH, and women and minorities, Gottesman said.

"It used to be that people would come to the

intramural program and be invited to stay," Gottesman said to **The Cancer Letter**. "It was an informal mechanism. Now it is a much more open process."

Under the new process, a position would be created at the request of a laboratory or branch chief and a formal search would be conducted to fill the position. A search committee would prepare a short list of candidates to submit to the institute director and the institute scientific director. After consultation with the laboratory chief, one name would be selected and forwarded to Gottesman for final approval.

As recommended by the Marks-Cassell committee, the process will become more standardized across the institutes. "We want a more unified way of doing the reviews," Gottesman said.

During an open portion of the meeting this week with BSC chairmen, much of the discussion was about the varying practices for tenure review among the different institutes and the role of the BSCs.

The tenure track gives a scientist six years to establish an independent record before being considered for tenure. During this time the scientist will be evaluated by their laboratory or branch chief and by their scientific director.

Formal reviews will be conducted within three years by the BSCs. The advisors will recommend whether the institute keep the candidate on the tenure track, drop the candidate, or consider the candidate for early evaluation for tenure, according to "The Tenure Program of the National Institutes of Health," a report Gottesman provided the BSC chairmen.

Some of the BSC chairmen said that without better salaries and space allotments, recruitment to NIH will continue to be difficult.

NIH is negotiating with HHS "to use the Senior Biomedical Service" to pay better salaries for top scientists, Varmus said. Chances of obtaining this approval are "good," he said, though the plan is "stuck in the dark bureaucracy of the department," he said.

The tenure track process and the potential for higher salaries are important changes, said Barry Pierce, chairman of the NCI Div. of Cancer Etiology BSC. However, the current freeze on promotion from GS-13 to GS-14—in essence, providing a salary greater than \$50,000 per year—limits a young scientist's potential, Pierce said.

NIH is under the Clinton Administration constraint to reduce the number of GS-14 employees, who are considered middle-level management, Gottesman said. "Most GS-14s at NIH are not administrators, but run small labs. Until we can get some relief from this

constraint, we will have trouble with promotions," he said.

Clara Bloomfield, chairman of the NCI Div. of Cancer Treatment BSC, asked how the tenure track slots would be allotted to the institutes.

"That's the determination of the scientific director," Gottesman said. "The scientific directors control a lot of resources."

NIH has begun using a "new paradigm" of sharing resources, Gottesman said. "The distribution of resources we have now is historical—you get a fixed percentage increase from what you had last year. Another extreme is pooling all resources with the NIH director. That could be problematic for political reasons," he said.

"We have started to use a paradigm of sharing, a bottom-up approach," Gottesman said. When a request for a tenure track position comes to his office, Gottesman said, "I can say this is inappropriate, we already have too many of these, why don't you collaborate with this person [in another institute]."

#### Who Controls Resources?

Under the changes recommended by the Marks-Cassell committee, the scientific directors would have less absolute control over resources.

The committee recommended major changes to the selection of members of the Boards of Scientific Counselors, and charged the BSCs with reviewing the scientific directors of the institutes.

The recommendations, if put into place, are likely to shift power over the intramural program away from the scientific directors and to the BSCs and Gottesman's office.

According to the committee's report, "The Intramural Research Program":

- New BSC members should be recommended by a vote of the current BSC members. Attempts should be made to include scientists with a broad range of background and views. Nominations may be made by the members of the BSC, the scientific director of the institute, Gottesman's office, and others. The invitation to join the BSC should come from both Gottesman's office and the BSC chairman, and not from the institute scientific director.

- The BSC chairman should be elected from and by the BSC membership. The chairman should serve a set term. The term of appointment for members should be four years, and membership renewable for one term.

- A rule that excludes scientists who serve on

extramural review panels such as NIH study sections and councils should be abolished.

- At least one-third of each BSC should be composed of scientists whose major grant funding comes from sources outside of the institute. It would be preferable if the BSC chair did not receive the majority of his or her research funds from the institute.

- Every four years, the BSC should review the status of the institute's intramural program and should vote whether to recommend the institute's scientific director for a new four-year term. A major criterion for evaluation of the scientific director should be the extent to which he or she has considered or implemented the recommendations of the BSC with regard to resource allocation to individual scientists. The report of the BSC would be sent to Gottesman, who in turn would make a recommendation to the institute's director.

It is not clear what would happen if the BSC, the institute director, and Gottesman have different opinions of the scientific director. At NCI, each of the division directors are scientific directors.

"These are the most controversial recommendations," an NCI scientist said to *The Cancer Letter*. "NIH has been a very hierarchical system, but now the scientific directors will be serving at the pleasure of a board, and not only a board, but the deputy director for intramural research."

#### Meeting Closed

The selection of BSC members and review duties were listed as topics on the agenda of the Aug. 1 meeting of the BSC chairs, but Gottesman closed the meeting to the public before these items were discussed.

In an interview following the meeting, Gottesman acknowledged that the new tenure program and the BSC review of scientific directors will provide the BSCs and NIH Building 1—the offices of the NIH director and his deputies—with more control over the allocation of intramural program resources.

"We're trying to get away from the word centralization," Gottesman said to *The Cancer Letter*. "There are occasions where pooling of resources makes sense where you have scarce resources. To some extent there has to be top-down oversight of that process.

"My personality tends to be on the collegial side," Gottesman said. "I don't do anything without the consultation of the scientific directors. Dr. Varmus

shares that. We are very interested in coming up with the best solutions."

Following is a summary of the tenure track appointments process as outlined in the tenure program report dated June 17.

#### Tenure Track And Tenure Appointments Process

Step 1: Scientific Director (SD), ICD [institute, center or division] Director, and Lab/Branch Chief, after consultation with senior scientist in the ICD, determine need for a new tenure track position.

Step 2: Scientific Director establishes a search committee with concurrence of the ICD Director and advertises for tenure track candidates.

Step 3: Search committee evaluates applications including letters of reference, invites promising candidates to campus for interviews and seminars, and recommends one to three candidates to the Laboratory/Branch Chief, the SD, and the ICD Director. The SD and the ICD Director select one name and forward it to Deputy Director for Intramural Research [DDIR] for approval. DDIR reviews and approves selection process and candidate.

Step 4: SD, Lab/Branch Chief, in consultation with potential candidate, prepare and sign Tenure Track Agreement. Copy is sent to the Deputy Director for Intramural Research.

Step 5: Candidate signs Tenure Track Agreement and is appointed or converted to tenure track position, starting tenure track clock.

Step 6: Yearly, Section/Lab/Branch Chief prepares oral and written performance evaluation for candidate.

Step 7: Approximately every three years, Board of Scientific Counselors (BSC) reviews candidate's performance and qualifications for tenure, and decides whether candidate should be continued in tenure track, dropped from track, or advanced for tenure decision.

Step 8: Before tenure track time elapses, SD and ICD Director review candidate and decide whether to propose candidate for tenure, continue candidate in tenure track, or drop from track.

Step 9: Candidate is informed in writing of BSC, Chief, SD and ICD Director decisions.

Step 10: If candidate is advanced to consideration, ICD Promotion and Tenure Review Committee is formed to solicit outside letters and assemble and review credentials. Promotion and Tenure Review Committee, in concurrence with SD and ICD Director, makes a recommendation to the NIH Central Tenure Review Committee.

Step 11: NIH Central Tenure Review Committee reviews credentials and makes recommendation to DDIR.

Step 12: DDIR makes tenure decision.

Step 13: DDIR informs SD of decision. SD informs candidate, in writing, of the decision.

Step 14: If candidate is not approved for tenure or is dropped from tenure track, he or she has one terminal year to wrap up work and find another job.

## NSABP Executive Committee Joins Fisher's Suit Against Pitt

The executive committee of the National Surgical Adjuvant Breast & Bowel Project earlier this week joined as plaintiffs in the suit filed by Bernard Fisher against officials of the Univ. of Pittsburgh and the cooperative group's interim leadership.

In the amended suit, the executive committee joined Fisher in demanding the scientist's reinstatement as chairman of NSABP and seeking an injunction against Pitt "interference with the governance, projects and independence" of the cooperative group.

The executive committee also joined Fisher in seeking a declaration by the court that Pitt acted unlawfully and had violated their rights.

However, the committee did not join Fisher in his demand for reinstatement as the principal investigator of the cooperative group as well as his demand for payment of punitive damages and award of attorney's fees. These demands figure in the amended complaint as Fisher's alone.

The suit, if it continues, is likely to test the legal foundations of cooperative groups, which are typically private organizations based at research institutions and sustained by federal funds.

The latest development is all the more significant since, according to NCI, the NSABP executive committee has the authority to select the cooperative group's next chairman and, upon approval by the Institute, present the candidate's name for a vote by the cooperative group's members.

That process is expected to be completed by mid-October (**The Cancer Letter**, July 29).

In recent months, two entities have been interviewing candidates for chairman of the group.

One search is being conducted by a subcommittee of the NSABP executive committee.

Another search is conducted by the Univ. of Pittsburgh, which, according to NCI guidelines, will be obligated to present its candidate for approval by

the NSABP executive committee.

Thus, with the executive committee joining the Fisher suit, the university, a defendant, will be forced to present its candidate to the executive committee, a plaintiff.

### NSABP: Chairman Search Goes On

Though the executive committee has called for Fisher's reinstatement as chairman, it indicated that the search for his successor will continue.

"The process will be careful, exact, open and honest—but it will also take time," Peter Deckers, chairman of the search committee and a member of the NSABP executive committee, wrote in a letter to cooperative group's investigators.

"[The executive committee members] believe the NSABP as a clinical organization, and especially the P-1 trial as a prevention trial, are threatened with extinction unless the leadership issue is settled now," Deckers, executive vice president, clinical affairs at the Univ. of Connecticut Health Center, wrote in the letter, dated July 31.

"The NSABP executive committee has requested that Dr. Fisher's legal counsel include the NSABP in Dr. Fisher's suit against the Univ. of Pittsburgh. We do this for the expressed purpose of seeking relief in the judicial system, relief that will grant us a restraining order that will recognize the damage being done to the NSABP on the daily basis, the threat this is to the future clinical endeavors in America, and the absolute need to restore Dr. Bernard Fisher immediately to all of his authorities and responsibilities as chairman of the NSABP.

"New science in breast and colorectal cancer is not being debated, accrual is negligible, effective, accurate data management is threatened. Indeed, an inertia has settled on the NSABP that weakens its already severely eroded vitality on a daily basis," Deckers wrote.

Deckers was on vacation and could not be reached by **The Cancer Letter**.

Defendants in the suit include the university, chancellor Dennis O'Connor, vice chancellor, health affairs, Thomas Detre, and NSABP interim chairman Ronald Herberman.

Also named is the Washington law firm of Hogan & Hartson and attorney Martin Michaelson, who represented Pitt in the early days of controversy over scientific fraud at NSABP.

The NSABP executive committee did not join Fisher in his claim that Michaelson, having obtained



information from Fisher in confidence, used it against the scientist (**The Cancer Letter**, July 22).

The NSABP executive committee will be represented by Fisher's attorneys John Bingler and James Lieber, both of Pittsburgh.

Sources said the decision by the executive committee was reached as a result of two meetings, one in Fisher's house, and another by telephone hookup.

#### **Broder: Selection to Follow Ordinary Procedure**

At least prior to the executive committee joining the suit, NCI leadership expected the cooperative group to follow more or less ordinary procedure for the selection of chairman.

"We believe that the selection of a new chair should follow the usual procedure and be in the hands of the membership, consistent with the NSABP constitution and NIH procedures," NCI Director Samuel Broder wrote in a June 30 letter to Deckers.

However, the letter continued, "we at NCI will be called upon to defend that the process was open and fair," Broder wrote.

According to Broder, the new chairman will not have the power previously held by Fisher, since the grants that support the operations center and the biostatistics center would be recompeted separately.

"We believe that the best path to accomplish these functions is to seek the most qualified grantee (or contractor) to do the various jobs through open competition," Broder wrote.

"The membership can elect the new chair, and we at NCI will provide that person with headquarters support to permit him or her to provide scientific and clinical leadership... There are a number of issues regarding the statistical support, data integrity and auditing functions of the NSABP that are not suitable for a popular election per se," Broder wrote.

A copy of the letter was obtained by **The Cancer Letter**.

On July 5, NCI issued guidelines for transition and recompetition of the grant that supports NSABP. The excerpted text of the guidelines follows:

1. The NSABP executive committee will select the next chairperson in accordance with procedures specified in the NSABP Constitution and Bylaws. Candidates, including a nominee from the Univ. of Pittsburgh, will be solicited in a free and open fashion from academic surgical departments nationwide.

2. NCI will assure that the Chairperson-elect will have the full cooperation of the NSABP operations

center and biostatistical center at the Univ. of Pittsburgh. The Chairperson-elect, upon approval by NCI, will assume full scientific authority for NSABP activities and for the development of the recompeting application. The administrative functions of the group, including auditing, data management, affiliate reimbursements, etc., will be discharged by Donald Trump, who will continue to serve as Executive Officer.

3. The NSABP cooperative agreement supporting the operations centers and biostatistical center will remain at the Univ. of Pittsburgh until new awards are made following a formal recompetition. NCI will assist in the negotiation of working arrangements between the Univ. of Pittsburgh, the Chairperson-elect, and the Chairperson-elect's institution. Such arrangements could include a subcontract to create and maintain the chairperson-elect's office at his/her institution, with funding to support flexibility in expanding the scientific activities of the NSABP.

4. At the time of recompetition, NCI will require separate applications for operations functions and biostatistical functions.

#### **Operations functions include:**

- General scientific oversight, assuring development of research plans for each disease studied;

- Logistical and clerical support for the process of protocol development, including interactions with NCI;

- Periodic review of performance and membership status of each member, affiliate and CCOP, based on data provided by the biostatistical center.

- Logistical and financial support to scientific committees;

- Disbursement of third-party payments for participants without cooperative agreements from NCI.

#### **Biostatistical functions include:**

- All aspects of collection and management of group data;

- Establishment and implementation of all quality control and study monitoring procedures;

- Coordination of the group's on-site audit program;

- Implementation of appropriate registration, randomization and analytical procedures for group studies.

5. The NSABP executive committee will select a biostatistical center that will offer a grant proposal at the time of recompetition, and will do so after an

open and formal process of peer review.

6. The NCI-conducted peer review process will be accomplished by publication of a Request for Applications which will invite separate applications for an operations office, a biostatistical center and individual member cooperative agreements.

7. It is anticipated that the application receipt date for the RFA will be no later than Nov. 15, 1995.

## **RFA Available**

**RFA CA-94-013**

**Title: Chemoprevention Clinical Trials Involving Modulation/Function Of Genes And/Or Gene Products**

Letter of Intent Receipt Date: Oct. 15

Application Receipt Date: Nov. 23

The NCI Div. of Cancer Prevention and Control invites applications for cooperative agreements to stimulate and facilitate investigator initiated chemoprevention research involving agents that may effect gene expression and cellular growth and to encourage development of short-term clinical trials that evaluate the modulation/function of gene products by chemoprevention agents.

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private. The cooperative agreement (U01) mechanism will be used. Because the nature and scope of the research proposed in response to this RFA may vary, it is anticipated that the sizes of awards will vary also.

Recipients will have primary responsibility for the development and performance of the activity. However, there will be government involvement with regard to (1) assistance in securing an Investigational New Drug (IND) approval from the Food and Drug Administration (FDA), (2) coordination and assistance in obtaining the chemopreventive agent, (3) monitoring of safety and toxicity, and (4) quality assurance of the clinical chemistry aspects of the study.

If an investigator anticipates requiring considerable assistance in obtaining the chemopreventive agents or in securing the Investigational New Drug (IND) permit, from the Food and Drug Administration, such assistance must be sought in writing from the Program Director, prior to submitting the application.

Awards will not be made until all arrangements for obtaining the IND and the agent are completed. Final awards will also consider not only the cost of

the clinical trial, but also the cost of the agent and its formulation.

Approximately \$2.0 million in total costs per year for five years will be committed to fund applications. Three to six awards will be made. The number of awards is dependent on the receipt of a sufficient number of applications of high scientific merit. The total project period for an application submitted in response to the present RFA may not exceed five years. The earliest feasible start date for the initial awards will be July 1995.

Clinical trials of agents effecting gene expression or gene products are being sought. The goal is the development of short-term clinical trials that will evaluate the modulation/function of genes or gene products by chemopreventive agents. The studies should be developed in phases that may include a pilot phase in humans that could later proceed to a full-scale intervention.

One or more biomarker endpoints might be initially evaluated to determine baseline parameters and, subsequently, to serve as a follow-up after the administration of the prevention measure or the chemopreventive agents in vivo and/or in vitro. The main emphasis should be on small, efficient studies aimed at improving future research designs, providing a molecular basis for the action of the chemopreventive agent(s), or providing improved intermediate endpoint biomarkers. After successful completion of the pilot phase (i.e., demonstrated modulation of endpoint biomarkers), subsequent studies could include a clinical trial monitoring the test system, a cancer incidence or mortality endpoint, and a designated agent.

Studies that develop and evaluate biotechnologies for the identification of new genes, gene products and DNA probes to identify human disease or to identify individuals at high risk or predisposition to cancer are also encouraged.

For the initial human phase, the proposed study might describe the relevance of the marker test system to clinical or public health cancer prevention, the rationale for the selection of the study population, potential intervention agent or procedure. The project could result, later, in the markers and agent being evaluated in a full-scale, double-blind, randomized, risk reduction clinical trial.

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