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ASCO Calls For New Clinical Study Section, Endorses NCAB Action In Senate Testimony

The American Society of Clinical Oncology has called for the establishment of an NIH study section devoted exclusively to the review of clinical research grant proposals.

The society endorsed the National Cancer Advisory Board's recommendation for a new study section (*The Cancer Letter*, May 7) in testimony submitted last month to the Senate Labor, HHS and Education Appropriations Subcommittee.

"Compounding the problem of inadequate resources is the lack of an appropriate mechanism for peer review of investigator-initiated clinical
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In Brief

Appelbaum Directs Clinical Div. At Hutchinson; Vogelstein Wins Pezcoller Award; Curiel To UAB

FREDERICK APPELBAUM has been appointed director of the Div. of Clinical Research at the Fred Hutchinson Cancer Research Center. Appelbaum, a member of the Hutchinson faculty for 15 years, succeeds **John Hansen**, who has returned to the position of head of the immunogenetics program. . . . **BERT VOGELSTEIN**, Johns Hopkins Univ., has been selected from 28 candidates to receive the Pezcoller Award by the Italy-based Pezcoller Foundation, for his work on genetic markers for colorectal cancer progression. The award of 100,000 ECU (approximately \$120,000), will be presented in November. . . . **DAVID CURIEL**, Univ. of North Carolina Lineberger Comprehensive Cancer Center, has joined the Univ. of Alabama at Birmingham Comprehensive Cancer Center to establish and direct the center's gene therapy research. Curiel held a fellowship in the NCI-Navy Medical Oncology Branch in 1989-90. . . . **ALBERT LOBUGLIO**, director of the UAB Comprehensive Cancer Center, was presented with the UAB President's Medal by UAB President Charles McCallum in June. . . . **GROUND BREAKING** ceremony was held June 25 for the Cancer Center of Georgia, located at Georgia Baptist Medical Center in Atlanta. **Alvin Watne** is medical director of the cancer center and **David Harrell** is chief executive officer of the medical center. . . . **JORGE YUNIS** has been appointed director of the new cancer biology division at Thomas Jefferson Univ. Yunis was vice chairman, department of neoplastic diseases, Hahnemann Univ. . . . **BARTON KAMEN**, professor of pediatrics and pharmacology, Univ. of Texas Southwestern Medical Center, was named first holder of the \$500,000 Carl B. and Florence E. King Foundation Distinguished Chair in Pediatric Oncology Research. . . . **'IN BRIEF'** is continued to page 8.

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ASCO Calls For New Study Section In Testimony To Senate Committee

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research, particularly for those studies with direct relevance to patient care," ASCO said in its statement. "Of the 101 different study sections coordinated by the National Institutes of Health Div. of Research Grants, not one is dedicated to the review of clinical research proposals."

ASCO plans to bring wider attention to the issue of peer review through testimony and lobbying, said Stacey Beckhardt, ASCO director of government relations.

"This is an issue we have been talking about with NCI for a number of years, and while the Institute is supportive, we have not seen enough movement," Beckhardt said to *The Cancer Letter*. "The way the study section is set up now, clinical investigators just don't have a fair shot at the dollars available."

Clinical cancer research proposals (R01 grants) are reviewed by the Experimental Therapeutics 2 (ET2) study section, formed 10 years ago to review "the experimental therapy of clinical neoplastic diseases and associated disorders," according to the "Referral Guidelines for Initial Review Groups of NIH" (1990).

However, according to ASCO, ET2 reviews too broad an array of grant proposals in both preclinical and clinical research, to the detriment of the clinical proposals.

"Clinical research is a very broad term, but we are talking about those things with a patient care component," Beckhardt said.

Text Of ASCO Testimony

The ASCO statement continued:

"The peer review problem has been exacerbated in recent years by pressure to increase the number of

research project grants, a mechanism typically reviewed by DRG study sections. In response to this pressure, NCI has encouraged clinical scientists to submit this type of application.

"In the absence of a DRG study section dedicated to clinical research, grant proposals with clinical relevance are at a disadvantage. These research applications have a high rejection rate because:

- ▶ "study section members are more likely to be grant recipients who in turn are more apt to specialize in preclinical research; and

- ▶ "the complexity of outcomes in patient-oriented research suffers in comparison with the more easily defined variables common to basic research.

"A decade ago, NIH sought to address this problem by creation of a new study section intended to foster clinical research grants. However, in practice, NIH's solution has offered little to the clinical investigator since the new study section--Experimental Therapeutics 2--has, over time, become dominated by preclinical research applications. As a result, clinical research proposals remain underfunded.

"The barriers to obtaining funding for clinical research grant proposals have created the perception of an unfair peer review system, which in turn discourages young investigators from clinical research endeavors. At its May 4, 1993, meeting, the NCAB concluded that the shortfall for clinical studies was a 'crisis.' To address this problem, NCAB recommended the creation of a new study section for clinical research.

"ASCO agrees with NCAB's assessment. We firmly believe NIH was correct when it attempted to establish a new study section for clinical grant review. We suggest its failure was setting a mandate for ET2 that was so broad it encompassed both clinical and preclinical work. To ensure adequate and knowledgeable evaluation for clinical grants, we must charter a new study section exclusively to review clinical proposals. Members on this review body should predominantly be investigators accomplished in the conduct of this type of research."

CTEP Data On Clinical Proposals

The ASCO statement supported a "long-term incremental approach" to meeting NCI's bypass budget. The society opposed earmarking of funds for specific disease areas, instead recommending a \$56 million earmark for "clinical cancer research with a therapeutic intent." ASCO recommended a \$380 million increase for NCI in FY 1994.

According to NCI's Cancer Therapy Evaluation Program, the number of clinical applications submitted

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to ET2 has tripled from 54 to 156 from fiscal 1991 to 1993. The number of clinical awards rose from 10 in FY91 to 22 in FY92, only to drop back to 12 in FY93. The percentage of clinical awards has varied: 18 percent in FY91, 25 percent in FY92, and 8 percent in FY93.

Preclinical submissions decreased from 92 in FY91 to 86 in FY93, while preclinical awards went from 22 in FY91 to 12 in FY93. The percentage of preclinical awards has been higher than that for clinical awards: 24 percent in FY91, 27 percent in FY92 and 14 percent in FY93.

Clinical Oncology Grant Funding: Recent History Of A Controversy

Are clinical cancer researchers getting a fair shot at grant funding available from NIH? Is the NIH peer review system biased in favor of basic laboratory research?

Over the past three years, the opinion has been building among clinical oncology researchers that they are not receiving a fair percentage of grant support. The clinicians, represented on the National Cancer Advisory Board and the American Society of Clinical Oncology, say the problem warrants the creation of an entirely new peer review group.

Also favoring a clinical oncology study section is NCI Director Samuel Broder.

On the other side of the controversy is the NIH Div. of Research Grants (DRG), which operates the peer review system, and members of the existing peer review group that is said to be at fault.

The two sides have been in disagreement for several years, but a recent action by the NCAB and Congressional testimony by ASCO have set the stage for a confrontation.

In May, NCAB called for the creation of a new study section for peer review of clinical research. NCAB Chairman Paul Calabresi is trying to schedule a private meeting with DRG Director Jerome Green within the next several weeks to present the NCAB's views, Calabresi said to **The Cancer Letter**.

In late June, ASCO endorsed the NCAB's action in written testimony to the Senate Appropriations Subcommittee that funds NIH.

Over the past three years, nearly all of NCI's actions on grants funding have related to the issue of funding for clinical oncology research.

NCI has tried to encourage clinical investigators to submit grant applications, conducted a study of the large program project (P01) grant mechanism, created a grant called the Interactive Research Project Grant,

and phased out the long-term Outstanding Investigator Grant.

NCI asked for a clinical oncology study section two years ago, but NIH declined.

Now, once again, NIH is reviewing the data on clinical oncology applications, DRG Deputy Chief for Review Faye Calhoun said to **The Cancer Letter**. However, the number of purely clinical applications is insufficient to justify the creation of a study section, she said.

All sides seem to agree that something needs to be done for the future of clinical oncology research.

"NIH was devised for a time when there was an excess of resources and a deficiency of applicants," said Emil (Jay) Freireich, M.D. Anderson Cancer Center, a leading proponent of a new study section. "The peer review system has become arbitrary and capricious because it is totally out of date."

"All the stress relates to the fact that money is tight," said Henry Friedman, Duke Univ., and a member of the Experimental Therapeutics 2 study section who does not support the creation of a study section. "This year 14 percent of NCI grants will be funded, and that may go as low as 10 percent next year. The peer review system was never designed to distinguish this selectively."

Lack Of Growth In Clinical Research Funds

The controversy begins with money, or lack thereof.

In 1991, NCI Director Samuel Broder began explaining at meetings with NCI division Boards of Scientific Counselors, with the NCAB, with ASCO and the American Assn. for Cancer Research, where the Institute's money had gone in the past decade.

Using the measurement of dollars adjusted for inflation, Broder showed that NCI's budget fell 6 percent in constant dollars since 1980 (**The Cancer Letter**, Feb. 8, 1991).

Meanwhile, the NIH budget showed real growth of 27 percent since 1980.

Areas that fared the worst were mechanisms that are unique to NCI or used predominantly by NCI. These included:

- ▶ Clinical cooperative groups, down 30 percent in constant dollars since 1980. These groups conduct most of the definitive phase 3 studies of new cancer treatments.

- ▶ Cancer prevention and control, down 30 percent.

- ▶ Cancer centers, down 15 percent.

The budget item that had 20 percent real growth, Broder said, was "Research Project Grants" (RPGs), an NIH term that includes investigator-initiated R01 grants and program project (P01) grants.

The RPG line has strong political backing. In 1990, when NIH for budgetary reasons decided to reduce the number of RPGs to be funded, there was an outcry from scientists around the country. This resulted in Congressional appropriations committees telling NIH to fund at least 6,000 RPGs and calling for a financial management plan for the Institutes.

"Simply saying we don't have enough money is not really going to solve the problems we need to solve," Broder said to the NCAB. "We need to come up with programs and we need to deal with trends that are at least a decade old."

The first program NCI came up with was to attempt to tap into the RPG funds by encouraging researchers who normally had not used the R01 mechanism to submit grant applications.

Freireich Report Links Research Funds, Training

Emil (Jay) Freireich, M.D. Anderson Cancer Center, spent all of 1990 on loan to NCI as Broder's special assistant. During the year, Freireich visited 20 cancer centers around the country to evaluate the training of clinical oncology investigators.

The result was a report, "A Study of the Status of Clinical Cancer Research in the United States (1990)," published in the "Journal of the National Cancer Institute," Vol. 83 No. 12, June 19, 1991.

The study "confirmed a continuing decrease in the quality and quantity of young physicians entering academic careers in clinical oncology research, defined as cancer research requiring clinician-patient interaction."

Freireich identified two problems: the training programs and the "research environment." The problem with the research environment is a "strong and widespread perception that grant proposals for clinical oncology research are at a competitive disadvantage with proposals for cancer research in the laboratory," Freireich's paper said. Thus, promising researchers were forsaking clinical investigation for clinical practice or basic laboratory research.

Freireich advocated that NIH form a new study section for the review of R01 grant proposals in clinical oncology.

NCI's Centers, Training & Resources Program of the Div. of Cancer Biology, Diagnosis & Centers, led by Brian Kimes, held a workshop in the fall of 1990 to determine whether Freireich's conclusions were correct, which it did (*The Cancer Letter*, Nov. 23, 1990).

"It was the perception of the majority of participants that the Experimental Therapeutics 2 study section in the NIH Div. of Research Grants, although consisting of highly qualified scientists and physicians,

does not contain sufficient expertise in the clinical research as defined by this workshop and thus would not serve as the most suitable peer review group to review this kind of research," the report said.

The workshop report made five recommendations, including that "a study section in DRG be either realigned to consist primarily of peers who are actually doing clinical oncology research or create a new study section with this kind of charge and expertise even if it has to be done as an 'experiment.'"

The report was published in "Cancer Research," Feb. 1, 1991.

Not Enough Applications, DRG Tells NCI

Following the Freireich report and the NCI workshop, Broder asked Jerome Green, director of the NIH Div. of Research Grants, to establish a study section for clinical oncology.

NCI Cancer Therapy Evaluation Program Director Michael Friedman broke the news to the DCT board in early 1991 that DRG would not create a new study section because the current study section for clinical research, Experimental Therapeutics 2, is "underutilized" (*The Cancer Letter*, March 8, 1991).

ET2 was created in 1983 expressly for reviewing grant applications in clinical research (see ET2 guidelines later in this story). Facing a shortage of clinical applications, ET2 took the "spillover" applications from ET1 and other study sections. The study section's membership gradually shifted away from purely patient-oriented research, NCI executives said.

In the spring of 1991, NCI called on clinical investigators to flood the system with their grant applications.

"We're going to ask everyone to please submit their best ideas," Friedman said to the DCT board. The reasoning was that a larger number of clinical applications would force ET2 to focus entirely on clinical research, so that clinical applications would not compete with basic research for the best priority scores. This would create pressure on DRG to appoint more clinical researchers to the study section.

NCI issued a Program Announcement in clinical therapeutic research in April 1991 with the intent of encouraging applications that would be reviewed by ET2.

In a presentation to the NCAB in May 1991, NCI Div. of Extramural Activities Deputy Director Marvin Kalt emphasized the importance of obtaining research project grant funds. "It is the RPG pool of funds that continues to enjoy growth in absolute dollars, so is most likely to be the source of expanded research

opportunities of all types," Kalt said. "This is the pool that clinical researchers must reach for, if their numbers are ultimately to increase" (*The Cancer Letter*, May 24, 1991).

"This is a grand experiment," Friedman said at the same NCAB meeting.

"I personally don't see any substitute other than to have a chartered, standing study section to review and prioritize the high quality research that comes in," Broder said to the NCAB that May.

Pressure On P01 Grants

At the same May 1991 NCAB meeting, Broder said NCI was having difficulty finding enough funds for program project, or P01, grants.

Congress had asked NCI to fund 840 new and competing research project grants in FY91. To meet this target, NCI would have to reduce funding for P01s, since P01s cost four or five times that of an R01 and only count as one grant, though they are made up of several related projects.

Until 1991, P01s accounted for 25 percent of NCI's research project grants dollars, but only five percent of the number of grants (*The Cancer Letter*, May 31, 1991). Clinical investigators had relied on P01s to provide a sustained research effort involving both clinical and basic laboratory investigations.

The NCAB passed a resolution asking NIH to provide NCI with flexibility to fund more P01s.

Next, NCI tried to find a way around what became known as "the numbers game" by creating a new type of grant that would have some of the advantages of a P01, while still counting as separate grants.

The "Interactive Research Project Grant" (IRPG), also called the interactive R01, would allow a minimum of three investigators to submit concurrent, linked R01 grant applications.

NCI's CTEP reported in January 1992 that ET2's workload of clinical applications submitted in response to CTEP initiatives was up 50 percent from the previous year.

"Send in your R01s, or encourage your colleagues to send in R01s," Broder urged the DCT board (*The Cancer Letter*, Jan. 17, 1992). "One reason we've made so much progress in basic science is that investigators have a reasonable opportunity on their own to submit applications, and an opportunity for training and career development. I don't think a comparable opportunity exists for those going into clinical research. I don't think we can accomplish this goal only by setting aside money for RFAs."

There were problems with the interactive R01. DRG separated the applications submitted as a package and

sent them for review to different study sections, CTEP Director Friedman told the DCT board (*The Cancer Letter*, July 10, 1992). "That is almost sure to result in not having an overall view of the project and in not funding the project," he said.

How could the Institute ensure that interactive R01s were reviewed by a single study section? Issue an RFA and conduct the review with ad hoc study sections formed by NCI.

"We think that having interactive R01s submitted outside of the RFA is not likely to result in funding the whole project," CTEP's Friedman said.

NCI divisions issued a flurry of RFAs in 1992 soliciting interactive R01 submissions.

Other major grants funding changes NCI initiated:

- ▶ Phase out of the seven-year Outstanding Investigator Grant. The grant came under criticism for its length of time and amount of money NCI could use to fund R01 grants. The OIG was begun in 1985 to fund experienced investigators working on high risk projects.

- ▶ Began the Specialized Programs of Research Excellence in breast, prostate and lung cancer. These center grants were designed as a counterpart to the cancer center core grants. The SPORes would offer training and career development opportunities, and serve to encourage clinical researchers to submit R01 grants, Broder said.

- ▶ A study of NCI's P01 funding was presented to the NCAB in September 1992 (*The Cancer Letter*, Oct. 2, 1992). This led to a change in the review of P01s from ad hoc study sections to a two-tiered system.

The Genesis Of 'Crisis'

In December 1992, NCAB Chairman Calabresi formed the Clinical Investigations Task Force to study the issues surrounding funding for clinical research.

At M.D. Anderson, Freireich had become aware of a book by a Rockefeller Univ. professor emeritus, Edward Ahrens Jr. Titled "The Crisis in Clinical Research," Ahrens' book contained research and data to support the view that a major restructuring in all of clinical research and training is needed, not only for clinical cancer research (Oxford Univ. Press, 1992).

Ahrens called for restructuring of the NIH grants review process, primarily placing more MDs with experience in patient-oriented research on study sections. He also called for restructuring the education and training of clinical investigators.

"NIH has become the National Research Council for biology," Freireich said recently to *The Cancer Letter*. "Why should 60 percent of the reviewers be PhDs who cannot conduct clinical research? The only way to get

funded is to do basic research."

The Outstanding Investigator Grant "was a great program" because it funded productive investigators who in turn trained the next group of clinical investigators, Freireich said.

"The bottom line is, the peer review system is totally outmoded and inefficient," Freireich said. "The whole DRG needs to be revamped."

Last May, Calabresi and other Task Force members attended the Clinical Research Meetings, held in Washington by the American Federation for Clinical Research, the American Society for Clinical Investigation and the Assn. of American Physicians.

"There is a widespread perception that the problems facing clinical investigation constitute a crisis," AAP President Jean Wilson, Univ. of Texas Southwestern Medical Center, began his presidential address. "Despite this widespread concern with the state of our discipline, our problems have not improved and have probably worsened in the past 15 years."

Increased funding for biomedical research would not solve the problem. The crisis, Wilson said, "is the failure to recruit sufficient young people into the field to ensure continuing progress in the years ahead." Only about half as many medical graduates are training for academic careers as are needed to sustain clinical research efforts and medical school faculties, Wilson said.

Wilson made two proposals:

► Devise a medical school curricula that allows potential academicians to make earlier commitments to an academic career. More medical students should be encouraged to take a year off for an intense research experience. A model project of this type is the Howard Hughes Program at NIH.

► Ease the debt problem for medical students opting for an academic career, as opposed to those going into MD/PhD programs who leave medical and graduate school debt-free. Wilson proposed debt forgiveness of federally funded student loans for physician scientists who complete a minimal time as full-time investigators.

Calabresi happened to run into Freireich at the Clinical Research meetings and invited him to the NCAB Task Force that same day. The two spoke to the Task Force about the "crisis" and the need for reform.

After hearing the data from CTEP that the funding rate for its R01s had not increased even though applications had tripled, the Task Force passed a motion to urge DRG to form a new study section.

Kimes and Friedman provided advice on how to go about it. It would take a grass-roots effort from the

clinical community to convince DRG to form a new study section, they said. NCI had done what it could.

Reaction Among ET2, DRG

ET2 members and DRG staff were angered by the implication that review was unfair to clinical research. The study section refrained from making a public statement, though some members thought it ought to, a source said to **The Cancer Letter**.

ET2 member Henry Friedman spoke to **The Cancer Letter** with the caveat that his remarks reflected his opinion and not that of the study section.

"The accusation has been leveled that the peer review process for clinical research is not working and there is a bias against clinical research. The implication is that PhDs are not credible reviewers for clinical oncology.

"The problem is that the real etiology of the dissention is there is a limited amount of money. If the funding pool was expanded so that payline was 20 to 30 percent, there would be relief from investigators and reviewers.

"Since there is not likely to be a massive infusion of funds into generic cancer research in this day of limited funding, is there really a need for a new study section?

"I am a clinical investigator and an R01 funded laboratory investigator. I do both. Based on my experience in ET2, the charges simply have no substance.

"ET2 is an exquisitely selected group of people directed by a Scientific Review Administrator [Marcia Litwack] committed to fair review of laboratory and clinical research. The composition has been geared for its wide experience for reviewing lab, clinical, and translational research. The notion that because you are a PhD you cannot review a clinical grant is short-sighted and blatantly inflammatory.

"ET2 is committed to funding quality work. The problem is that there is a limited pool of money.

"Few applications get funded on the first go-round. Though many laboratory people will read the concerns of the study section and address them, the clinical investigators do not seem to resubmit with any frequency.

"The hardest on review of clinical research are the clinicians, not the laboratory researchers, because they are aware of the problems that can happen.

Clinical research proposals that are not highly scored "have not presented a compelling story," Friedman said. "You need preliminary data to prove you can do what you say you are going to do. Some of the stuff coming in is not good quality. The system

is so stressed that what may have been funded at 30 percent may not be funded at 14 percent.

"We all feel bad, but the answer is not to indict the study section which has tried to give fair play to clinical investigation. I believe the review process is very balanced."

According to another source close to the review process, in two of last three ET2 meetings, the best scoring applications were clinical. While applications being tracked by CTEP do not fare well, clinical applications submitted in response to initiatives from NCI's Biological Response Modifiers Program tend to have better scores, the source said.

"On the average, the clinical applications are not very good," the source said. Clinical researchers rarely will resubmit a revised application, even though very few clinical or basic applications get funded on the first try. "It is strictly a matter of grantsmanship."

ET2 "is really interested in fostering clinical research," the source said. "The pattern is not quite as bad as you are led to believe."

"If they think that a committee of clinicians is going to solve their problems, they are mistaken," the source said. "Clinical people are very hard on applications. They nitpick them to death."

Other investigators question the need for a new study section. R01 grants, some say, are not appropriate for clinical trials due to the long waiting time between submission of an application and funding.

"What is needed in clinical research is a liberalization of P01 grants, which have essentially come to a halt for clinical research," Charles Moertel, chairman of the North Central Cancer Treatment Group, said to **The Cancer Letter**. "If they want to do something to help clinical research at a basic level, they should come to an agreement with Congress that the P01 is the most effective way to conduct clinical research, and stop this nose-counting on R01s."

ET2 Referral Guidelines

Following is the purpose of the Experimental Therapeutics 2 study section as published in the "Referral Guidelines for Initial Review Groups of NIH" (1990):

"General Statement: The emphasis in applications assigned to this study section is on the experimental therapy of clinical neoplastic diseases and associated disorders. Included are applications concerned with the clinical assessment of the antitumor efficacy of single chemotherapeutic agents, combination chemotherapy and combined modalities such as

surgery, radiation and chemotherapy. Also included are clinical cancer immunotherapy studies, and biochemical pharmacology and pharmacokinetic studies of chemotherapeutic agents in common clinical use.

"Specific Areas:

"I. Drug Evaluation. Evaluation of compounds for their antitumor efficacy against a variety of human tumors, assays of multiple chemotherapeutic agents and combined modalities in a variety of clinical combinations and against various tumors; investigation of drug toxicity and possible reversal; influence of routes of administration on drug effect and drug absorption; dosage schedule in relation to drug effect, half-life of drugs in the body; penetration of blood brain barrier, and other related pharmacological studies.

"II. Biochemical Pharmacology. Investigation of agents used clinically with respect to mechanism of action, drug metabolism, drug resistance and cell kinetics, both in clinical studies and in studies with model systems.

"III. Clinical Investigations. Studies of the fate and distribution of clinical compounds. Studies of mechanisms of drug toxicity, drug resistance and reversal both in clinical studies and with model systems. Included are clinical trials of anti-cancer agents, singly, in combination, and/or combined modalities.

"IV. Biological Response Modifiers. Studies of the effectiveness and mechanism of action of biological response modifiers in the treatment of cancer, e.g., cancer immunotherapy studies both in the clinic and in studies with animal models."

Two OAM Advisors Criticize Third Over Membership On ACS Panel

Two advocates of unconventional cancer therapy who are expected to be appointed to the advisory panel of the NIH Office of Alternative Medicine have demanded that a third prospective member resign from a panel of the American Cancer Society.

The target of the attack was Barrie Cassileth, a psychosocial oncologist and adjunct professor at Duke Univ.

Last week, at a meeting of the ad hoc panel of advisors to OAM, Cassileth was called aside by Ralph Moss, an author of books critical of the "cancer establishment" and Frank Wiewel, head of People Against Cancer, an advocacy group.

According to Cassileth, Moss and Wiewel told her that she had been "tarred" by her membership in the

ACS Subcommittee on Questionable Methods of Cancer Management and that unless she resigned from that body she would not be named advisor to OAM.

Members for the OAM board of advisors have been selected by NIH staff, but the permanent panel has not been formed because of the Administration's freeze on formation of advisory boards. In the absence of a permanent advisory board, OAM is relying on input from ad hoc advisors.

Cassileth told **The Cancer Letter** that she did not respond to Moss and Wiewel's statement directly, and only thanked them for their concern. On the following day of the meeting of the ad hoc panel, Moss distributed the most recent issue of "The Cancer Chronicles," a newsletter he edits.

The newsletter's front page editorial stated:

"Barrie Cassileth has been an exemplary member of the OAM ad hoc advisory board--conscientious, fair and intelligent. But Barrie is also a member of the ACS Subcommittee on Questionable Methods of Cancer Management... She helps plan ACS's actions on cancer alternatives.

"This is not hearsay. An internal ACS memo printed in **The Cancer Letter** [June 18] was written by Cassileth, and then adopted by the full ACS board. In it, Cassileth outlines how ACS should develop a "proactive, immediate response to media reports on cancer treatment and diagnosis...

"It's time to find out on which side of the medical fence Dr. Cassileth resides," the editorial concluded.

At the same meeting, another likely member of the OAM advisory committee, Berkley Bedell, a former Iowa Congressman whose lobbying of Sen. Tom Harkin (D-IA) led to the creation of OAM, suggested that Cassileth give him a copy of the ACS memo.

"He said, send me a copy of the letter, if you want to, and that may help you clear yourself," Cassileth said.

Bedell confirmed that the conversation had taken place.

"I told her that if the letter is not damaging, it might be of help to her if I could have a copy," Bedell said to **The Cancer Letter**. "I would like to know better whether she is a moderating influence on them or not."

Contacted by **The Cancer Letter**, Wiewel confirmed that he and Moss had told Cassileth that service on the ACS subcommittee was incompatible with service on the OAM board.

"One cannot serve two masters," Wiewel said to **The Cancer Letter**.

"It's my feeling that the ACS group is not interested in any way in fair evaluation of alternative cancer

therapies and that they are dedicated to the elimination of these therapies. It has been proven that there has been no formal evaluation taking place on the part of ACS. Instead, they have chosen to put alternative therapies onto their list, that has now essentially become a black list. It's very McCarthy-like," Wiewel said.

Jay Moskowitz, NIH Deputy Director for Science Policy and Technology Transfer, told **The Cancer Letter** that none of the parties involved were speaking for NIH.

"None of the people you've mentioned works for OAM, and no one was speaking for OAM in those conversations," Moskowitz said.

Asked whether an affiliation with ACS was incompatible with membership on the OAM panel, Moskowitz said, "Everyone has a right to participate in any panel they have been selected for."

Moskowitz said he had not been aware of the incident. "Any of the parties that want to bring this to either the attention of [OAM Director] Joseph Jacobs or my attention should do so," he said.

Cassileth said the confrontation and the editorial were a disappointment to her.

"I am disappointed that Moss and Wiewel would fear someone who promotes honest and open evaluation of treatments," she said to **The Cancer Letter**.

"I am not easily intimidated, and I have no intention of resigning from ACS," she said. "Whose side am I on? Exclusively that of the patient, through efforts to distinguish between quackery and useful therapies."

Jacobs was traveling and could not be reached for comment.

In Brief

MSKCC Called 'Best Cancer Hospital' By U.S. News; 10 New ONS Chapters

(Continued from page 1)

... **Memorial Sloan-Kettering** Cancer Center has been ranked the best cancer hospital in the nation by "U.S. News & World Report" in the magazine's 1993 "America's Best Hospitals Guide." The magazine, in conjunction with the National Opinion Research Center, used a method for objective assessment of hospital care, according to a statement from U.S. News. . . . **TEN NEW** chapters of the Oncology Nursing Society were chartered last May, giving the society a total of 167 ONS chapters in 48 states. ONS membership is more than 24,000.