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THE CANCER LETTER

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Senate Committee Ok's $1.9 Billion Budget For NCI, Same As House Appropriation

The Senate Appropriations Committee last week approved a $1.9 billion appropriation for NCI, the same amount approved by the House earlier this month.

The bill was expected to go to the floor of the Senate next week.

Under the Senate measure, NIH would get $11.3 billion, $395 million more than the comparable budget for FY 1994, but $138.7 million less than the President's request for 1995, and $11 million more than the House allowance.

"A significant portion" of the incrase over the House allowance is intended for brain research, according to the committee report on the bill.

(Continued to page 2)

NSABP Executive Committee Is Seeking Applications From Surgeons To Lead Group

The executive committee of the National Surgical Adjuvant Breast & Bowel Project is seeking applications for chairman of the cooperative group. In a memorandum to directors of NCI designated comprehensive cancer centers, chairmen of departments of surgery and deans of US medical schools, NSABP executive committee requested assistance "in providing the names of senior academic physicians capable of assuming the administrative and scientific authority and responsibilities of the position of chairman of NSABP." Following is the text of the memorandum from Peter Deckers, chairman of the cooperative group's search:

We believe NSABP is the premier clinical trials organization in the world. Under the charismatic and effective leadership of Dr. Bernard Fisher, this organization, during the past 30 years, has conducted seminal prospective randomized controlled clinical trials in breast and colorectal cancer and, as a result, the local-regional control of invasive and in situ breast cancer has been revolutionized. Moreover, adjuvant chemo and/or hormonal therapy is now consensus treatment in selected subsets of women with breast cancer and men and women with colorectal cancer. The NSABP seeks to continue and to augment its pioneering work in these areas. It also seeks to continue accrual and analysis of women at high risk for breast cancer now enrolled and to be enrolled in its first prevention trial, P-1, a comparison of tamoxifen versus placebo.

Effective leadership is essential and urgent! We seek first and foremost a respected physician—preferably a surgeon, a man or a woman of

(Continued to page 8)

Senate Bill Emphasizes "Balanced Research Program"

(Continued from page 1)

The bill also:

- Emphasizes research on breast, cervical, ovarian, and prostate cancer, as well as a "balanced research program" for NCI.
- Commends NCI for its efforts to "strengthen the quality assurance and auditing of clinical trials."
- Encourages NCI to consider supporting research on shark cartilage (see story, page 7).
- Expands the NIH director's authority to transfer funds from the individual insitutes to include transfers for nonemergency research purposes.
- Provides $111 million for NIH buildings and facilities, $169,000 less than the administration's request, $2.3 million more than the FY94 appropriation. The funds are for modernization and improvement of the NIH infrastructure, safety and health improvements to the NIH Clinical Center, other safety programs, implementation of a model medical pathological waste management and disposal system, and for concept development to rebuild the Clinical Center Complex.
- Provides $1.3 billion for AIDS research throughout NIH, $40.4 million above the FY94 level, but $41.4 million below the Administration's request, and the same amount as the House allowance. Under the NIH Revitalization Act of 1993, the funds will be transferred within 30 days after enactment of the appropriations bill to the individual NIH institutes.

Excerpts from the committee report follow.

Report Language on NCI Appropriations

The Committee recommends an appropriation of $1,863,514,000 for the National Cancer Institute. This is $48,290,000 less than the administration's request, $55,905,000 more than the fiscal year 1994 appropriation, and the same as the House allowance. Funds previously included in this appropriation for AIDS research are now provided in the Office of AIDS research account to be transferred back to the Institute consistent with the provisions of the 1993 NIH reauthorization. Like the House, the Committee intends that within the funds provided, the highest priority be given to research in breast, cervical, ovarian, and prostate cancer.

Balanced Research Program—The Committee recognizes the importance of a strong cancer research program which includes basic and applied science, cancer prevention and control programs, information dissemination to the scientific community and lay public, and an effective network of cancer centers. Basic research remains the cornerstone of our ability to make progress in all other areas of cancer research and must be given equal emphasis with disease specific research in allocating program resources. The Committee believes that the potential to move research progress from the bench to the bedside has never been greater, and encourages the Institute to support greater emphasis on translational research within the funds provided.

Clinical trials—The Committee is pleased with NCI's efforts to strengthen the quality assurance and auditing of clinical trials, and looks forward to a continuation of these efforts in fiscal year 1995.

Breast cancer—Breast cancer rates in the Northeast and in the middle Atlantic States are high, and several epidemiological studies are being planned to explore the reasons for these high rates. For example, the Long Island breast cancer study project is looking at the various factors contributing to breast cancer, including factors such as electromagnetic exposures, water, airplane exhaust, organic solvents, polychlorinated biphenyls [PCB] and polybrominated biphenyls [PBB], and pesticides. These factors will be examined in conjunction with case-controlled studies of women in the community.

The Committee strongly supports such research, and notes that nothing in this bill is intended to limit NCI's discretion to carry out these vital epidemiological studies using funding appropriated under this act. The Committee intends to carefully follow the progress of this ongoing research, which has important health implications for all women, and has provided sufficient resources to permit these studies to continue on schedule.

Prostate cancer—The Committee is pleased that NCI has expanded the funding available for a broad range of activities to improve prostate cancer treatment outcomes. Prostate cancer continues to be the most commonly occurring cancer in men and the second leading cause of cancer death in men. The Committee is concerned that the incidence continues to increase and urges the maintenance of a strong prostate cancer

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program at the Institute. Particular attention should be given to the very high rates of prostate cancer among African-American men. The Committee urges NCI to collaborate with the urology program at the NIDDK on research geared toward the development of effective early detection techniques and innovative treatments for the disease.

Psychosocial support—Noting the increasing evidence that providing psychotherapeutic support services for cancer patients and their families is a low-cost, highly effective addition to other medical treatment, the Committee continues to believe that NCI should require that NCI-supported cancer centers provide supportive psychotherapeutic services to cancer patients at all stages of diagnosis and treatment, and to their families. The Committee encourages NCI to expand its research in this area to include social work services because social workers are among the primary providers of these services. The Committee is greatly concerned that socioeconomically disadvantaged and cultural minority populations are most likely to have higher rates of cancer morbidity and mortality.

Accordingly, the Committee expects NCI to expand research on psychotherapeutic, psychosocial support, and community care services that are tailored for these vulnerable populations.

Proton beam—For the past 4 years, at the Committee's initiative, NCI has provided funds for the planning, design, and construction for a competitively selected and peer-reviewed, hospital based proton therapy center. Proton therapy research has been supported by NCI through the peer review process because of its potential in the treatment of inoperable cancers and certain heart and vascular diseases. The Committee is pleased that the project is on schedule and that a 50/50 institutional match has been provided. The Committee urges continuation of this initiative.

Cancer centers—The Committee expresses its support for NCI's network of cancer centers, and urges continuing support for meritorious centers that have established, funded planning grants, particularly to those providing services to underserved rural populations.

Native Americans—Cancer is the leading cause of death for Alaska Native women, the second leading cause of death for American Indian women, and the third leading cause of death in American Indian and Alaska Native men. The Committee urges NCI to continue to expand its efforts targeted toward these groups. The Committee also vrishes to be assured that the citizens of the State of Hawaii have ready access to state-of-the-art cancer care through the opportunity to participate in federally supported clinical trial groups.

The Committee is also concerned about the unusually high rates of invasive cervical cancer at very young ages among Alaska Native women, and urges the Institute to work with the Indian Health Service and the Centers for Disease Control and Prevention in devising culturally appropriate educational messages which would support early screening and evaluation. Implementation of such a plan should be directed toward the goal of improving Alaska Native women's awareness of cervical cancer, and the need for early education about the human papilloma virus and its role in development of the disease. A plan should also focus attention on the slightly less high rates of lung cancer, colorectal cancer, gastric cancers, and nasopharyngeal cancers (related to Epstein-Barr virus) among Alaska Natives as well.

Nursing—The Committee urges NCI to continue to work collaboratively with the NINR to address research issues involving nursing practice in the field of cancer.

Neurofibromatosis—The Committee recognizes that the public's investment in neurofibromatosis [NE] research is continuing to show dramatic results on a cost-effective basis. Since the breakthrough discovery of the second NE gene and gene product last year, there has been further determination of the connection between NE and cancer, including leukemia, colon cancer, breast cancer, and melanoma, a substantial increase in the number of researchers engaged in NE research, discovery of more NF1 mutations and the dramatic commencement of a nationwide trial clinical drug treatment program on NF1 patients. These advances open up exciting new research opportunities including development of an animal model for NF1, further determining the function of the NF1 and NF2 genes and their connection to cancer and advancing the clinical drug treatment program for NF patients. Since NF is closely linked to cancer, brain tumors, and learning disabilities, over 100 million Americans stand to gain from the advances occurring in NE research. Accordingly, the Committee supports a substantial increase in funding for NF research.

Bionutrition—Diet may rank second only to smoking in its association with cancer according to the Institute of Medicine "Report on Nutrition and Food Sciences." Obesity, reduced dietary fat, and increased intake of fruits and vegetables are major considerations in the prevention and treatment of cancer. Research areas of opportunity identified by the Institute of Medicine include the role of fat in the etiology of cancer and the role of the constituents of fruits and vegetables in determining cancer risk. The Committee is concerned, however, because the National Cancer Institute may be terminating its investment in clinical nutrition research units. The Committee believes that CNRU's and similar programs are essential to link basic and clinical science. The Committee also encourages NCI to further explore the role of nutrition and women's health including breast cancer.

Diethylstilbestrol—The Committee continues to strongly support increased efforts to study and educate the public about the impact of exposure to the synthetic hormone diethylstilbestrol [DES]. NCI and other institutes, along with the Office of Women's Health have developed a plan for expanded activities in this area. The Committee has included sufficient funds for NCI to expand its fiscal year 1994 levels of support for both its DES research and education efforts. The Committee is aware of reports that there may be third generation DES health effects—health problems among the sons and daughters of DES daughters and sons—and urges that this issue be studied.

Shark cartilage—The Committee is encouraged to hear of promising cancer research involving shark cartilage and encourages NCI to consider supporting this research. It is hoped further research will yield the identification of the active molecules from shark cartilage to be used for the development of synthetic or molecularly engineered versions of the naturally active material.

NIH Office Of The Director

The Committee recommends an appropriation of $215,045,000 for the Office of the Director. This is $18,477,000 less than administration's request, $12,437,000 more than the fiscal year 1994 appropriation, and $4,429,000 less than the House allowance.

Minority health initiative—The minority health initiative is a major trans-NIH project intended to close existing minority health gaps and to increase opportunities for minorities to pursue careers in the biomedical sciences. The goals of the MHI include increasing intramural and extramural research aimed at improving minority health across the lifespan, developing proven protocols for intervention in health behaviors affecting the longevity and quality of life for minorities, and implementing programs that prepare more minorities for careers in the biomedical sciences.

Women's health initiative—The women's health initiative is a large integrated study of prevention of the leading causes of death, disability, and frailty in postmenopausal women. Components of the study include: a clinical trial to test promising preventive interventions for cancer, heart disease, and osteoporosis; an observational study to define new predictors for disease and risk status; and a community prevention study to test approaches to improving healthful behaviors of minority women. The goal of these studies is valid information for women and their health providers about prevention of disease and disability.

Office of Alternatiue Medicine—The Committee has provided $6,000,000 for Office of Alternative Medicine. The Committee has provided sufficient funds for the Office to expand the number of field investigations to investigate and validate the efficacy of alternative treatments. The Committee has also provided sufficient funding for additional scientific investigators who shall be available to travel, as necessary, to conduct preliminary medical investigations into these alternative treatments.

In addition, the Committee is pleased that the NIH Revitalization Act formally created the Alternative Medicine Program Advisory Council. The Committee urges the Council to meet as soon as possible after its members have been formally appointed, and urges the Council to help develop an operating budget and a long-term strategic plan for the Office of Alternative Medicine. Furthermore, of the amount appropriated for the Office of Alternative Medicine, the Committee has included $750,000 for the creation of a data base in alternative medicine. The purpose of the data base is to bring together all the existing data and literature on alternative medicine and develop organized, systematic, and up-to-date reviews of the relevant scientific data. The data base should prepare and maintain a register of randomized controlled trials and other research efforts in this area, and should also contain a compilation of basic and clinical research relevant to alternative and complementary medicine. This review of the literature should also be made available to health care providers and consumers.

Office of Behavioral and Social Sciences Reseerch—The Committee is distressed to learn that the Office of Behavioral and Social Sciences Research at NIH has not yet been established. It is now more than 1 year after its authorization, yet the office remains unstaffed and unfunded, with a mandated report to Congress unwritten. It is the desire of the Committee that the NIH Director act quickly to establish the OBSSR. Examples of the areas that would be encompassed in any definition of behavioral research include—but are not limited to—research in health and behavior, personality research, social and developmental psychology, cognitive science, treatment effectiveness, psychopathology, and biological bases of behavior. The Committee expects the NIH to take immediate steps to implement the OBSSR, including the initiation of a search for a director of the office. The Committee has provided $2,000,000 for the office for fiscal year 1995. The Committee directs the NIH to report to the Committee by February 1, 1995, on specific steps to establish the OBSSR, appoint a director, and develop an operating plan for the office.

Office of Rare Disease Research—The Committee is pleased with the establishment of the Office of Rare Disease Research and the initiation of planning for the rare disease clinical research data base and monitoring system. The recommendation includes a $1,000,000 over the budget request for the Office of Rare Disease Research. Funds are provided to enable the Office to move ahead with implementation of the clinical data base, to support scientific workshops and symposia to stimulate rare disease research, and to support the planning and operational activities of the Office.

Neuroscience research—The cost of brain disorders is tremendous in both economic and social terms. More people are hospitalized with neuropsychiatric disorders than any other major disease group, including cancer and cardiovascular diseases. The Committee is very encouraged by the progress that has been made since the implementation of the "Decade of the Brain" in 1990, and urges NIH to make this one of its highest research priorities at the nine individual institutes that conduct neuroscience research. The Committee requests that the Director of the NIH report at next year's Committee hearings on the progress in this effort.

Transfer authority—The Committee has broadened the transfer authority permitted the Director of NIH by deleting the requirement that transfers be made only in emergency situations. The Committee hs granted the Director authority to allocate up to 1 percent of an Institute's or center's funding, given the current stringent fiscal situation and the rapid pace at which scientific advances occur. However, such transfers are subject to the normal reprogramming procedures, not merely a notification to Congress. Because the Committee has granted the Director of NIH this additional authority, the Committee has not provided funding for the director's discretionary fund.

Technology transfer—The Committee believes that the level of investment in the NIH research programs mandates a strong and effective program of technology transfer. Technology transfer is critically important if the research investment in the NIH Intramural Program is to realize its full potential in advancing the frontiers of science and providing innovation for the millions of Americans who are plagued with catastrophic and chronic disease. The Committee is dismayed that, to date, technology transfer efforts at the NIH have been unable to effectively address important policy and legal issues necessary to support the execution of cooperative research and development agreements [CRADA's].

Specifically, the Committee is concerned about NIH technology transfer capabilities with regard to carrying out the necessary fiduciary and legal responsibilities related to patent prosecution; staff capabilities with respect to representing NIH interests in commercialization of research, negotiating commercial issues related to collaborations with industry, and working as full partners in the CRADA process with industry; and internal communication and coordination with regard to execution of CRADAs within the categorical institutes and the NIH overall. The Committee believes that these issues serve as the greatest deterrents to industry's willingness to collaborate with the NIH and participate in technology transfer. These factors have raised serious concerns with the Committee about the NIH's ability to carry out its mandate of technology transfer. The Committee will continue discussions with the NIH Director on these important matters and is anxious to see NIH develop a plan with expediency to address these concerns.

Intramural research—The Committee commends the National Institutes of Health and its external advisory committee for its report on "The Intramural Research Program," submitted on April 11, 1994. Like the House, the Committee encourages the Director to implement the suggested reforms, and requests NIH to impliment a plan for the renovation of a downsized research hospital to replace the existing clinical center. That plan should also include at proposal for financing the cost of this facility, to the maximum extent possible, by reallocating existing resources. In addition, the Committee shares the advisory committee's concerns about the impact of the Federal Government's overall personnel downsizing proposal on the levels of bench scientists in the NIH's Intramural Research Program.

The Committee concurs with the concern expressed in the House report over the recent proliferation of Deputy Assistant Secretaries for Health and the assessment that a reduction should be able to be absorbed without seriously affecting any critical activity of the Federal Government. However, rather than transfer the $2,000,000 and no less than 30 FTEs from OASH to FDA, the Committee has transferred the funds and the FTEs to the National Institutes of Health to strengthen the Intramural Program through increasing the number of bench scientists at the NIH. The NIH Intramural Program has suffered unduly in the mandated reductions of administrative costs and personnel in the GS-14 and above ranks. Bench scientists have attained their grade status based on scientific and technical expertise, rather than as a result of supervisory or managerial responsibilities. This transfer is consistent with the spirit of the "National Performance Review" and the goal of reducing administrative positions and costs and placing resources where the greatest chance of meeting this Nation's critical health needs may be achieved. This transfer will result in a total employment target at the NIH of no less than 16,424 full-time equivalents.

Indirect costs—The Committee has not included bill language proposed by the administration that would create a 1-year pause in indirect cost payment increases to institutions receiving research support from NIH. The administration's proposal fails to provide an effective or equitable resolution of this issue. It is the Com mittee's understanding that the Office of Management and Budget [OMB] and the Office of Science and Technology Policy [OSTP], in consultation with the research community, has begun a comprehensive review of indirect costs, as called for in the administration's budget proposal. The Committee expects that this process be considered carefully, and geared to arrive at a timely and long-term solution to the indirect cost issue. Additionally, the Committee has received reports that many universities that receive NIH grants are permitted to charge to grants the cost of tuition for faculty, staff, and their families. It is the Committee's understanding that these benefits are not covered by regulations that apply to defense contractors and other Government suppliers. The Committee believes that this matter should be addressed by the administration's comprehensive review.

Research report—The Committee is concerned that at a time when there is such opportunity to understand and cure disease, funding for health research supported by the NIH in the next fiscal year is held to below the inflation index for medical research due to budget constraints. Similarly, other Federal research agencies are confronted with constrained resources resulting from the virtual freeze in discretionary outlays. This freeze will make decisions over how best to allocate funding for research and development in the future all the more difficult as research opportunities collide with other governmental responsibilities required for preserving, protecting the health, safety, and economic security of our citizens. These realities have compelled the Committee to consider the composition of the overall Federal Government research and development budget, which currently totals more than $70,000,000,000 a year. In particular, the Committee is concerned whether that research budget is designed to meet new national security concerns, military, economic, and health, that confront our Nation in a post-cold war world. The Committee is concerned, for example, that medical research is not at its optimal level of priority and support relative to its importance to national security.

Because of these new circumstances, the Committee has provided $1,000,000 within the Office of the Director to commission a study by the National Academies of Sciences and Engineering and the Institute of Medicine. The study should consider the criteria that should be used in judging the appropriate allocation of funds to research and development activities, the appropriate balance among the different types of institutions that conduct such research, and the means of assuring continued objectivity in the allocation process. The academies and Institute should consult with the Office of Science and Technology Policy in planning the framework for the report. The academies and the Institute should submit the report to both the House and Senate Appropriations Committees by Dec. 31, 1995.

Costs of disease study—The Committee has heard from NIH and others about the effect that particular diseases have on medical and other social costs. There are so many claims, however, that their individual relevance is hard to discern. The Committee, therefore, directs NIH to develop a table showing all of the estimates of the societal impact of the diseases on which NIH ICD's conduct research, by disease and ICD, for the most recent years estimates are available. Medical costs should be shown separately from the costs of lost productivity or other indirect effects. The study should show the total of the estimates, accompanied by any discount NIH believes may need to be applied to reflect possible double-counting. NIH should indicate on the same chart fiscal year 1994 spending on the diseases in question.

Diagnostic radiology—The field of diagnostic radiology has played an integral part in the development of new treatments for a variety of diseases, including cancer, heart disease, and brain disorders. Medical imaging procedures, in fact, now contribute to the final patient diagnosis in more than 75 percent of all hospital admissions. The Committee is concerned, however, because extramural research initiatives in this important field are currently fragmented among several institutes, with no central focus or coordinating point. Without a central focus, the Committee is concerned that the pace of new advances is being slowed. For example, mammography has been shown to miss up to 15 percent of small breast lesions, especially in young women. Recent research findings, however, indicate that new magnetic resonance imaging techniques, using the patient's own cells tagged with magnetic particles, may prove to be far more accurate for detecting small tumors in the breast. The advantage of this new technique is that it would rely on MRI instead of x-rays, which are harmful to the breast. The same technique may also offer promise in the detection of metastatic ovarian cancer. The Committee believes that every opportunity to improve diagnostic techniques must be aggressively pursued. The Committee, therefore, encourages NIH to explore ways in which the diagnostic radiology programs now spread throughout the various research institutes could be better coordinated.

Academic research enhancement award—The Committee reaffirms its strong support for the AREA Program, which stimulates research at institutions that provide baccalaureate training for a significant number of our Nation's research scientists, but which historically have not been recipients of NIH support. Also, the Committee urges NIH to consider the overall level of NIH support for an academic institution, rather than only the level of support provided to a school within an institution when awarding grants.

Skin diseases—The Committee was very pleased to learn of progress in skin biology and skin disease research. Research on skin and its diseases falls under the purview of several NIH institutes. The Committee requests the Director to develop a report, in time for next year's hearings, regarding skin disease research activities supported by the NIH. The report should review current funding levels, how basic research activities can be strengthened, and how findings of basic research can be evaluated more quickly for the translation into patient care. The Director is encouraged to involve representatives of the extramural skin disease research community and concerned voluntary health organizations in the development of the report.

Bionutrition—A trans-NIH initiative was developed in fiscal year 1994 regarding bionutrition and should be continued in 1995. Bionutrition involves creating a linkage between basic and clinical science in order to translate the knowledge of basic science into im proved medical care to meet human needs. This linkage requires the support of clinical nutrition research units, centers, and program projects. Diet and nutrition have a substantial impact on health. Nutritionally well-balanced diets may significantly reduce the risk of many diseases, while improper dietary patterns may increase risk for diseases that are costly to treat. Dietary choices and their specific effects on health are the product of complex interactions among physiological, environmental, behavioral, social, and genetic factors. For example, physiological requirements for many nutrients increase during pregnancy and proper maternal nutrition is critical to normal fetal development. Genetic factors play an equivalent pivotal role in health as evidenced by the effect of sodium on the development of high blood pressure in certain individuals or the high degree of individuality in plasma cholesterol response to dietary fat and cholesterol. For a specific compound, the definition of excessive is, therefore, influenced by genetic and physiological factors. Excessive alcohol consumption is linked to higher risk of high of blood pressure and hemorrhagic stroke as well as cirrhosis and early death. However, there is also evidence from epidemiologic studies suggesting that moderate alcohol consumption may be positively associated with cardiovascular health. In addition to alcohol, wine contains antioxidants that may offer a protective element for cardiovascular disease. The Committee urges NIH to support and assist research efforts in these areas, especially the impact of alcohol on cardiovascular health and longevity and on the dietary role of antioxidants and moderate alcohol consumption, and to develop a working strategy to assure future research on this important issue.

Sen. Mack Seeks NCI Support For Shark Cartilage Research

The language in the Senate Appropriations Committee report encouraging NCI to support research on shark cartilage was included at the request of Sen. Connie Mack (R-FL), Capitol Hill sources said.

Mack became interested in shark cartilage as a result of discussions with Kumar Mahadevan, executive director of the Mote Marine Laboratory in Sarasota, FL, sources said.

The language Mack inserted in the appropriations committee report encouraged NCI to undertake further research of the substance.

"It is hoped further research will yield the identification of the active molecules from shark cartilage to be used for the development of synthetic or molecularly engineered versions of the naturally active material," the report said.

Proponents of shark cartilage as a prevention or treatment for cancer have claimed that the substance acts as an angiogenesis inhibitor, which prevents tumors from forming blood vessels necessary for growth.

The efficacy of orally administered shark cartilage has never been proven in a randomized trial, scientists said to **The Cancer Letter**.

The major proponent of shark cartilage in the US is I. William Lane, whose book, "Sharks Don't Get Cancer: How Shark Cartilage Could Save Your Life," described the material as a cancer prevention agent. On its cover, the book calls shark cartilage "a remarkable new breakthrough prevention and treatment of cancer and other degenerative diseases."

Shark cartilage is sold as a food supplement and is available at health food stores and through People Against Cancer, an organization based in Otho, IA. Frank Wiewel, the group's president, has been nominated for membership on the advisory committee of the NIH Office of Alternative Medicine.

"There is no evidence that any specific component of shark cartilage is extracted during the digestive process in a concentration high enough to do any good," said Saul Green, a basic scientist who evaluates unconventional therapies. "I would support any scientific evaluation of shark cartilage under several conditions: 1) the protocol for testing be carried out by people on both sides of the question, 2) the results would be monitored by totally independent body, 3) that the results be published in an open journal, and 4) that if the results are negative, the proponents agree to quit making and selling shark cartilage."

Tumors have been found in sharks, mainly chondrosarcomas, cancers that grow in the cartilage, said John Harshbarger, director of the Registry of Tumors in Lower Animals at the Smithsonian Institutions. The registry is funded by NCI.

"The statement that sharks don't get cancer is not true," Harshbarger said to **The Cancer Letter**. "The literature of the registry has recorded at least two dozen shark tumors, and most are cartilage tumors. If shark cartilage contains something that prevents cancer, then why do sharks get cartilage tumors?"

A 1991 paper in the European Journal of Cancer listed more than a dozen substances known to be angiogenesis inhibitors that are being tested worldwide.

ORI Takes Over Misconduct Inquiry Of Fisher, NSABP

The HHS Office of Research Integrity has taken over the inquiry into allegations of scientific misconduct by Bernard Fisher and two other officials of the National Surgical Adjuvant Breast & Bowel Project.

As a result of the ORI action, the inquiry will be moved from the Univ. of Pittsburgh, the institution where NSABP is based.

The transfer will lead to a substantial narrowing down of misconduct allegations against Fisher, NSABP's ousted chairman, and other respondents, biostatistician Carol Redmond and administrator D. Lawrence Wickerham.

Using its definition of scientific misconduct, ORI can focus only on the narrow question of whether the scientists acted improperly when they published data that they knew to include fraudulent submissions.

Pitt's inquiry, now suspended, sought to address three other allegations: failure to monitor endometrial cancer caused by tamoxifen, failure to implement procedures for auditing, and failure to disclose funding from drug companies.

"The focus of the investigation has now been narrowed and clarified," John Bingler, Fisher's attorney, said to **The Cancer Letter**. "At least so far as that the charges are clear—that's an improvement."

In a statement, Pitt said the university asked ORI to take over the inquiry, which began last April.

"By mid-June, the university became increasingly concerned about the difficulty of continuing an inquiry into a matter that had become embroiled in a heated national public health debate, intense Congressional scrutiny, widespread media coverage, and challenges and litigation threats by the respondents in the inquiry," the university said in a statement dated June 22.

"The university, accordingly, asked ORI, which had already announced that it would take the case if it proceeded beyond an inquiry, to take the inquiry."

The university said the transfer was not precipitated by Fisher's recent suit against Pitt, NSABP interim leadership and the Washington attorneys who advised the integrity proceedings.

"ORI has made it clear that the transfer is not related to the litigation filed against the university by one of the respondents in the inquiry or to the inability of the university or its independent inquiry to conduct a fair and competent inquiry," the statement read.

Generally, preliminary inquiries are conducted by the institutions receiving HHS grants. However, in a minority of cases where it appears that institutions would be unable to conduct such inquiries, ORI takes over the proceedings.

The university said it reserved the right to conduct its own inquiry following the ORI proceedings.

NSABP Seeks "Proven Leader"

(Continued from page 1)

established national reputation with a proven record of academic, clinical and administrative achievement. Ideally, the individual selected should be knowledgeable, competent and experienced in the design and conduct of clinical trials, familiar with the unique characteristics of the NSABP and its membership, a credible authority and scholar in biology and therapy of breast and/or colorectal cancer, a proven leader capable of managing the international NSABP organization and its diverse membership and, finally, an established scientist familiar with the appropriate and correct design of clinical trials.

The individual selected should have considerable experience and success in the preparation and obtainment of extramural peer review funding support from diverse agencies, including the American Cancer Society and NIH.

The membership of NSABP is strengthened by its diversity. [Therefore,] credible candidates representing minority groups are not only welcomed, but encouraged to apply.

An immediate letter of intent with a brief statement of personal capabilities and accomplishments as well as a curriculum vitae should be submitted as soon as possible. Materials should be submitted to: Peter Deckers, Executive Vice President, Clinical Affairs, Chairman, Dept. of Surgery, Univ. of Connecticut Health Center and Medical School, 263 Farmington Av., Farmington, CT 06030, Tel. 203/679-2291, Fax 203/679-1130.

Candidates will be required to present their personal and professional credentials and to describe their institutional support for this endeavor. Moreover, a plan for orderly conduct of NSABP administrative, organizational and scientific activities will be required. A statement of the candidate's strategic vision for the scientific direction of NSABP during the next five years is encouraged. The NSABP executive committee plans to submit a name for chairman to its membership for ratification by early October. When that is completed, the name of this individual will be submitted to NCI for approval.