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Decision To Screen For Prostate Cancer Should Include Patients, ACS Panel Says

The American Cancer Society last week convened a working group of experts to re-examine the Society's 1992 prostate cancer screening guideline.

The language drafted at the workshop reflects what appears to be the latest approach to screening guidelines: When the data do not support a blanket recommendation, involve the patient in decision-making.

Similar language was included in the prostate cancer screening guidelines published by the American College of Physicians last week, and another similar clause is expected to figure in the final NIH

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In Brief

Ozer, Comis Join Allegheny Cancer Centers; Two Cooperative Groups Under Same Roof

HOWARD OZER and **ROBERT COMIS** were named directors of the Philadelphia and Pittsburgh components of the Allegheny Health Education and Research Foundation's newly established **Allegheny University of the Health Sciences Institute of Human Oncology**. Ozer will serve as director of the Allegheny University Cancer Center in Philadelphia, formerly Hahneman University Cancer Center. He is the former director of the Winship Cancer Center at Emory University School of Medicine. Comis will serve as director of the Allegheny Cancer Center at Allegheny General Hospital in Pittsburgh and director of Allegheny Cancer Clinical Trial Research Center in Philadelphia. He is the former clinical director at Jefferson Medical College. Both report to **Norman Wolmark**, director of the AUHS Institute of Human Oncology. The hiring of Comis places two NCI cooperative groups under Allegheny's roof. Comis is chairman of the Eastern Cooperative Oncology Group, and Wolmark is chairman of the National Surgical Adjuvant Breast and Bowel Project. . . . **OTHER APPOINTMENTS** at the Allegheny center in Pittsburgh include **Lawrence Wickerham**, a surgical oncologist from the University of Pittsburgh, and associate chairman and director of operations for the NSABP; lung surgeon **Rodney Landreneu** and colorectal surgeon **David Medich**, both from the University of Pittsburgh; and **Mark Roh**, former chief of liver tumor surgery at M.D. Anderson Cancer Center, who was named director of the Division of Surgical Oncology and professor of surgery. Recent appointments at the Allegheny center in Philadelphia include **Suzanne**

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ACS Updates Guidelines For Prostate Cancer Screening

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consensus document on mammographic screening for women in their forties.

Sources said the ACS draft guideline was compiled as a result of a meeting of about 30 experts who gathered in Phoenix last week to review the 1992 screening guideline.

Though all those present at the meeting ultimately agreed on the language, the draft still requires approval by the ACS Prostate Cancer Advisory Group, the Detection and Treatment and Medical Affairs committees and the Society's board of directors. The approval process is expected to be completed in June, sources said.

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

The proposed guideline statement reads:

"Both Prostate-Specific Antigen and Digital Rectal Examination should be offered annually, beginning at age 50 years, to men who have at least a 10-year life expectancy, and to younger men who are at high risk. Information should be provided regarding the potential risks and benefits."

By contrast, the 1992 guideline states:

"[DRE] and [PSA] should be performed on men 50 and older. If either is abnormal, further evaluation should be considered."

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Editors: **Kirsten Boyd Goldberg, Paul Goldberg**
Founder: **Jerry D. Boyd**

P.O. Box 9905, Washington, D.C. 20016
Tel. (202) 362-1809 Fax: (202) 362-1681
Editorial e-mail: kirsten@www.cancerletter.com
Subscriptions: subscrib@www.cancerletter.com
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The differences between the two statements do not represent a "major or essential change" in the Society's position, a document that summarized the workshop conclusions states. "Rather, these are clarifications or modifications which reflect our present knowledge," the document states.

However, the differences between the two documents appear substantial:

- PSA is mentioned first in the draft guideline, a change that reflects the importance of the test.
- The words "should be offered annually" in the draft replace the more categorical "should be performed."
- The draft guideline recommends considering a man's age, life expectancy and his risk factors when deciding whether to screen.
- The draft guidelines refers to "risks" as well as "benefits" of prostate cancer screening, thereby acknowledging a down-side of the procedures. Several observers said that the most far-reaching change is the draft guideline's recommendation that men should be provided information on screening.

The complete text of the narrative that accompanies the draft guideline follows:

"The annual screening of men for the detection of early prostate carcinoma should begin by age 50 years. However, men in high risk groups, such as those with a strong familial predisposition (e.g. two or more affected first degree relatives) or African Americans may begin at a younger age (e.g. 45 years). More data on the precise age to start prostate carcinoma screening are needed for men at high risk.

"Screening for prostate carcinoma in asymptomatic men detects tumors at a more favorable stage (anatomic extent of disease). There has been a reduction in mortality for prostate carcinoma, but it has not been demonstrated that this is related to screening. An abnormal PSA test result has been defined as a value of above 4.0 ng/ml. Some elevations in PSA may be due to benign conditions of the prostate.

"DRE of the prostate should be performed by health care workers skilled in recognizing subtle prostate abnormalities, including those of symmetry and consistency, as well as the more classic findings of marked induration or nodules.

"DRE is less effective in detecting prostate carcinoma compared with PSA."

Research Issues

In addition to revising the guideline, the

workshop participants identified the following research questions:

- The influence of risk factors on the age when screening should optimally begin. "Of particular interest is the question of at what age screening men with a family history or presence of genetic risk is justifiable and cost-effective," the document states. "The same uncertainty pertains to the precise age at which African-Americans may begin to benefit from screening.
- The influence or patient characteristics, risk factors and prior test outcomes on the optimal screening interval.
- The psycho-social impact of screening, particularly the implications of false-negative and false-positive results.
- Cost-effectiveness. This would include evaluation of strategies for efficient delivery of screening.
- Enhancements to PSA testing, including evaluation of usefulness of measuring PSA density, PSA velocity, PSA doubling time, PSA forms, as well as age and race specific PSA.
- New tests, including PSMA, hK2, telomerase and prostate markers in other body fluids.
- Imaging techniques.
- Biopsy techniques.
- Follow-up of negative biopsy.
- Additional population based and case-controlled studies should be conducted to assess the efficacy of current screening practices.
- Impact of early detection. "Data demonstrating decreased mortality, decrease in stage at diagnosis and the associated co-morbidities need to be modeled to better project the long term effect of screening," the document states.
- Definition of high risk groups, based on factors that include diet, race and history.

The ACS draft guideline appears to be consistent with the screening policy of the American Urological Association. The AUA policy states:

"Annual DRE and PSA measurement substantially increase the early detection of prostate cancer. These tests are most appropriate for male patients 50 years of age or older and for those 40 or older who are at high risk, including those of African-American descent and those with a family history of prostate cancer. Patients in these age/risk groups should be given information about these tests and should be given the option to participate in screening or early detection programs. PSA testing should continue in a healthy male who has a life expectancy of ten years or more…"

The American College of Physicians Guideline

Introducing its guideline on prostate cancer screening, the American College of Physicians cautioned against routine screening of all men for prostate cancer.

The organization's recommendations, published in the March 15 issue of the journal Annals of Internal Medicine, state:

"Recommendation 1: Rather than screening all men for prostate cancer as a matter of routine, physicians should describe the potential benefits and known harms of screening, diagnosis, and treatment; listen to the patient's concerns; and then individualize the decision to screen.

"Recommendation 2: The College strongly recommends that physicians help enroll eligible men in ongoing clinical studies."

According the recommendation, physicians should consider that "the balance of benefit and harm from early treatment is unknown… because no controlled studies of the effect of early treatment on death rate from prostate cancer have been done," the recommendation states.

"The area of greatest controversy is screening for men between 50 and 69 years of age," the recommendation states. "For men in this age group, the physician should be particularly guided by the patient's preference and by the patient's and physician's interpretation of the risk-benefit equation."

The guideline states that physicians conduct counseling and document their discussions with patients.

The ACS draft guideline and the College guideline differ in their recommendations for men considered to be at a higher than average risk for developing the disease. While ACS recommends that these men start screening before age 50, the College doesn't.

"No direct or indirect evidence from large studies quantifies the yield and predictive value of early detection in such men," the College states in its guidelines.

"Black men and men with a family history of prostate cancer should be made aware of their higher lifetime risk," the recommendations state.

"However, available evidence does not suggest that they should be cared for differently from men at

average risk."

The American College of Physicians represents 100,000 health professionals.

FDA News

FDA Eases Two-Trial Standard For Proof Of Drug Efficacy

The Food and Drug Administration last week issued two documents describing the agency's proposed new guidelines designed to accelerate the approval of new and supplemental indications for drugs and biological products.

The agency said its new guidelines would base approval decisions on "all available data," a policy that could ease the requirement that drug sponsors demonstrate that their products were proven efficacious in at least two clinical trials.

For example, in some cases a drug's effectiveness can be demonstrated from existing efficacy data, by evidence from a single new trial supported by existing clinical data, or through evidence from a single multi-center study, the agency said.

"The science of drug development and clinical evaluation has evolved so significantly that we now have more ways to determine the benefits and side effects of new drugs," said Michael Friedman, FDA lead deputy commissioner. "This initiative outlines how we can simplify the approval process while continuing to uphold standards that have earned the public's confidence."

The two newly released documents are:

● "Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products," an overview of the agency's general policy on drug approval. The document was written by an internal FDA working group, headed by Friedman, wrote the report.

● "FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products," an overview of evidence acceptable for approval of supplemental applications for cancer treatments. The document describes FDA efforts to update labeling of cancer therapies. The overview was written by the FDA Division of Oncology Drug Products.

"Our proposal does not lower FDA's commitment to high effectiveness standards—it identifies situations in which multiple new clinical trials are not needed," said Janet Woodcock, director of the FDA Center for Drug Evaluation and Research. "In some instances, we can rely on published scientific reports."

"The initiative allows more flexibility in the assessment of biological products," said Kathryn Zoon, director of the FDA Center for Biologics Evaluation and Research.

Encouraging Words For Supple mental Uses

The cancer treatment document appears to be designed to address the allegations frequently repeated by drug sponsors that FDA makes its inordinately difficult to get approval for supplemental indications for cancer drugs.

"Applicants interested in submitting supplemental marketing applications should not be discouraged by exaggerated perceptions of the data that should be submitted to label a product for a new anticancer indication," the document said. "Nor should they be discouraged by the misperception that the agency considers such applications to be of relatively little importance."

The type of data required to support a new use will depend on the cancer indication, the agency said.

"In the refractory cancer setting, for example, where no therapies are available with meaningful benefit, nonrandomized studies showing that a new treatment provides a significant objective response rate with tolerable treatment toxicity may be sufficient to support approval under the accelerated approval regulations," the document said.

Studies performed at multiple centers, with consistent results, are more persuasive, the document said.

"Additional clinical data to support a new use of an already-marketed product may be less extensive since existing controlled trial data may provide additional support for the new use," the document said.

The document provided eight scenarios discussing the agency's interpretation of the quality and quantity of data required to support supplemental indications.

As an alternative to pharmaceutical company submission of data, FDA said it would accept study data from independent cancer clinical trial organizations, including NCI-sponsored cooperative groups, to support supplemental indications.

"Such data can be submitted to FDA without additional data collection, auditing, or analyses by a pharmaceutical company submitting a supplemental marketing application as long as (1) the clinical trials

organization can provide the data necessary for FDA to check and verify all major study findings...and (2) the clinical trials organization is willing to work with FDA to resolve any issues that may arise during FDA review.

"FDA has had extensive experience in the review of data and analyses from such independent organizations during the past several years and has found the data and the analyses to be generally highly credible and reliable," the document said.

Agency Seeks Advice From Community

FDA said it has surveyed private, academic and professional groups involved in cancer research for their views on appropriate uses not described in the labeling of cancer treatment products.

The agency also has met with drug sponsors to encourage the submission of supplemental marketing applications.

The agency said it plans to review periodically the labeling of cancer treatment products to consider whether new uses or dosing regimens, supported by clinical studies, should appear on the labels. FDA will contact drug sponsors to encourage the submission of applications to add such information to the labels.

If drug sponsors do not respond, "FDA may pursue other avenues, depending on specific circumstances and in accordance" with the law, the document said. FDA could issue a public notice inviting an application for the supplemental indication from any applicant, or seek analysis of the data by other governmental bodies, such as the NCI, the document said.

According to the document, the agency will appoint a special assistant in the Division of Oncology Drug Products in CDER and in the Oncology Branch of the Division of Clinical Trial Design and Analysis in CBER to "monitor, track, and manage the progress of all efforts to maintain updated product labeling for all products used in cancer treatment.

"This will include managing efforts to seek the views of major groups and individuals in the cancer research and treatment community, management and monitoring of actions regarding possible labeling revisions, and preparation of regular progress reports," the document said.

Examples Of FDA Approvals

The documents cite several instances in which FDA approved new or additional indications based on data other than that collected in new clinical trials.

For instance, when the course of the disease and the beneficial effects of the drug are sufficiently similar for both adults and children, the agency has allowed the Pediatric Use section of product labeling to include information extrapolated from adult efficacy data, FDA said.

Examples of such pediatric labeling include ibuprofen, a non-steroidal anti-inflammatory drug, and ondansetron, a treatment for chemotherapy-induced nausea.

In the case of enalapril, a drug for heart failure, the agency accepted two different effectiveness findings, each from a different study, one of which showed symptom improvement and the other improved survival. The drug was approved for both treatment of symptoms and improving survival.

The agency cited the example of its approval of the multiple sclerosis indication for beta-interferon (Betaseron). The supplemental indication was approved on the basis of a single multicenter study which showed both a decreased rate of exacerbations and a decrease in disease activity. Though the two endpoints were entirely different, they were logically related, the agency said.

Comments Due May 30

Copies of the two new guidance documents may be obtained from:

- Drug Information Branch, Division of Communications Management, HFD-210, CDER, FDA, 5600 Fishers Lane, Rockville, MD 20857 (tel: 301-827-4573)
- Office of Communication, Training and Manufacturers Assistance, HFM-40, CBER, FDA, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing the request.

The document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the CBER FAX Information System at 1-888-CBERFAX or 301-827-3844.

Electronic versions of the documents are available via Internet using the World Wide Web. Connect to either CDER at http://www.fda.gov/cder and go to the "Regulatory Guidance" section or CBER at http://www.fda.gov/cber/cberftp.html.

Comments on the draft proposals can be submitted by May 30 to Dockets Management Branch (HFA-305), FDA, 12420 Parklawn Dr. Rm 1-23, Rockville, MD 20857.

FDA To Regulate Products From Human Cells, Tissue

FDA has proposed a new regulatory framework for products derived from human cells and tissues.

The proposed regulations are designed to provide a tiered approach with the level of regulation proportionate to the degree of risk, the agency said.

Tissue processing facilities would be required to register with FDA and to list their products, and labeling and promotion of the products would have to be clear, accurate and balanced, FDA said.

The agency listed the proposed regulations:

- FDA would not regulate cells and tissues removed from and transplanted into the same person in a single surgical procedure.
- For most conventional and reproductive tissues that are minimally processed and used for their normal functions, registration, product listing, and adverse event reports would be required.
- FDA would require that all tissues (except those removed and transplanted back into the same patient in one surgical procedure) be handled according to "good tissue practices."
- FDA would also prescribe procedures for testing the tissue for infectious agents and screening the donor about potential exposure to disease agents.
- For tissue stored for use in the same person from whom it was obtained (or in a sexually intimate partner of a reproductive-tissue donor), FDA would recommend but not require that similar testing and screening procedures be followed. To protect health care workers, FDA would also require labeling according to whether the tissue poses a potential biohazard.
- For most tissue transplanted from one person to another, FDA would require infectious disease testing, donor screening, and processing controls.
- FDA would require controlled clinical trials and pre-market approval to demonstrate safety and effectiveness for tissues and cells processed to alter their biological or functional characteristics; tissues and cells used to perform other than their normal functions; many tissues and cells used for metabolic purposes; and tissues and cells that are combined with medical devices, drugs, or other biological products. Somatic cell therapy and gene therapy would be covered by this category of regulation, as would many forms of stem cell therapy.

The regulations would be phased in over the next two to three years, the agency said.

NCI Extramural Program

Advisors Approve $22 Million For Diagnostic Imaging Trials

Advisors to NCI have approved in concept the Institute's plan to set aside $22 million to form a network for clinical research in cancer diagnostic imaging.

The funds would support a network of academic centers, an operations center, data management center, scientific committees, accrual and quality assurance. The network would conduct definitive clinical evaluation of new imaging technologies in comparison with standard techniques, as well as early clinical testing of promising technologies.

The group also would conduct research on the cost-effectiveness of new imaging innovations.

The NCI Board of Scientific Advisors also approved in concept the set-aside of $18.75 million over five years to support program project grants proposing innovative approaches to "Diversity Generation and Smart Assay Development for Cancer Drug Discovery."

The board tabled three concepts:

- Pediatric Brain Tumor Clinical Trials Consortium, which proposed a set-aside of $15 million to support 10 awards.
- Cancer Survivorship Issues, proposed to set aside $10.5 million to fund 5 to 6 R01 grants and 5-6 R03 grants for research that would lead to the reduction of physical and psychological morbidity associated with long-term cancer survival.
- Health Maintenance Organization Cancer Research Network, a proposal for funding cooperative agreements.

The tabled concepts were expected to be rewritten and brought back to the BSA at a future meeting.

The excerpted texts of the approved concept statements follow:

Cooperative Trials in Diagnostic Imaging. Concept for an RFA, set-aside of $22 million over five years. NCI Division of Cancer Treatment, Diagnosis and Centers.

This initiative will support the creation of a multi-center network win expertise in the assessment of imaging diagnostics technologies. The goals of the group will be investigator-initiated research involving key aspects of imaging technology assessment:

a. The timely and definitive clinical evaluation

of imaging innovations, in comparison to standard techniques, as soon as preliminary clinical experience justifies definitive testing.

Evaluation should include measures of diagnostic accuracy and, where possible and appropriate, medical benefit.

b. the early clinical testing of promising imaging technologies or devices in selected institutions having the necessary expertise in order to derive appropriate preliminary information that can guide further stages of testing.

c. development of preliminary estimates of the cost-effectiveness, where appropriate, of new diagnostic and diagnostic/therapeutic interventions compared to standard approaches. Having such information generated by a research group unconnected with particular commercial concerns at the time of initial proof of efficacy will help payers with coverage decisions and providers with purchasing decisions.

Organizational structure: The scientific core of the group will consist of imaging investigators from a number of academic centers of excellence in clinical imaging sciences; these academic centers will be supplemented by the participation of additional institutions (academic or community-based) able to contribute significantly to the accrual of important multi-center efforts. Efforts will be coordinated by an operations center; data will be gathered and analyzed by a biostatistics and data-management (BDM) office.

The funding structure of the group will include support for the following: a) operations coordination; b) biostatistics and data management; c) scientific committees; d) accrual e) quality assurance. The group will have a chair (PI of the operations award), PIs for each of the major scientific areas of the group, and a PI for BDM.

Reimbursement for accrual to studies will be on a per-case basis by subcontract from the operations office. This will give the group the flexibility to include valuable clinical collaborators that may come from outside the core group (for example, surgical or radiotherapy subspecialists involved in studies of treatment interventions).

The PIs who chair the major scientific committees will have a budget that supports the development of a scientific agenda and specific protocols. The identity of the various committees will be determined by the applicants and will reflect the scientific agenda of the group.

Innovative Approaches to Diversity Generation and Smart Assay Development for Cancer Drug Discovery. Concept for an RFA, set-aside $18.75 million over five years, five awards. Program director: Mary Wolpert, Developmental Therapeutics Program, DCTDC.

This initiative seeks to catalyze the formation of centers for cancer drug discovery that will exploit opportunities presented by the rapidly advancing state of contemporary chemistry and biology. Proposals responsive to this RFA will bring together chemists and biologists who will propose novel approaches to the discovery of compound classes potentially active against cancer. These approaches will include the application of purely synthetic or biosynthetic combinatorial approaches to generate libraries of novel structures. Conceivably both techniques might be utilized by different components of the same research group, and active products of the biosynthetic approach may serve as novel scaffolds for elaboration using combinatorial synthetic technology.

In close association with the generation of compound libraries, applicants should also propose the development of novel assays directed at molecular events or targets important in the neoplastic process and suitable for assaying the compound libraries. Applicants may employ any biological system that is likely to be informative in the context of this initiative. Structures based on clinically-approved anticancer drugs will not be considered responsive to the RFA.

Products of these efforts may ultimately lead to candidates for preclinical and clinical development. At the discretion of the investigators, NCI is prepared to assist with any steps necessary to bring promising therapeutic candidates to clinical trial.

The vehicle for supporting this initiative will be the program-project grant (P01). Collaborators may come from the same or different departments in the same academic institution, or from different institutions, or from (an) academic department(s) and industry.

Each P01 will be assembled by a Principal Investigator to form a multi-disciplinary consortium of skills needed to pursue successfully the following components: generation of novel structures not based on clinically-approved anti-cancer drugs; screening of novel structures against defined biological or biochemical targets; optimization of lead structures to improve suitability as a lead structure.

In Congress

Specter, Harkin To Introduce Bill For Research "Trust Fund"

Sens. Arlen Specter (R-PA) and Tom Harkin (D-IA) last week said they planned to introduce a plan to establish a "trust fund," which could increase biomedical research investments by as much as 50% in four years, when the plan is fully phased in.

The National Fund for Health Research Act (S441), proposed by Specter and Harkin would levy a 1 percent surcharge on all health premiums paid in the US.

The proceeds collected by the trust fund would be allocated to NIH components.

"There's a lot of talk about the need for the government to act more like a business," Harkin said at a March 13 press conference unveiling the proposal. "We ought to begin by doing what any smart business would do—and that is to invest in research and development."

Analogous plans have been introduced by Harkin and Sen. Mark Hatfield (R-OR) since 1993. However, all previous efforts to enact the trust fund legislation have been unsuccessful.

Harkin said the bill was not adopted because in years past it was considered in the context of other national issues, primarily the plans for reforming the health care system. Now, the proposal stands alone, Harkin said.

This year, the proposal is endorsed by over 100 healthcare associations, including the American Association for Cancer Reasearch, the American Cancer Society, and the National Breast Cancer Coalition.

Though Harkin described the plan as a "win-win situation" for medical research and the insurance companies, he and Specter acknowledged that the measure does not have the support of the insurance industry.

"I think it's a matter of educating the public, and educating the insurance companies," Specter said at the press conference.

"If the insurance companies really focus on what this additional research could do for them in terms of cutting their costs, I think we could get this. If we had their support it would be an enormous step forward—but if there is sufficient public support, I think it can be done.

"It's up to us to develop that public support," he said.

In Brief

Allegheny Plans To Recruit 100 More Cancer Specialists

(Continued from page 1)

Ildstad, bone marrow specialist from the University of Pennsylvania; **Richard Hayden**, head and neck surgical specialist from the University of Pennsylvania; and **Gerald Marks**, a specialist in minimally invasive surgery from Jefferson Medical College. **Allegheny Health, Education and Research Foundation** said it plans to recruit up to 100 additional cancer researchers and physicians over the next two years. . . . **WALTER CURRAN** was elected Group Chair of the Radiation Therapy Oncology Group at the RTOG annual meeting in February. Curran is professor and chairman of the Department of Radiation Oncology at Thomas Jefferson University. He also serves as director of ambulatory care at the Kimmel Cancer Center of Jefferson Medical College and as co-director of Jefferson's brain tumor program and lung cancer center. . . . **UNIVERSITY OF ROCHESTER CANCER CENTER** researchers **Russell Hilf** and **Robert Bambara** have received a $1 million NCI grant to research the mechanisms of the action of tamoxifen. Hilf is professor of Biochemistry/ Biophysics and Oncology and interim director of Laboratory Research, and Bambara is professor of Oncology in Biochemistry/Biophysics. . . . **RAVI BHATIA** has joined the Department of Hematology/ Bone Marrow Transplantation at the City of Hope National Medical Center as staff physician and laboratory investigator. Bhatia recently received a five-year, $350,000 grant from NCI to study how interferon can restore normal hematopoiesis in some patients with CML. . . . **NIH CONSENSUS STATEMENT** on breast cancer screening for women 40-49—the final version—is scheduled to be released March 21, NIH sources said. The statement will be posted on the NIH Consensus Development Program website at http://consensus.nih.gov when it becomes available. . . . **CORRECTION:** The NCI-EORTC Symposium on New Drugs in Cancer Therapy is scheduled for June 16-19, 1998, not this year, as listed in **The Cancer Letter**, March 14.

NCI Contract Award

Title: Collection and Taxonomy of Shallow Water Marine Organisms. Contractor: Coral Reef Research Foundation, Los Angeles, CA; $2,636,859.