THE CANCER LETTER

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Justice Department Clears SWOG Study Of Breast Cancer Treatment Costs

The US Department of Justice last week gave approval to the Southwest Oncology Group to conduct a comparative study designed to evaluate the costs and outcomes of treatments for breast cancer.

In a letter to SWOG, Anne Bingaman, Assistant Attorney General in charge of the Antitrust Division, said the cooperative group's plan to exchange information on costs and prices of the treatments would not constitute price-fixing.

Bingaman's "business review letter," dated Nov. 2, in effect clears

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In Brief

Lenhard Elected President Of ACS; House Science Committee Approves CRADA Bill

RAYMOND LENHARD JR., director of community programs and clinical information systems, Johns Hopkins Oncology Center, was elected president of the American Cancer Society at the society's Board of Directors meeting last week in Chicago. Lenhard is a past president and current member of the ACS Maryland Division Board of Directors and Executive Committee. . . . **HOUSE SCIENCE COMMITTEE** has approved the National Technology Transfer and Advancement Act of 1995. The bill, HR2196, is designed to make Cooperative Research and Development Agreements between federal laboratories and the private sector easier to negotiate. Objectives of the bill are to provide: assurances to US industry that they will be granted sufficient rights to justify prompt commercialization of inventions arising from CRADAs; new incentives to federal laboratory personnel; and clarifying amendments to strengthen technology transfer law. . . . **COLUMBIA-PRESBYTERIAN** Medical Center has received a $12 million gift from Herbert Irving, vice chairman of Sysco Corp. The contribution will help fund the Herbert Irving Cancer Institute, established to centralize the medical center's cancer treatment programs. Irving is a member of the hospital's Board of Trustees. . . . **TWO EXPERTS** in cancer genetics have joined M.D. Anderson Cancer Center. **William Benedict** and **Hong-Ji Xu**, both of Baylor Univ., have been appointed associate professors at Univ. of Texas M.D. Anderson. Their collaborative research has focused on tumor suppressor genes. At M.D. Anderson, they will pursue related but independent research, the center said. . . . **ROGER POWELL**, program director in the NCI Radiation Research Program, retired earlier this month after 28 years at NIH.

Cost-Efficacy Of Clinical Trials Is Object Of SWOG Study

(Continued from page 1)

the way for other, similar trials that go beyond the endpoints of safety and efficacy and address the questions of resource utilization, cost and benefit.

These trials are particularly important because they seek to establish the cost of clinical trials versus the cost of standard care for cancer, several observers said.

"It's important for us to understand how cost-effective clinical trials are in relation to standard care," Charles Coltman, chairman of SWOG said to **The Cancer Letter**. "That's information that has to be gathered."

This information could be used to convince insurers to reimburse patient care costs in clinical trials as well as to convince Congress to provide Medicare reimbursement for patients enrolled in trials.

"There is a significant interest in this kind of correlative studies," David Parkinson, head of the NCI Cancer Therapy Evaluation Program said to **The Cancer Letter**. "Increasingly, we are viewing clinical trials in terms of their societal endpoints."

Parkinson said cost issues are addressed in two other intergroup cooperative trials of bone marrow transplantation as a breast cancer treatment and one trial of treatments for myeloma.

First Antitrust Opinion In Cancer Clinial Trial

"The Department has no intention to challenge SWOG's proposed conduct," Bingaman wrote to the cooperative group's attorneys.

According to Bingaman, the proposed trial falls into a "safety zone" that allows competing health care providers to participate in written surveys of costs and prices.

Bingaman's letter constitutes the Antitrust Division's first opinion on the issues of potential price-fixing and restraint of trade in a cancer clinical trial.

The opinion was issued under the business review procedure, which allows organizations to ask the Antitrust Division whether particular actions would be subject to a challenge under the antitrust laws.

SWOG chairman Coltman said the cooperative group decided to seek Bingaman's opinion on advice of its attorneys.

As a model case to be presented for review by the Antitrust Division, SWOG used a protocol of an intergroup study conducted by the Cancer and Leukemia Group B (CALGB 9344).

The SWOG part of the study is called SWOG 9410.

Coltman said the rationale of Bingaman's letter would apply to a wide variety of trials that would be designed by the group. "We are planning to do other studies to answer the cost-effectiveness question," he said.

The trial approved by Bingaman will track about 3,000 patients at high risk of recurring breast cancer.

The patients will be assigned at random to six groups and will receive treatments consisting of various combinations and doses of cyclophosphamide, Adriamycin, Taxol and tamoxifen.

The trial will track the cost of drugs, the number of days patients spend in the hospitals, the number of visits from physicians and nurses, as well as the cost of laboratory tests and x-rays.

Data, including cost comparisons, will be collected from at least five providers across the US, the cooperative group said. The information collected will be sufficiently aggregated to make it impossible to identify the costs of a particular provider.

SWOG officials said the cooperative group intends to publish the results in a form that would not recommend a particular treatment over others.

"In the past, we looked at benefits in terms of the response rates, side effects and survival," Mace Rothenberg, SWOG executive officer, said to **The Cancer Letter**. "Now, we also consider the impact of therapy in terms of cost, so we can compare the benefits of therapies on the societal basis."

Rothenberg said SWOG is seeking sponsors for resource utilization trials.

THE CANCER LETTER

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While the letter to SWOG is the Antitrust Division's first statement on cancer clinical trials, the issue of collection of cost and pricing data by health care providers has come up in the past.

Last year, Bingaman gave clearance to a an effort by Birmingham, AL, employers and health care providers to collect data on the relative performance and cost of services at area hospitals.

According to the letter, dated June 20, 1994, the project, called the Birmingham Cooperative Clinical Benchmarking Demonstration Project, planned to analyze the data on the treatment of acute myocardial infarction, obstetrical delivery and pneumonia.

Standards Improve Quality Of Mammograms, GAO Finds

Implementation of federal mammography quality standards has significantly improved mammogram quality at facilities nationwide, according to a new General Accounting Office report.

The Mammography Quality of Standards Act of 1992 required mammography facilities to meet specific technical standards, substantially the same as those advocated by the American College of Radiology in its voluntary accreditation program begun in 1987.

The act empowered FDA to implement the standards and conduct annual inspections of facilities. In order to become fully certified, many facilities have had to improve their equipment and practices, the report said.

"Early indications are that the act has had a positive effect on the quality of mammography services," the GAO report said. "Before the act, states varied widely in the standards they imposed, and only a few states had standards comparable to those established under [the act]."

Facilities Encouraged To Upgrade

Contrary to congressional fears that facilities might shut down rather than spend the money to improve mammography, the standards have encouraged facilities to upgrade, the report concluded.

"While some facilities have chosen to cease mammography services rather than comply with higher standards, the number that have done so is relatively small compared with the total number of facilities available to provide services," the report said. "Those facilities that chose to stop delivering such services were generally small-volume providers located within 25 miles of another certified facility."

FDA has given facilities that did not meet the standards repeated opportunities to meet the requirements and correct problems, the report said.

The impact of the act on mammography quality has been greatest in states that had no or few standards previously, the report said.

Between Oct. 1, 1994, when the act took effect, and Aug. 1, 1995, ACR reviewed 7,525 mammography units from about 5,510 facilities for accreditation, the report said. Of those, 2,598 units, or 35%, from about 1,900 facilities failed to meet the accreditation requirements.

After a second review, ACR found about two-thirds of these units to be in compliance, and granted them full accreditation, the report said.

Of the units that were denied accreditation after failing the second review, 277 facilities have taken corrective actions and qualify for reinstatement, the report said.

"These data suggest that the accreditation process has resulted in improvement at these facilities," the report said.

According to the report, FDA plans to issue final regulations regarding accreditation in October 1996. FDA has approved ACR and the states of California, Arkansas and Iowa as official accrediting bodies. Because of its earlier voluntary program, ACR serves as the major accrediting body, responsible for more than 95% of the accreditation workload, the report said.

Delay In Annual Inspections

While accreditation is a mail-in process, inspections may be conducted on-site, under the authority provided FDA in the act.

Annual inspections were scheduled to begin in October 1994, but FDA experienced delays in training enough inspectors, the GAO report said. FDA planned to train 200 inspectors by last June, but only 159 inspectors were trained by that time. Annual inspections began in January 1995.

"Early results from annual inspections indicated that many facilities fell short of full compliance with the MQSA requirements," the report said. "As of June 9, 1995, inspectors had inspected 1,843 facilities and found that 601, or 33%, had deficiencies that needed to be corrected. Of these, 119 facilities were considered to be in serious noncompliance with

MQSA standards."

The most common violations involved the facilities' use of personnel who did not meet qualification requirements, the report said.

Under the inspection program, FDA issues a warning letter to facilities in serious noncompliance. Facilities are required to respond in writing in 15 days, listing specific steps they plan to take to correct violations, the report said.

Failure to correct deficiencies could result in fines, suspension or revocation of the facility's certificate, or a court order prohibiting the facility from performing mammograms.

As of last July, FDA had not closed any facilities for noncompliance, the report said.

Provisional Certificates Issued

From the start of the accreditation and inspection program, FDA was concerned that many facilities would need time to improve their practices, the report said. The agency began to communicate with facilities 10 months before the certification deadline, informing them of the requirements.

"Even with advance notice, however, almost 4,700 of the more than 10,000 mammography facilities nationwide failed to complete the accreditation process in time to receive full certification by the Oct. 1, [1994] deadline," the GAO report said. "The two main reasons for this outcome, according to ACR officials, were the failure of facilities to submit materials in a timely manner and the submission of applications that did not meet the accreditation requirements."

FDA issued provisional certificates to these facilities, giving them six-month extensions. FDA also granted 90-day extensions for facilities whose provisional certificates expired before accreditation requirements could be met, the report said.

As of mid-July, 242 facilities were still in the 90-day extension status, indicating that they continued to have problems satisfying all requirements, the report said.

To minimize the need to shut down facilities permanently, FDA established a reinstatement process, the report said. As of mid-July, 279 facilities were granted reinstatement, allowing them to resume mammography services while pursuing accreditation.

A total of 488 facilities were denied accreditation for failing to pass the second review between Oct. 1, 1994 and Aug. 1, 1995, according to ACR records. As of Aug. 1, 301 of the facilities had either passed accreditation on appeal or had been reinstated.

For these facilities, the average time from notification of denial until reinstatement was about 15 days, the GAO report said.

Only six of the facilities said they did not intend to resume mammography services.

"Facility closures, both in anticipation of the act and since the act took effect, appear to have had a limited effect on access to mammography services," the GAO report concluded. "Of the 10,000-plus facilities that were providing mammography services before MQSA, FDA identified 404 facilities, or about 4%, that had ceased to provide mammography services between October 1993 and October 1994, when MQSA became effective."

A study found that 97% of the closed facilities were within 25 miles of a certified facility, and 62% were within one mile of a certified facility.

Copies of the GAO report, "Mammography Services: Initial Impact of New Federal Law Has Been Positive," document no. GAO/HEHS-96-17, are available by contacting the General Accounting Office, Documents Distribution, tel: 202/512-6000.

Five Investigations Probe NIH Radiation Contamination

Five separate investigations have been launched to probe the events surrounding the internal contamination of 27 NIH employees with the radioisotope phosphorus-32:

•The Federal Bureau of Investigation is exploring possible criminal conduct in the case that involved the contamination of a water fountain and the ingestion of the radioactive material by the NCI researcher Maryann Wenli Ma, a postdoctoral fellow who was pregnant at the time she was contaminated (**The Cancer Letter**, Nov. 3).

•NRC is probing the NIH radiation security procedures and compliance. The NRC team that conducted an inspection at NCI following the contamination is preparing its report, NRC officials said.

NRC earlier this month denied the request by Ma and husband Bill Wenling Zheng that NIH be stripped of its license to use radioactive materials.

In a letter to Ma's and Zheng's attorneys, a senior NRC official wrote that the agency has found "weaknesses" in the NIH control and security of

radioactive materials.

"These weaknesses are not, however, sufficiently widespread or egregious so as to warrant suspension or revocation of the license," Carl Paperiello, director of the NRC Office of Nuclear Materials Safety and Safeguards, wrote in a letter dated Oct. 30.

Paperiello also disagreed with the assertions in the petition that NIH lacked an effective bioassays program. "The NRC finds reasonable assurance that the existing bioassay program has adequate capability to detect and monitor the exposure and intake," Paperiello wrote.

In another letter, to Michael Gottesman, NIH Deputy Director, Intramural Research, Paperiello requested that NIH provide a point-by-point response to the Ma and Zheng petition.

The letter to Gottesman, dated Nov. 2, said NRC needs the information to formulate its response to the petition. NRC set a 30-day deadline for NIH to produce its response to allegations.

•In addition to assessing the issues of security and compliance by NIH, NRC has forwarded Ma's and Zheng's petition to its Office of the Inspector General. The IG's office is being asked to review the allegations of "improper or inadequate actions by the NRC staff," Paperiello wrote to the lawyers for Ma and Zheng.

•NIH Director Harold Varmus has asked the HHS Office of the Inspector General to launch a "non-criminal exploration" of the case.

In a letter dated Oct. 31, Varmus requested a meeting with the HHS Inspector General June Gibbs Brown. The purpose of the meeting would be "to focus this request so as not to duplicate work already undertaken," Varmus wrote.

•An investigation of the case was started by the Subcommittee on Human Resources and Intergovernmantal Relations of the House Committee on Government Reform and Oversight.

Rep. Christopher Shays (R-CT), chairman of the subcommittee, has requested that NIH and NRC turn over all materials relevant to the investigation. The two agencies are expected to provide the materials to Shays later this week.

Following the launch of the investigations, NIH has tightened the security requirements for basic researchers who work with radioactive materials.

All rooms posted for radionuclide now have to be locked when not occupied and all radioactive material has to be kept under lock when it's not being used, Gottesman wrote in a memorandum to NIH staff.

Also, within two months NIH plans to move all radioactive materials now stored in the corridors, Gottesman wrote in the memo dated Oct. 26.

Researchers found to have violated the new requirements would be suspended from using radioactive materials for 14 to 30 days.

On second violation, the suspension would be increased to 60 days, and on third violation, the NIH Radiation Safety Committee would be asked to consider revoking the researcher's authorization to work with radioactive materials, Gottesman wrote.

Ma, a postdoctoral fellow from China, was 17 weeks pregnant when she ingested an estimated 1,000 microcuries of the radioisotope. Two weeks later, NIH officials reported another incident, in which 26 employees ingested smaller amounts of P-32 after drinking from a contaminated water fountain. Ma and Zheng are employed by the NCI Laboratory of Nuclear Pharmacology.

NCI Review Groups Merged In Response To White House

NCI has consolidated all of its grant review committees under one large umbrella group with eight subcommittees, Institute officials said recently.

The NCI Initial Review Group was created in response to a White House executive order last year that required federal agencies to reduce the number of chartered advisory committees by one-third.

NCI eliminated four separate chartered grant review committees and consolidated their functions under the single NCI Initial Review Group.

The four previous review committees were the Cancer Center Support Grant Review Committee, the Cancer Education Review Committee, the Cancer Research Manpower Review Committee and the Cancer Clinical Investigation Review Committee.

Under the new structure, which became effective Sept. 29, the NCI Initial Review Group has the following subcommittees:

•Subcommittee A--Cancer Centers
•Subcommittee B--Comprehensiveness
•Subcommittee C--Basic and Preclinical
•Subcommittee D--Clinical Studies
•Subcommittee E--Prevention, Epidemiology and Control
•Subcommittee F--Manpower and Training

•Subcommittee G--Education
•Subcommittee H--Clinical Groups

The consolidation enables the subcommittees to more easily shift reviewers and applications around as needed, Robert Browning, chief of the NCI Grants Review Branch, said to **The Cancer Letter**. "Though the reason for the consolidation was the executive order, it has proved to be a boon," Browning said. "It gives us more flexibility for deploying our people."

In addition, NCI established a separate committee, the NCI Extramural Special Emphasis Panel, to conduct reviews of all contracts and some grants, such as when there are grant applications for which there no subcommittee has the appropriate expertise, or for one-time Requests for Applications.

Clinton Administration officials had said the elimination of chartered committees would streamline government and save money.

Kidney Cancer Association Seeks Research Propoals

The National Kidney Cancer Association is seeking proposals for clinical or translational research on nutrition or chemoprevention in renal cancer.

The association will award $25,000 to the MD or PhD researcher who submits the best proposal as determined by the association's Medical Advisory Board. Proposals should be in NIH format, nine pages or less, including references.

Deadline for submission is March 1. Contact National Kidney Cancer Association, 1234 Sherman Ave., Evanston, IL 60202-1375, tel: 708/332-1051.

AACR Seeks Applicants For Gertrude Elion Award

The American Association for Cancer Research is seeking applicants for its annual Gertrude Elion Cancer Research Award.

The award, provided through an educational grant from Glaxo Wellcome Oncology, is presented to a nontenured scientist at the level of assistant professor engaged in meritorious basic, clinical, or translational research at a nongovernment, not-for-profit research facility. The one-year, $30,000 award recognizes research excellence in cancer etiology, ddiagnosis, treatment or prevention.

Application deadline is Feb. 15. Contact AACR, tel: 215/440-9300, fax: 215/440-9313, e-mail: aacr@aol.com.

Health Organizations Endorse "Patients's Rights" Document

A group of more than 100 national health organizations has endorsed a set of principles for patients enrolled in managed care health plans and called upon the managed care industry to adopt the program.

The National Health Council, an umbrella organization of more than 118 groups, endorsed 10 "Principles of Patients' Rights and Responsibilities."

Groups joining the council include the American Cancer Society, the American Lung Association, the American Medical Association, the National Coalition for Cancer Survivorship and the Susan G. Komen Breast Cancer Foundation.

"As managed care expands across all payers, including Medicare and Medicaid, it will, by necessity, cover more of those historially viewed as 'at risk'--those who are chronically ill and disabled, as well as those whose care tends to be more costly and complicated," John Seffrin, executive vice president of the American Cancer Society, said. "This campaign takes the lead to make sure all patients receive the care they need and deserve."

To inform consumers about their rights as patients, the council has summarized the 10 principles in a pamphlet, titled "Putting Patients First."

In addition to the principles, the brochure contains a guide to evaluating health plans and a directory of toll-free numbers that provide accurate, up-to-date information concerning 170 diseases and medical conditions.

Patient Protections Needed

The "Principles of Patients' Rights and Responsibilities" suggest the need for patient protections in several areas:

•choice among a reasonable number of providers and timely referral to specialists when needed;

•easily understood information on plan restrictions or limitations on the use of certain health care providers, prescription drugs and experimental treatments;

•access to an open, simple and timely process to appeal negative coverage decisions on tests and treatments patients believe to be necessary;

•information about provider credentials and facility accreditation reports, provider expertise relative to specific diseases and disorders, and the

criteria that provider networks use to select and retain caregivers; and

•the right to know the basis for provider payments and any potential conflicts of interest that may exist.

As part of the program, the National Health Council is encouraging patients to take responsibility for pursuing healthy lifestyles, become knowledgeable about health plans, participate in decisions about their health care, and cooperate on mutually accepted courses of treatment.

In addition, the Council is encouraging consumers to contact voluntary health agencies for more information about the latest cures and treatments for various medical conditions and/or diseases.

"During this time of rapid change in the health care industry, the American consumer will be faced with many questions about health care options and benefits," said National Health Council President Joseph Isaacs. "Our 44 voluntary health agency members are an invaluable source for unbiased, objective information concerning a variety of medical issues. We encourage the public to contact these agencies directly for answers to questions."

Copies of the council's brochure, "Putting Patients First," are available by sending a stamped, self-addressed envelope to: Putting Patients First, National Health Council, Suite 500, 1730 M St. NW, Washington, DC 20036-4505.

Cancer Meetings Listed For Next Three Months

December

American Society of Hematology—Dec. 1-5, Seattle, WA. Contact ASH, tel: 202/857-1118.

***Combinatorial* Library Methods for Basic Research and Drug Discovery**—Dec. 2-4, Tucson, AX. Contact Arizona Cancer Center, conference coordinator, tel: 520/626-2276, fax: 520/626-2284, e-mail: meetings@azcc.arizona.edu.

Molecular Basis of Gene Transcription—Dec. 2-6, San Diego, CA. Contact American Association for Cancer Research, tel: 215/440-9300, fax: 215/440-9313.

American Society for Cell Biology Annual Meeting—Dec. 9-13, Washington, DC. Contact American Society for Cell Biology, tel: 301/530-7139.

San Antonio Breast Cancer Symposium—Dec. 10-13, San Antonio, TX. Contact Lois Dunnington, Cancer Therapy & Research Center, tel: 210/567-4745, fax: 210/567-4822.\

American Brachytherapy Society Annual Meeting—Dec. 10-13, Scottsdale, AZ. Contact American Brachytherapy Society, tel: 215/574-3158, fax: 215/923-1737, e-mail: abs@acr.org.

January

The Cell Cycle—Jan. 11-17, Taos, NM. Contact Keystone Symposia, tel: 303/262-1230.

Blood Stem Cell and Bone Marrow Transplants—Jan. 15-21, Keystone, CO. Contact Keystone Symposia, tel: 303/262-1230.

Molecular Biology of HIV—Jan. 17-23, Taos, NM. Contact Keystone Symposia, tel: 303/262-1230.

Cancer and the Cell Cycle—Jan. 17-20, Lausanne, Switzerland. Contact American Association for Cancer Research, tel: 215/440-9300, fax: 215/440-9313.

Tissue Engineering—Jan. 23-29, Taos, NM. Contact Keystone Symposia, tel: 303/262-1230.

Breast and Prostate Cancer: Basic Mechanisms—Jan. 29-Feb. 4, Taos, NM. Contact Keystone Symposia, tel: 303/262-1230.

February

Gene Therapy for Hematopoietic Stem Cells in Genetic Disease and Cancer—Feb. 4-10, Taos, NM. Contact Keystone Symposia, tel: 303/262-1230.

International Congress on Anti-Cancer Treatment—Feb. 6-9, Paris, France. Contact Prof. David Khayat, SOMPS, Hopital de la Pitie-Salpetriere, 47 Bd de l'Hopital, 75651 Paris CEDEX 13 France.

Genitourinary Conference—Feb. 8-10, Houston, TX. Contact Univ. of Texas M.D. Anderson Cancer Center, Pam Hamre, Conference Services, tel: 713/792-2222.

American Association for the Advancement of Science, Annual Meeting and Science Innovation Exposition—Feb. 8-13, Baltimore, MD. Contact American Association for the Advancement of Science, tel: 202/326-6440.

Molecular Regulation of Platelet Production—Feb. 16-22, Taos, NM. Contact Keystone Symposia, tel: 303/262-1230.

Clinical Hematology and Oncology—Feb. 19-22, La Jolla, CA. Contact Scripps Clinic, tel: 619/554-6310.

Program Announcement

PAR-96-006

Title: **Initiative For Minority Student Development**

Application Receipt Date: February 1

The National Institute of General Medical Sciences announces an initiative directed toward increasing the number of underrepresented minorities entering careers in biomedical research. The objective of this program announcement is to significantly increase the number of underrepresented minority students entering competitive careers in biomedical research by promoting the initiation and development of new programs, as well as the expansion and enhancement of existing programs, to motivate and foster the development of underrepresented minority students in biomedical research careers.

Programs developed under this initiative must be specifically designed to target underrepresented minority students majoring in the biomedical sciences or in medical, dental, or veterinary training who are interested in pursuing research careers. For the purposes of this program announcement, underrepresented minority students are individuals belonging to a particular ethnic or racial group that has been determined by the grantee institution to be underrepresented in biomedical or behavioral research. Nationally, individuals who have been found to be underrepresented in biomedical or behavioral research include, but are not limited to, US citizens who are African Americans, Hispanic Americans, Native Americans and Pacific Islanders. The term "science" is used in this announcement to mean the natural, physical, and behavioral sciences and mathematics relevant to biomedical research.

NIGMS recognizes the heterogeneity in institutional settings and institutional missions. Therefore, the emphasis of this initiative will be on the institution's program, as defined by its own goals and specific objectives, to make a substantial contribution to ameliorating the underrepresentation of minority groups in biomedical research. Some institutions may have the greatest opportunity for impact by motivating undergraduate students. Other institutions may be poised for success in developing graduate students. Still others may wish to motivate and develop the research skills of students in—or recently graduated from—medical schools or other biomedically relevant professional schools.

Applications may be submitted by any domestic private and public, educational institutions. The application may be directed toward the development of underrepresented minority scientists who are in any phase of their career development, from the undergraduate level through the Ph.D. Applications proposing to develop the competitive research skills of recent clinical doctorates are also eligible. An applicant institution may submit only one application for this program announcement. Institutions holding active MBRS regular research (S06) or undergraduate (S14) awards are not eligible.

Inquiries: The PA may be obtained electronically through the NIH Grant Line (data line 301-402-2221) and the NIH Gopher (gopher.nih.gov), and by mail and e-mail from: Clifton Poodry, NIGMS, 45 Center Dr., Room 2AS.37-MSC 6200, Bethesda, MD 20892-6200, tel: 301/594-3900, fax: 301/480-2753, e-mail: poodryc@gm1.nigms.nih.gov

NCI Contract Awards

Title: Preclinical toxicology studies of chemopreventive agents. Contractors: IIT Research Institute, Chicago, $489,940; SRI International, Menlo Park, CA, $465,746; Southern Research Institute, Birmingham, AL, $262,626; Univ. of Illinois at Chicago, $226,408.

Title: Acquisition of 5-year data for international trial, screening for breast cancer in women 40-49 (UK 40 Trial). Contractor: Institute for Cancer Research, Royal Cancer Hospital, Surrey, UK, $386,957.

Title: Purchase of data for the NCI international overview analysis of randomized controlled breast cancer screening trials. Contractor: Univ. of Edinburgh, Scotland, $297,745.

Title: Microstimulation model for Colorectal Cancer Branch. Contractor: Erasmus Univ. of Rotterdam, The Netherlands, $437,409.

Title: Referral data base for specimen and data resources. Contractor: Westat Inc., Rockville, MD, $365,924.

Title: Operation of an animal diagnostic laboratory. Contractor: Univ. of Missouri-Columbia, $827,061.

ORI Finds Misconduct By Texas Medical Student

The HHS Office of Research Integrity has made final findings of scientific misconduct in the following case:

Richard Thwaites, Univ. of North Texas Health Science Center at Fort Worth: Based on an investigation conducted by the institution, ORI found that Richard Thwaites, former medical student, engaged in scientific misconduct by fabricating data in a clinical trial study supported by a PHS grant. Thwaites has accepted ORI's finding and, for a three year period has agreed to exclude himself from contracting or subcontracting with any federal agency and from eligibility for, or involvement in, nonprocurement transactions (e.g., grants and cooperative agreements) and exclude himself from serving in any advisory capacity to PHS.

No scientific articles were published that relied on the fabricated data.