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FDA Considers Regulation Of CME Programs Paid For By Drug Companies; Goal To Limit Promotion

The Food & Drug Administration is considering implementing new policies to regulate scientific or educational communications funded by drug companies that the agency considers promotional activities. The agency's Div. of Drug Marketing, Advertising & Communications has released a "draft concept paper" outlining the policies it wants to impose, which would affect any continuing medical education activity that

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In Brief

NCI Encourages New Grants In Four Cancer Sites In Forthcoming PA, Broder Informs Grantees

SAMUEL BRODER, NCI director, has sent a letter to all NCI grantees announcing that NCI will soon publish a program announcement requesting new grants for research on breast, prostate, ovarian, and cervical cancer, which Congress urged NCI to make a high priority. "All current and potential grantees are encouraged to submit new research project grant applications and competitive supplements for new and innovative research related to the four cancer sites," Broder wrote. In particular, NCI is encouraging submission of FIRST awards (R29s) to provide support for new independent biomedical researchers. Applications will be reviewed by standing NIH study sections. Deadline for new grant applications is Feb. 1; March 1 for competing supplements (**The Cancer Letter** will publish the PA as soon as it is available). . . . **GARTH POWIS** has joined the Arizona Cancer Center as director of basic science. Powis was formerly professor of pharmacology at Mayo Clinic, Rochester, MN. He will head Arizona's basic cancer research program. . . . **SOUTHERN RESEARCH** Institute announced the retirement of **Daniel Griswold** as vice president of chemotherapy and toxicology research. Griswold succeeded the late Frank Schabel in 1983. **David Prejean,** director of toxicology research, will become vice president. **Steadman Harrison** has been appointed director of chemotherapy research. . . . **KAY SHAFFER,** Medical College of Wisconsin, was elected president of the American Assn. of Women Radiologists at its annual meeting. **Karen Reuter** was elected president-elect. Other officers are vice president, **Lynne Steinback;** treasurer, **Ellann McCrory;** secretary, **Judy Destouet.** . . . **LESLIE LAUFMAN** has been named principal investigator for the Columbus Community Clinical Oncology Program following the resignation of **Jerry Guy** as PI. . . . **ERIC OLSON,** has been appointed chairman of the biochemistry and molecular biology department and holder of the Robert Welch chair in chemistry at M.D. Anderson Cancer Center.

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FDA Considers Strict Policies On Drug Promotion Through CME

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receives drug company funding. An FDA spokesman said that formal regulations have not yet been drafted based on the concept paper.

Under the proposed policies, FDA would limit scientific or educational activities that are supported by drug companies, including medical seminars, sessions at physician specialty meetings, grand rounds, presentations to formulary committees, and publications such as company supported medical journals, and medically oriented television programs, videotapes, software, and slide kits. According to the concept paper, related public relations activities directed to lay audiences will be covered in a separate policy.

The concept paper was criticized by the Coalition for Healthcare Communicators, a recently formed group of nine medical publishing, broadcasting, continuing medical education and advertising associations.

"FDA intends to create a new limitation on the free flow of scientific information by defining any communication that receives funding from a pharmaceutical company as 'promotion' and extending their regulatory controls to physicians and CME providers who accept company support, with the exception of company supported events that meet a series of burdensome tests. These tests may bear little relationship to actual clinical experience and practice," the Coalition said in a letter to doctors. "The rights of scientists to develop data on new drug treatments and to share that data publicly should not be impeded by FDA restrictions."

THE CANCER LETTER

Editor: **Kirsten Boyd Goldberg**
Associate Editor: **Lisa M. O'Rourke**
Founding Editor: Jerry D. Boyd

Editorial/Subscriptions Office
PO Box 15189, Washington, DC 20003
Tel: (202) 543-7665 Fax: (202) 543-6879

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The Coalition noted that the Accreditation Council for Continuing Medical Education has established guidelines addressing financial support and conflict of interest.

The FDA document, titled "Drug Company Supported Activities In Scientific or Educational Contexts: Draft Concept Paper," takes the position that the proposed policies "avoid undue intrusion in the free exchange of scientific information within the education, research and health care communities."

FDA, the paper says, "recognizes that the pharmaceutical industry provides funding for a significant proportion of the continuing medical education in this country. [FDA] also recognizes that discussions of unapproved uses of drugs, which would not be permissible in a drug company's promotional activities, are of great interest to the medical community and that when presented in an objective, balanced, and scientifically rigorous manner, with full disclosure of the relationships between the presenters and the drug company, are an important component of scientific exchange.

"A major purpose of the concept paper, therefore, is to describe a category of educational activities that may continue to be funded by drug companies and yet avoid regulation as advertising or promotional labeling."

FDA said the "key distinction" for the purposes of FDA regulation is whether the drug company has "attempted to influence the scientific or educational activity to promote sales of its product."

The paper continued: "The agency's policy has been that drug company supported, but 'independent' activities occurring in scientific or educational contexts fall within a limited exception to its general approach" to regulation of drug company communications.

Proposed Policy

The proposed FDA policy would require that in order to avoid 'promotional intent,' an educational activity supported by a drug company would have to meet certain standards for independence. The drug company also would have to ensure the "objectivity, balance, and scientific rigor" of the activities. The company would be required to sign an agreement with the educational provider about the design of the activity to ensure that the standards are met.

FDA listed the following factors that would determine independence:

--Selection of provider: "The relationship between the drug company and the provider should not be such that the drug company appears to be in a position to exert influence over the content of the activity through the provider." Sales and marketing

staff should not be involved in the scientific or educational activity.

--Independent experts: "The drug company should play no role in the selection of presenters or authors. If experts who have financial relationships with the company are included in the activity, their recent and current relationships to the drug company should be disclosed."

--Disclosure of financial relationships: "The provider should agree to provide for meaningful disclosure to the target audience of the actual source of funding for the activity by the drug company, and of relationships between the provider and the drug company and between individual presenters and the drug company."

--Topic: "The focus of the activity should be on broad aspects of a disease and on a variety of treatments. The focus should not be a specific drug product marketed by the drug company or a competing drug product."

--Number of performances: "Support of repeated presentations enables the drug company to judge content and to selectively support repeat presentations only of programs favorable to its product. Live scientific activities should ordinarily not be repeated."

--Drug company involvement: "The drug company should agree not to engage in any activities, including scripting, ghostwriting of papers, preparation of audiovisual aids, training of presenters, or targeting of points for emphasis, that might influence the treatment of topics."

--Ancillary promotional activities: "The drug company should agree not to have any promotional activities in proximity to the educational activity, such as participation by sales representatives, nearby promotional exhibits, or advertisements in any printed materials disseminated in the program. This does not prohibit the required acknowledgement of the drug company's support for the activity."

--Liaison: "Liaison with the provider should be through the drug company's medical or scientific departments.... Individuals who are involved in the company's promotional, sales, marketing or public relations activities, even if employed in the medical or scientific departments, should play no role in planning, organizing, or carrying out the supported activity."

--Medical writers and articles: "'Independent' scientific or educational articles about a company's drugs or directly competing drugs should not be written by medical writers employed by the firm, including free lance writers hired by the firm for specific projects.

FDA listed the following factors that would determine "objectivity and balance":

--Provider: "The provider should be an organization that has a record of generating objective, non-promotional educational programs or publications."

--Favorable and unfavorable information: "The provider should agree that if a drug product either marketed by the drug company or in competition with a drug marketed by the drug company is to be the subject of substantial discussion, the data will be objectively selected and presented and will accurately reflect the entire body of valid scientific evidence on the products, that both favorable and unfavorable information about the drug will be fairly represented, and that alternative therapies, if any, will be discussed in a balanced manner."

--Superiority claims: "The provider should agree that suggestions of superiority of one product or treatment over another will be supported by the overall body of available data, and will not result from selective presentation or emphasis on data favorable to a particular treatment."

--Investigational uses: "The provider should agree that when unapproved uses are discussed, the speaker will disclose that the drug is not approved for the use under discussion. The provider should also agree that discussions of unapproved uses will be especially objective and scientifically rigorous, e.g., will focus on uses under active investigation by groups such as the National Institutes of Health."

--Peer review and accreditation: "The provider should agree that the activity will be independently peer reviewed or accredited by an independent accrediting organization."

--Experts: "The provider should agree that experts representing a diversity of legitimate medical opinion on the topic under discussion will be included as authors or presenters in the activity."

--Debate: "If the program is live, meaningful opportunities for scientific debate or questioning should be provided during the program."

"Scientific rigor," under the FDA proposal, also would have to be included in the drug company's agreement with the educational provider, and should include elements such as complete data, disclosure of any limitations of the data, ongoing research and interim analyses will be represented as not yet conclusive.

Written comments on the concept paper may be sent to FDA, Div. of Drug Marketing, Advertising & Communications, HFD-240, 5600 Fishers Lane, Rockville, MD 20857, Attention: Drug Company Supported Activities in Scientific or Educational Contexts.

Wyden Asks Healy To Clarify CRADA 'Reasonable Pricing' Clause

The year was 1989. Facing public outrage over the high price of AZT, NIH decided to require "reasonable" pricing for any drug to be developed through future partnerships between the institutes and industry.

Reasonable as that requirement may have seemed at the time, two years later, NIH, Congress and the pharmaceutical industry are sparring over what "reasonable" means.

In fact, according to NIH Director Bernadine Healy, at least two major pharmaceutical companies have decided not to pursue Cooperative Research and Development Agreements with NIH out of fear that a price deemed reasonable to the institutes would be unreasonable to them.

Healy herself would not have been able to resolve their doubts.

NIH is "at this stage probably unqualified" to interpret the clause, she said last month in testimony before the Subcommittee on Regulation, Business Opportunity and Energy of the House Committee on Small Business.

To resolve the ambiguity, NIH has created an interagency working group that is expected to make its recommendations to the NIH director by the spring, said Reid Adler, director of the NIH Technology Transfer Office and head of the working group.

NIH is the only federal agency to include such a clause in its CRADA contracts. The NIH contract's clause 8.3 reads:

"NIH/ADAMHA have a concern that there be a reasonable relationship between the pricing of a licensed product, the public investment in that product and the health and safety needs of the public. Accordingly, exclusive commercialization licenses granted for NIH/ADAMHA intellectual property rights may require that this relationship be supported by reasonable evidence."

Questioning Healy at the December hearing, Rep. Ron Wyden (D-OR), demanded a clarification:

"There must be better, tougher language within NIH licensing agreements and the model CRADA agreement which ensure that companies can make a reasonable profit, but which also protects consumers from price-gouging," Wyden said.

"I am troubled by the reality that drug manufacturers have used NIH technologies to develop products, and then have gouged consumers on the pricing of pharmaceuticals developed in whole or in part from federal research," he said.

Wyden first brought up the subject of fair pricing in a hearing last summer on NCI's CRADA with Bristol-Myers Squibb for the development of taxol (**The Cancer Letter,** Aug. 9, 1991).

It must be noted that the NIH, unlike, say the Department of Justice, does not have (and is not asking for) an arsenal of enforcement measures for enforcement of all that is reasonable.

There is only one thing the institutes can do: they can ask industry partners to submit confidential statements justifying their pricing.

But that is done only when it appears that pricing is, well, unreasonable.

Only one drug, ddI, has gone to market following the passage of the pricing clause and NIH saw no cause to require the drug's manufacturer, Bristol-Myers Squibb, to justify the price of the drug, said Adler.

Going beyond the pricing clause, the NIH has been fostering competition between drug manufacturers to hold down the price, Healy said.

"In the arena of AIDS drugs, ddI is licensed to Bristol-Myers Squibb, ddC is licensed to Hoffman-LaRoche, and AZT was developed with Burroughs-Wellcome," she said. Inventorship of AZT is under litigation.

"Thus, for this class of anti-AIDS drugs, we can expect a vigorous level of competition to benefit the consumer," Healy said. "Indeed, competition within a family of drugs is an important general end-result of NIH-supported research and technology transfer. So is the accelerated pace of pharmaceutical development that we have witnessed so dramatically in the case of AIDS antiviral agents."

With very few exceptions, CRADAs are pursued by smaller firms, with the larger pharmaceutical houses shying away. The larger firms prefer to have exclusive ownership of the drugs they develop, they are deterred by the pricing clause and have fears of disclosures of trade secrets. The NIH role in the litigation over ownership of AZT has made large pharmaceutical houses even more jittery, sources say.

Nonetheless, Healy said, NIH accounts for over 50 percent of CRADAs from all federal laboratories. "NIH CRADAs have cut years off the clinical development time frame for several therapeutics and have accelerated the development of animal models for various human diseases."

According to Healy:

--Almost 1,200 inventions made in Public Health Service intramural laboratories have been patented or are pending patents;

--300 of those inventions have been licensed to industry.

in royalties for the PHS in fiscal 1990.

"As one example, a CRADA established between the NIH and Genetic Technology Inc. (GTI), made it possible for [NHLBI scientist] French Anderson and his colleagues to conduct a historic gene therapy experiment," Healy said.

"The CRADA provided the company with an incentive to financially exploit the technology with an option for exclusive licensing rights, while enabling NIH to develop better biological delivery vehicle.

"The company contributed to the partnership by providing intellectual expertise and essential materials as well as financial support for the laboratory personnel," Healy said.

Lung Cancer Deaths Level Off In White Males, NCI Study Says

While the lung cancer death rate among white males has levelled off and is expected to decline in the mid-1990s, death rates among blacks and women are not expected to drop until after the year 2000, an NCI study found.

According to the study, "Strategies to Control Tobacco Use in the U.S.: A Blueprint for Public Health Action in the 1990s," the declining death rate reflects the white males' change in behavior in response to publicity linking smoking and health hazards. One in two adult white males smoked 25 years ago. Today, smoking rate is down to 27 percent.

"White males clearly changed their behavior in response to the first wave of publicity about the dangers of smoking in the early 1950s, but it was not until the late 1960s that women and black males began to stop smoking in large numbers," said David Burns, professor of medicine at the Univ. of California and senior scientific editor of the report.

The wave of publicity that appears to have convinced a great many white men to quit smoking involved the sporadic newspaper and magazine articles about the hazards of smoking. Such articles, which began to appear in the 1950's, were confined to health issues, not touching upon aesthetics and social issues.

By contrast, the antismoking campaign of the late 1960s and early 1970s was more sustained and focused on television, typically using a wide range of socially directed messages which appealed to diverse audiences. During this period smoking began to decline among all major demographic groups in the nation.

"Women and black males have had a much slower decline in smoking--and have been aggressively pursued by advertising and marketing campaigns," said HHS Secretary Louis Sullivan.

The most recent figures show that in 1987, the white male age-adjusted lung cancer death rate was 73.2 per 100,000 population. In 1988, it was 73 deaths per 100,000 population.

Meanwhile, lung cancer death rates among women have increased 420 percent since the 1950s. About 51,000 U.S. women will die of lung cancer this year, making it the number one cause of cancer death in women.

Similarly, black men have a lung cancer death rate 35 percent higher than their white counterparts, and have substantially higher cigarette smoking rates. The age-adjusted lung cancer death rate for black men is 97 deaths per 100,000 population, compared to 73 deaths per 100,000 for white men. Thirty-three percent of black men smoke cigarettes compared to 27 percent of white men.

The 300 page NCI monograph concludes that additional smoking prevention activities and tougher restrictions on smoking could save thousands of lives over the next two decades.

"The strategies for controlling cigarette smoking outlined in this report offer our best hope of reversing the lung cancer epidemic which has plagued this century," NCI Director Samuel Broder said.

"I think the lesson learned here is clear: When attention to the smoking problem is high and sustained, the public responds; when our attention is diverted elsewhere, we tend to lose ground," he said.

In the foreword to the report, Broder attacked the cigarette promoters' attempts to use cartoon characters to promote Camel and Kool cigarettes.

"It is not difficult to imagine what impact large-scale, youth-oriented advertising will have on our young people," Broder said. "My greatest fear is by the time we resolve this problem, millions of our young people already will have become addicted to cigarettes."

Donald Shopland, coordinator of NCI's Smoking and Tobacco Control Program, called for limiting areas where smoking is permitted, increasing the cost of tobacco products, and restricting the access of minors to tobacco.

Copies of the report are available from NCI, NIH Building 31, Room 1OA24, Bethesda, MD 20892., phone 1-800-4-CANCER.

NCI Advisory Group, Other Cancer Meetings For Jan., Feb., Future

Chromosomes in Solid Tumors Workshop--Jan. 1-13, Tucson, AZ. Contact Arizona Cancer Center, 1515 Campbell Ave., Tucson, AZ 85724, phone 602/626-2276.

Research Colloquim in Radiotherapy & Related Disciplines in Honor of Dr. Eli Glatstein--Jan. 8, NIH Masur Auditorium, 8:30 a.m.-4:30 p.m. Contact Dr. Gregory Curt, phone 301/496-4251.

Antisense Strategies--Jan. 12-15, Philadelphia. Contact New York Academy of Sciences, phone 212/838-0230.

NCI Div. of Cancer Prevention & Control Board of Scientific Counselors--Jan. 16-17, NIH Bldg. 31 Rm 10. Open 8:30 a.m.-5 p.m. on Jan. 16, 8:30 a.m.-adjournment on Jan. 17.

FDA Biological Response Modifiers Advisory Committee--Jan. 17, Bethesda Holiday Inn, Bethesda, MD. Open 8:30 a.m. Topic: Chiron/Cetus interleukin-2.

NIH Consensus Conference: Diagnosis & Treatment of Early Melanoma--Jan. 27-29, Masur Auditorium, NIH Clinical Center. Contact Prospect Associates, phone 301/468-MEET.

National Cancer Advisory Board--Jan. 27-28, NIH Bldg. 31 Conference Rooms. Open 8:30 a.m. on Jan. 27.

Spectrums of Cancer Therapy--Jan. 29-31, Tampa, FL. Contact St. Joseph's Cancer Institute, 813/870-4991.

Cutaneous Malignancies: 1992 Skin Cancer Update--Jan. 31-Feb. 2, La Jolla, CA. Contact Susan Buntjer, Conference Coordinator, Scripps Clinic, phone 619/554-8556.

Imaging in the Health Sciences--Jan. 31-Feb. 2, Houston, TX. Contact Jeff Rasco, Conference Services, M.D. Anderson Cancer Center, phone 713/792-2222.

Radiation Therapy Oncology Group Semi-Annual Meeting--Feb. 7-9, Philadelphia. Contact Nancy Smith, RTOG, 1101 Market St., Suite 1400, Philadelphia, PA 19107, phone 215/574-3205.

Molecular Oncology as a Basis for New Strategies in Cancer Therapy--Feb. 10-14, Honolulu, HI. Contact American Assn. for Cancer Research, phone 215/440-9300.

Oncology Nursing Conference--Feb. 11-14, Houston, TX. Contact M.D. Anderson Cancer Center, Jeff Rasco, phone 713/792-2222.

Current Concepts in Cancer Management: Symposium for Primary Care Physicians & Cancer Care Providers--Feb. 13-15, Newport Beach, CA, Hoag Cancer Center. Contact Meeting Management, San Diego, CA 92121, phone 619/453-6222.

ACS National Conference on Prostate Cancer--Feb. 13-15, San Francisco. Contact Andy Cannon, American Cancer Society, 1599 Clifton Rd. NE, Atlanta, GA 30329, phone 404/329-7604.

Cancer Management Course--Feb. 17-18, San Juan, Puerto Rico. Contact Dr. Reynold Lopez, American College of Surgeons, 55 East Erie St., Chicago, IL 60611, phone 312/664-4050.

Clinical Hematology & Oncology--Feb. 17-19, La Jolla, CA. Contact Susan Buntjer, Scripps Clinic, phone 619/554-8556.

Society of Toxicology--Feb. 23-27, Seattle, WA. Contact Society of Toxicology, phone 202/371-1393.

NCI Div. of Cancer Treatment Board of Scientific Counselors--Feb. 24-25, NIH Bldg. 31 Conf. Rm. 6, open 8:30 a.m.

Frontiers in Cancer Care: Grief--Feb. 28, Cleveland, OH. Contact Education Coordinator, Ireland Cancer Center/Case Western Reserve Univ., phone 216/844-7858.

Future Meetings

Cancer Nursing: AIDS-Related Lymphomas--March 6, Cleveland, OH. Contact Education Coordinator, Ireland Cancer Center/Case Western Reserve Univ., phone 216/844-7858.

Adjuvant Therapy of Cancer--March 10-13, Tucson, AZ. Contact Arizona Cancer Center, 1515 Campbell Ave., Tucson, AZ 85724, phone 602/626-2276.

American Society of Preventive Oncology Annual Meeting--March 14-16, Bethesda, MD. Contact Dr. Richard Love, ASPO, 1300 University Ave., Madison, WI 53706, phone 608/263-6919.

Current Perspectives in Cancer Therapy: The Multimodal Approach--March 18, Cleveland, OH. Contact Education Coordinator, Ireland Cancer Center/Case Western Reserve Univ., phone 216/844-7858.

Diagnosis & Treatment of Neoplastic Disorders, Medical, Surgical, and Radiotherapeutic Aspects--April 2-3, Baltimore, MD, Johns Hopkins Univ. School of Medicine. Contact Office of Continuing Education, phone 301/955-2959.

Cytometry 2000 Annual Cancer Symposium--April 30-May 1-2, Detroit, MI. Contact Dr. Alexander Nakeff, Wayne State Univ. Div. of Hematology/Oncology, phone 313/577-7923.

Prevention of Human Cancer: Nutrition & Chemoprevention Controversies--June 3-6, Tucson, AZ. (Abstract Deadline March 1.) Contact Arizona Cancer Center, 1515 Campbell Ave., Tucson, AZ 85724, phone 602/626-2276.

Critical Issues in Tumor Microcirculation, Angiogenesis & Metastasis: Biological Significance and Clinical Relevance--June 8-12, Boston, MA. Contact Norman Shostak, Dept. of Continuing Education, Harvard Medical School, phone 617/432-0196.

Recent Advances in Urological Cancer Diagnosis & Treatment--June 17-19, Paris, France. Contact Dr. Saad Khoury, Clinique Urologique, Hopital de la pitie, 83 bd de l'Hopital, 75634, Paris Cedex 13, France, phone 45.70.38.62, fax 45.70.30.78.

Metastasis Research Society International Congress--Sept. 1-4, Paris, France. Contact Dr. Marie-France Poupon, IRSC-CNRS, 7 rue Guy Moquet B.P. 8, 94801 Villejuif, France, phone 33.146789259.

Mechanisms in Nutrition & Cancer Seminar--Oct. 12-14, Venice, Italy. Contact Dr. John Weisburger, phone 914/789-7141, fax 914/592-6317; or Dr. Claudia Ferrari, European School of Oncology, Via Venezian 18, 20133 Milan, Italy, phone 39-2-7063-5923, fax 39-2-226-4662.

RFPs Available

Requests for proposals described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs, citing the RFP number, to the individual named, the Executive Plaza South room number shown, National Cancer Institute, Bethesda MD 20892. Proposals may be hand delivered to the Executive Plaza South Building, 6130 Executive Blvd., Rockville MD. RFP announcements from other agencies will include the complete mailing address at the end of each.

RFP NCI-CP-33000-21

Title: Support services for occupational studies

Deadline: Approximately Jan. 3

NCI's Occupational Studies Section, Environmental Epidemiology Branch is seeking a contractor to perform the above project. This support contract is a recompetition of a contract being performed by Westat Inc., which expires on Jan. 31, 1993.

The contract will support data collection activities for 20 to 25 projects. The studies are designed by NCI investigators who also analyze and interpret study results. The contractor must be capable of providing support for a number of studies conducted simultaneously in widespread geographic regions of the U.S. and other countries (Turkey and China). A critical capability is to be able to respond quickly to changes in priority and to supply support to urgent new efforts. The types of support to be provided by the contract include: study initiation and liaison, preparation of study materials and procedures, data collection, data preparation, computer programming and data processing, study monitoring, quality control and reporting. These tasks may vary.

Communication between the contractor and NCI will often be

on a daily basis with regularly scheduled meetings to review and adjust procedures for assigning work. The contractor must be capable of performing random digit dialing. Personal computers shall be used wherever possible for data processing and manipulation. The NIH/DCRT computer facility shall be accessed by remote terminals to be provided by the contractor on its own premises. Monitoring of a wide spectrum of workplace exposures shall be performed by an industrial hygienist certified by the American Board of Industrial Hygiene who has access to equipment and a laboratory certified by the American Industrial Hygiene Assn. The contractor shall provide monthly and annual technical reports, monthly budget reports and a final technical progress report. Other deliverables shall include computerized data, raw data and biologic specimens and industrial hygiene samples. The required level of effort to be provided is 143,520 total direct labor hours for the entire period of performance. The contract will be a cost reimbursement, level of effort type for a 48 month period. Award is anticipated by Feb. 1, 1993.

Contract Specialist: Barbara Shadrick
RCB Executive Plaza South Rm 620
301/496-8611

RFP NCI-CP-21008-21

Title: Continuation of followup on participants in the breast cancer detection demonstration project

Deadline: Approximately Jan. 10

The Environmental Epidemiology Branch, Div. of Cancer Etiology and the Cancer Prevention Studies Branch, Div. of Cancer Prevention and Control, NCI, are jointly seeking a contractor for a proposed study which is a continuation of a follow-up study on a sample of 64,185 of the 280,000 women who previously participated in a five-year multi-center breast screening program--the Breast Cancer Detection Demonstration Project (BCDDP)--conducted during 1973 1980. Currently, approximately 58,371 women are known to be alive. Based on the responses received from this sources sought, this acquisition may be solicited as a 100 percent small business set-aside, SIC code 8731, with a size standard of 500. This is not an RFP and does not commit NCI to award a contract now or in the future. No rfp is available at this time.

The above sample of women was chosen to include all women who had a breast cancer diagnosed while they were in the screening project (4,275), all who had a biopsy or aspiration that was determined to be benign (25,115), all who had a surgical evaluation recommended by the project but did not undergo biopsy (9,629) and a sample of those who had neither surgery nor a recommendation for further evaluation (25,166).

Continuation of follow up will allow accrual of additional cases of breast cancer and other diseases, thus increasing the overall power of the study. It will also be essential to effectively utilize the risk factor data that were collected only in the last questionnaire. The contractor shall conduct further follow-up on a cohort consisting of the approximately 58,371 remaining women from the BCDDP. The average age of the cohort in 1990 was 65 years. The study is expected to last three years.

A summation of the specific activities to be performed by the contractor include a) establishing and maintaining a centralized office in which documents associated with this study can be stored and from which mail and telephone interviews can be conducted, b) modify existing mail and telephone questionnaires (may include content as well as format), c) provide personnel to conduct follow-up activities, d) obtain the following information for each participant: (1) vital status information on cohort members. (2) responses to one mailed questionnaire from living study subjects during the three-year study period, (3) e.g., copies of pathology reports, hospital discharge summaries and operative reports for colon polyps, all cancers and breast procedures reported since the last interview in 1987/89, (4) copies of death certificates for all deceased subjects since the last interview (approximately 5,700 deaths are expected), e) at the direction of NCI, the contractor shall: (1) randomly select a sample of approximately 200 participants for purposes of checking the reproducibility of the dietary and physical activity information obtained from the 1987/89 interview, (2) obtain eight 24-hour recalls from a sample of approximately 200 subjects for purposes of validating the diet information, (3) select a sample of approximately 200 participants who reported recent use of hormone replacement therapy in the 1987/89 interview for the purpose of validating self;reported use of estrogens and estrogens combined with progestins, (4) validate cancer status of subjects, match a sample of approximately 2,000 women with and without new cancer diagnoses to a population-based cancer registry to confirm status, f) have a trained nosologist code medical and death certificate data, using specified International Classification of Disease (ICD) codes, g) review and edit all collected and coded information, prepare all data for keypunching and develop and modify coding schemes as needed, h) code, keypunch and verify all data from items d), e) and f), above, i) establish and maintain control procedures to ensure standardization and a high level of quality of data collection and processing, including: (1) a written log or record book of all decisions affecting study design, conduct or analysis, (2) field manual with instructions easily understood, (3) training of personnel prior to the start of the study in the use of data collection (including telephone interviews) and coding techniques, (4) monitor the performance of the field activities, and (5) verify accuracy of coding and keypunching data, j) develop a ready-access, patient oriented storage system for information and materials collected on cohort members during previous phases of the BCDDP, k) develop computer programs to check all data for range, skip and consistency errors, and 1) produce and provide to NCI the data tapes of edited information collected on the study participants.

The estimated total level-of-effort for the three-year period of performance is 50,976 direct labor hours. This should include a Project Director (MA level or below), a Programmer/Analyst, Technical Support Personnel (e.g.: coders, tracers, abstractors, telephone interviewers, data entry personnel, key entry supervisor and tracing supervisor), and Administrative/Clerical Support. Technical evaluation criteria. in descending order of importance, shall be: 1) Method/Approach 2) Corporate Experience and Resources and 3) Personnel. Award is anticipated by Aug. 1, 1992.

Contract Specialist: Barbara Shadrick
RCB Executive Plaza South Rm 620
301/496-8611

[Due to the holiday break, approximate deadlines have passed on the RFPs below. Contact the contract specialist listed for further information on availability.]

RFP NCI-CP-21006-21

Title: Operation and coordination of a nationwide, multi-study, high volume death certificate acquisition and management system

Deadline: Approximately Dec. 31

The Biostatistics Branch, Div. of Cancer Etiology, NCI, is seeking a contractor for a project with a primary objective to acquire large numbers of death certificates simultaneously from Vital Statistics Offices (VSOs) of multiple states (sites), using the contractor's own distinct automated system. Based on the responses received, this acquisition may be solicited as a 100 percent small business set-aside, SIC code 7379, with a size

standard of $12.5 million. This is not an RFP and does not commit NCI to award a contract now or in the future. No RFP is available at this time.

An automated system is necessary because of the complexity and large volume of work involved. An average of 12,000 death certificates per year will be requested from VSOs throughout the U.S. About 1,000 death certificate requests will be sent to multiple VSOs per month and an approximately equal number of certificates will be returned from these sites monthly. The exact number and nature of studies that will require support cannot be accurately projected at this time. It should be noted that many studies are currently ongoing within the EBP. In the area of occupational epidemiology, cohort studies are under way to investigate a wide range of exposures, including acrylonitrile, formaldehyde, pesticides, organic and inorganic dusts, metal fumes and organic solvents (e.g., trichloroethylene, perchloroethylene, methylene chloride, benzene, benzidine). Some of the activities in the area of radiation epidemiology include: a survey of breast cancer among women treated for scoliosis, an evaluation of the use of low dose radiotherapy to treat uterine bleeding, long term follow up of patients who received multiple chest fluoroscopies during lung collapse therapy for tuberculosis, a study of patients treated for hyperthyroidism with radioactive iodine, and others.

The NCI Project Officer will provide the contractor with lists which show all pertinent information available on each deceased subject, such as date of death, town or city and/or state of death, as well as other known personal identifiers. For some decedents, requests to several states may be necessary before a copy of the death certificate can be obtained. The contractor shall use its automated system, assigned personnel, knowledge and experience to perform all of the logistical activities and procedures in order to accomplish the necessary death certificate acquisition tasks requested by the NCI Project officer. Rigorous quality control procedures must be followed at all times. Puerto Rico and other U.S. possessions may be included as necessary. Detailed information shall be kept on all outgoing and incoming materials, including logs, records and forms. Death certificates received by the contractor shall be carefully examined and classified as Found, Not Found or Out of Scope. Matching is based on the agreement of information on the death certificate with information and identifiers on subjects which the contractor has. Matching shall be done by experienced key personnel, as it is a very important step in the process. The contractor shall be required to submit monthly and annual technical progress reports and a final report.

The estimated total level-of-effort for the five year period of performance is 2,700 direct labor hours. Technical evaluation criteria, in descending order of importance, shall be: 1) Technical Approach, including: description and operation of the offeror's automated system, tabulation and description of relevant high-volume, multi-VSO projects simultaneously carried out over at least the past three years, and the offeror's current knowledge of information and logistics concerning death certificate acquisition at nationwide VSOs; and 2) Personnel, including: capabilities and experience of the death certificate acquisition manager in death certificate acquisition, and capabilities and experience of other key death certificate acquisition personnel. Emphasis shall be placed on the location and description of the physical facility in which the automated system is located and a description of the system as a distinct system within the company. The offeror should provide tabulation and a description of current pertinent regulations and requirements of each VSO throughout the country for acquisition of death certificates. A description, as well as curriculum vitae, of the death certificate acquisition manager's capabilities and experience in high-volume, multi-state/site/VSO death certificate acquisition, and in supervision of an automated system should be provided. The death certificate acquisition manager should have experience managing the automated system. All key personnel combined should equal one person-year. Award of this project is anticipated by Sept. 1992.

Contract Specialist: Barbara Shadrick
RCB Executive Plaza South Rm 620
301/496-8611

RFP NCI-CP-21051-25

Title: Cancer risk in women with augmentation mammaplasty
Deadline: Approximately Dec. 23

The Environmental Studies Section (ESS), Environmental Epidemiology Branch (EEB), NCI is seeking sources capable of performing the above named project. This is not a request for proposal and does not commit the NCI to award a contract now or in the future. No RFP package is available at this time. We are only seeking information from offerors with the capabilities to perform the stated project. This is a 100% Small Business Set-Aside, SIC Code 8731.

This contract will support NCI in performing a retrospective cohort study of women having undergone augmentation mammaplasty. Plans are to assemble a cohort from a variety of different surgery practices of approximately 9,000 women having undergone such operations during the period 1960 to 1985 (median follow-up of 10 years is sought) and to abstract patients' medical records for pertinent identifiers, operation details and other historical factors. Also to be assembled will be a comparison cohort from the same plastic-surgery practices as the breast augmentation patients of approximately 3,000 women with other types of plastic surgery, who will serve as a comparison cohort. Both cohorts will be traced over time and will be sent questionnaires to elicit details on risk factors for a variety of diseases and medical events subsequent to their operations. Any breast biopsies or occurrences of cancer will be validated by retrieval of appropriate medical records.

The Contractor must be capable of assisting NCI in assembling the required cohorts, which will require contact with a number of plastic surgery practices and professional organizations. In addition, the contractor will be responsible for developing abstract forms and questionnaires to be used in the project, tracing women over time, performing telephone interviews for non-responders to the mailed questionnaires, obtaining death certificates for deceased subjects, validating occurrences of subsequent medical events, developing coding schemes for collected data, computerizing collected data, and assisting with deriving expected values of subsequent events (both from the internal cohort and external standards) for epidemiologic analyses of long-term events among the cohort of interest.

The Contractor must be sensitive to the unique privacy issues involved with this project and assure extreme confidentiality of the data collected. Quarterly and annual progress reports, a final report and quarterly budget reports will be required. Other deliverables shall include computerized and raw data. The total estimated level of effort to be provided for a four-year period is 54,080 direct labor hours.

Award is anticipated by Sept. 30, 1992. Evaluation criteria, in descending order of importance, shall be: 1) Approach, 2) Experience and Capabilities of Personnel (Principal Investigator, Study Manager, Computer Programmer), 3) Experience in managing a study of this type and 4) Facilities and Equipment. Submit original and two copies of the capability statement.

Contracting officer: Nancy Coleman
RCB Executive Plaza South Rm 620
301/496-8611