THE CANCER LETTER FAX

Vol. 22 No. 37
Sept. 27, 1996

Price $265 Per Year US
$285 Per Year Elsewhere

NCI, HCFA Negotiate Demonstration Project As Congress, Advocates Exert Pressure

In recent months, officials from the Health Care Financing Administration have had a powerful motivation to continue negotiating with NCI.

HCFA has a choice:

The agency can negotiate a "demonstration project" to evaluate the impact of reimbursing routine patient care costs for Medicare beneficiaries enrolled in cancer clinical trials. Alternatively, the agency could be forced to set up such a project under legislation similar to one

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In Brief

White House Names Phillip Sharp To NCAB; Shine Re-Appointed As IOM President

PHILLIP SHARP was appointed to the National Cancer Advisory Board, the White House announced last week. Sharp, head of the Department of Biology and professor at the Center for Cancer Research and Department of Biology at the Massachusetts Institute of Technology, has served as a member of the President's Committee of Advisors on Science and Technology since 1994. He received the Nobel Prize in Physiology or Medicine in 1993. Sharp also is a trustee of the Alfred P. Sloan Foundation and serves as chairman of the General Motors Cancer Research Foundation Awards Assembly. . . . **KENNETH SHINE**, president of the Institute of Medicine since 1992, has been appointed to a second five-year term. Shine was appointed by Bruce Alberts, president of the National Academy of Sciences, upon the recommendation of the IOM Council with the concordance of the NAS Council. The new term will run from July 1, 1997, to June 30, 2002. The IOM provides scientific advice under the Academy's charter to the federal government and other public and private agencies. . . . **PRINCESS DIANA** joined first lady **Hillary Rodham Clinton** and several fashion designers at a White House breakfast Sept. 24 to raise money for the Nina Hyde Center for Breast Cancer Research at Georgetown University Hospital. The breakfast was the first of several fundraising events for the center, including a gala and an auction, held over three days. The center is named for the late Washington Post fashion writer, who died of the disease in 1990. . . . **AMERICAN CANCER SOCIETY** has awarded Cancer Control Career Development Awards to three primary care physicians. The awardees

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Congress, NCI Pressure HCFA For Clinical Trials Agreement

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currently pending in the Senate.

Though it would be far-fetched to expect that the bill sponsored by Sens. Jay Rockefeller (D-WV) and Connie Mack (R-FL) would be enacted by the 104th Congress, it is likely that a similar proposal would be reintroduced next year—unless HCFA and NIH strike a deal on their own.

"Interest from the Hill has motivated the parties to remain at the table," a Capitol Hill source said to **The Cancer Letter**.

The bill's proponents say that, at least this year, their goal is to exert pressure rather than to get the bill passed. Thus, as the parties bargain, they do so under the watchful eye of the bill's sponsors, prodded by not-so-subtle warnings about the consequences of heading for the door.

At this point, the negotiators are sorting through a tangle of issues and institutional positions. In fact, a series of related negotiations are being conducted, sources said.

—One set of negotiations, between NCI and HCFA, focuses on setting up the mechanism for a collaboration. On several occasions, these negotiations have involved the patient groups and the American Society of Clinical Oncology.

—Another set of negotiations, reportedly focused on cost issues, involves HCFA Administrator Bruce Vladeck and NIH Director Harold Varmus. These negotiations are conducted without participation by ASCO or the patients.

—A third set of negotiations aims to define the scope of coverage that would be offered through the demonstration project.

Several patient advocacy groups and professional societies argue that the project should use the language developed by ASCO to define clinical trials in which routine patient care costs would be covered.

The ASCO language, which figured in all the major health care reform bills three years ago, appears in the Rockefeller-Mack bill (S. 1963). The bill proposes that the demonstration project reimburse routine patient care costs in clinical trials approved by NIH, FDA, the Department of Defense, the Department of Veterans Affairs, and non-governmental entities "identified in the guidelines issued by NIH for center support grants" (**The Cancer Letter**, July 26).

NCI has taken the position that the Rockefeller-Mack definition of eligible clinical trials is so broad that it may open the door for coverage of patient care costs in trials that would not advance science or help patients, sources said.

Also, the Institute is not eager to place itself into the role of having to separate the good trials from the bad. Such a role would be a considerable drain on NCI resources, sources said.

Therefore, the HCFA demonstration project may require some new mechanism for determining the eligibility of trials, sources said.

The stakes in these discussions are high. One of the goals of the demonstration project—generating data that would allow cost comparisons of clinical trials versus standard care—could well be decisive in determining the future of clinical research.

Since Medicare practices are closely watched by all third party payers, the scope of coverage in the demonstration project is of critical importance to all parties involved, observers said.

Thus, patient advocates and oncology professional societies are hoping to make the HCFA demonstration project as broad as possible, far broader than a similar demonstration project between NCI and the Department of Defense. Responding to this pressure, HCFA officials are evaluating the potential cost to Medicare.

The White House, too, is watching the

THE CANCER LETTER

Founded 1974
Member, Newsletter Publishers Assoc.

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Subscriptions: subscrib@www.cancerletter.com
World Wide Web URL: http://www.cancerletter.com

Subscription $265 per year US, $285 elsewhere. ISSN 0096-3917. Published 48 times a year by The Cancer Letter Inc., also publisher of The Clinical Cancer Letter.

negotiations, partly because the President would be likely to announce the deal. In fact, a less significant deal for a clinical trials demonstration project between NCI and the US Department of Veterans Affairs is awaiting unveiling at the White House, sources said.

Patients Demand Seat At the Table

As it faces HCFA, NCI appears to benefit from the support of the patient advocates, who lend moral authority to the Institute's position, elevating it beyond the level of intra-agency wrangling.

However, the patients also present a formidable challenge to the Institute in the negotiations.

Two of the major groups, the National Breast Cancer Coalition and the National Coalition for Cancer Survivorship, have come out in favor of the standard, broad definition of clinical trials eligible for coverage.

Also, the patients are demanding a seat at the table as the agreement is being negotiated.

"I know of no reason why well-informed patients should not be involved in these negotiations," said Ellen Stovall, executive director of NCCS and a member of the National Cancer Advisory Board.

"All of the parties involved in these negotiations need to have an open dialogue, and it has to happen quickly, because the setting of standards of care is, de facto, falling to the marketplace," Stovall said to **The Cancer Letter**.

Stovall said NCI officials had invited her and ASCO executive director John Durant to one of the meetings with HCFA, but neither she nor any other patient activist has been consistently involved in the negotiations.

Fran Visco, president of NBCC and a member of the President's Cancer Panel, said she was not aware of the ongoing negotiations between top officials of NIH and HCFA.

"If that is the case, I don't think it's appropriate that negotiations should be conducted without input from the consumer groups," Visco said to **The Cancer Letter**.

Visco said the demonstration project should reimburse routine patient care costs for a wide range of clinical trials. "NBCC feels quite strongly that the demonstration project should offer broad coverage," she said. "I don't see how anyone who is supportive of quality clinical research would support a different view."

Recently, in an apparent effort to confront the HHS officials with the demands of patients and health care providers, Rockefeller and Mack called a meeting that was to include Stovall, Visco, Durant, and several others.

However, at the last minute HHS officials requested that the meeting be postponed, sources said.

After the postponement, Rockefeller wrote to HHS Secretary Donna Shalala, requesting that the meeting be rescheduled, sources said.

No new date has been set.

NCI Challenge To HCFA

Since the negotiations are conducted behind closed doors, it is unclear where NCI and HCFA stand on the issues at this time.

However, sources said, HCFA has given in on some of its traditional positions, opening the possibility for some form of a demonstration project.

One key document obtained by **The Cancer Letter** indicates that NCI has been forcefully pursuing its agenda, pointing out ways for HCFA and NCI to receive a "very sympathetic hearing" in Congress, and making implicit threats to walk away from the table if HCFA fails to budge.

"Let me know if you think there is any point in further discussion," wrote Robert Wittes, director of the NCI Division of Cancer Treatment, concluding a letter to Stephen Sheingold, director of the HCFA Technology and Special Analysis Staff.

The letter, dated July 17, the day Rockefeller introduced his bill, is significant because it outlines the positions of NCI and HCFA at the outset of the negotiations and offers a glimpse of the tactics employed by NCI.

The complete text of the Wittes letter to Sheingold follows:

The meeting last week was useful in many ways. For us it clarified the criteria you plan to use for deciding whether HCFA should support particular research studies. For convenience, let me summarize my understanding of the criteria:

1. Covered studies should be "authoritative." By this you seem to mean that the study has considerable therapeutic promise for the individual patient. There might be prior evidence of efficacy in the medical literature. Alternatively, approval of the study by a responsible sponsoring organization (you suggested that the NCI might be one such organization) might suffice. The off-label use of drugs in studies would be no barrier to support, but the off-label use of

devices would prohibit support.

2. All agents used in a covered trial must have FDA approval for at least one indication.

3. A decision about coverage must be made trial by trial; there would be no blanket approvals according to broad criteria decided on in advance.

4. The trial would have to have relevance to the Medicare population.

5. Coverage for the medical care on a particular trial could not be in violation of the Medicare statute. For example, there could be no coverage for trials of oral agents. This apparently is an area admitting some flexibility. You indicated, for example, that if one element of a complex, multi-agent protocol were an oral agent, this might not bar coverage of the study; on the other hand, if the oral agent were the entire focus of the study, coverage would be unlikely.

In our subsequent discussion, it became clear that you were focused mostly on coverage of fairly large trials (Phase III, with perhaps some Phase II studies included as well). Drugs that were in Group C would not present a problem, nor would studies of combinations of drugs already approved by the FDA individually. You seemed to agree also that many Phase I studies might be eligible for coverage—for example, those with FDA-approved agents that are escalated above standard doses or that are used in combination with modulators of various sorts.

We appreciate that HCFA's thinking has come a long way over the past several years. When we started conversations with HCFA in the late 1980s, the attitude was simply that the agency did not cover investigational treatment. Group C drugs have been an exception for a while, but the essential thing here is that Group C is a non-investigational mechanism; the NCI makes drugs having substantial anticancer activity available for treatment use under this mechanism, with no particular expectation or intent that research information will be generated. My guess is that, if the FDA keeps its promise about expedited approval for virtually all cancer drugs, Group C will no longer be necessary. We are also pleased to see that the phase of the study would not, in itself, constitute a barrier to coverage.

On the other hand, as we already indicated to you, the exclusion of investigational drugs from consideration is an enormous problem for us. As strongly as HCFA may feel about the correctness of this exclusion, the NCI considers it bad medicine and bad public policy. It is not necessary to reiterate yet again why life-threatening diseases represent a different kind of medical problem from conditions that are less serious. We have also explained before why NCI-sponsored studies incorporating investigational agents are at least equivalent to standard state-of-the-art care. Without coverage of the medical care costs associated with investigational drug trials, therefore, patients are being deprived of access to promising new avenues of treatment, and totally unnecessary barriers are placed in the way of medical progress. HCFA's attitude would be easier to understand if you maintained that fear of escalating costs was, in fact, the main issue; this at least we could counter by pointing out that you are already paying for many of these costs already. But you stated repeatedly at this meeting (and previous ones) that the main issue within HCFA was philosophical and/or legal. Legal barriers can clearly be circumvented by a well-conceived demonstration project, and philosophical disagreements can probably be attenuated by further examination of the medical consequences of continued denials.

A very incomplete partnership with HCFA—for example, an arrangement that stipulated your review and approval of a relatively small portion of our portfolio, mostly including large randomized trials of already fairly well-established approaches—would not help us at all. In fact, in many ways it would be worse than the present circumstance, since it would create the administrative necessity for review of a large number of trials that you are already paying for. More importantly, in what would undoubtedly be a precedent-setting agreement, it would make the NCI complicitous in a tacit admission that therapy with drugs and devices not yet approved by the FDA is not real therapy at all. I urge you to have this point of view reconsidered within HCFA.

If you are willing to reconsider, however, then a demonstration project looking at the effects and consequences of a new policy of reimbursing medical care in cancer would be an exciting prospect, and we would love to collaborate with you in an endeavor of this kind. Perhaps such a project would strain the resources of your demonstration group, but surely this must be a very important issue for you to settle. The consequences of your investigational-drug exclusion go far beyond cancer and extend into other medical realms that people either are very concerned about already (e.g., AIDS) or will be in the future, as soon as innovative new therapies come along to

be tested clinically (e.g., degenerative diseases of the nervous system). How better to demonstrate HCFA's concern with the health of the American people than to take a bold step like this and evaluate its consequences as you go along! At our previous meeting in Dr. Vladeck's office, there was some skepticism that OMB would permit a demonstration project of this sort. Frankly, given that there is every reason to think that such a policy would actually be cost-neutral, I would imagine that a joint proposal from HCFA and NCI would receive a very sympathetic hearing in OMB and in the Congress. My bet is that the Congress would have no philosophical objections to a proposal providing Medicare-eligible Americans access to the clinical trials programs of the National Cancer Institute.

Let me know if you think there is any point in further discussion.

Regulatory Agencies

Cancer Groups Petition FDA To Ease Silicone Implant Rules

Eight cancer patient and physician organizations have filed a petition urging FDA to ease its restrictions on access to silicone gel breast implants for women with breast cancer.

In 1992, FDA restricted access to silicone gel implants to those women participating in a clinical trial. That policy is no longer necessary because recent studies have found no association between silicone gel implants and clinically relevant connective tissue disease, the cancer organizations said in the petition filed Sept. 19.

"This is an extremely important issue for women with breast cancer," Rosemary Locke, a breast cancer survivor and Washington representative for the Y-ME National Breast Cancer Organization, said in a statement. "After battling cancer, women should be free to decide personally whether to receive breast implants.

"For many of us, our quality of life depends on having this freedom to choose," Locke.

The limitation amounts to a "de facto" moratorium on patient access to the implants, because the clinical trials serve only a small fraction of women who get mastectomies for breast cancer, the groups said.

FDA should make the implants available to women with breast cancer or at high risk of the disease through an informed consent procedure, the groups said. This procedure would be similar to the system in place for saline breast implants.

House Resolution Introduced

Rep. David McIntosh (R-IN), chairman of the House Regulatory Affairs subcommittee, introduced a House resolution (HR 527) that calls on FDA to allow women to choose silicone gel implants in reconstructive surgery following a mastectomy.

"It's important that women have the right and freedom to choose whether they want implants and to select the product that will give them the best results," McIntosh said at a press conference held by the organizations on Sept. 19.

"Because of FDA's overly restrictive policies, however, women today don't have that freedom," McIntosh said. "The FDA should act swiftly in response to both the cancer community's petition and the resolution."

Cosponsors of the resolution were Reps. Barbara Vucanovich (R-NV), John Myers (R-IN), Sue Myrick (R-NC) and Bill Baker (R-CA).

"Clear Statement" Needed, Groups Say

Studies published in the scientific literature since 1992 have consistently shown no substantial risk of disease associated with silicone gel implants, the groups said in the petition.

Meanwhile, FDA has issued inconsistent statements to patients and physicians, the petition said.

"FDA has failed to respond clearly to the scientific evidence," said Susan Sherr, a breast cancer survivor and deputy director of the National Coalition for Cancer Survivorship. "Women with implants are left under a cloud of fear and uncertainty about their own health. It is time for FDA to alleviate our doubts by issuing a clear statement reflecting the hard science."

Allen Lichter, chairman of the American Society of Clinical Oncology's Public Issues Committee, said the agency's actions could affect the future availability of other medical devices.

"FDA's policies towards silicone breast implants have broad implications concerning the availability of medical products used in the treatment of women with breast cancer as well as other patients," Lichter

said. "If faced with such overly burdensome and non-scientifically based regulation, companies will not be willing to develop new, potentially life-saving devices."

More than a dozen epidemiological studies conducted since 1992 could not demonstrate a statistically significant causal connection, the petition said.

"These studies...collectively provide compelling evidence that silicone gel implants pose no recognized increased risk of connective tissue diseases and most classic auto-immune symptoms," according to the petition.

"In contrast, the 'research' which has been used to suggest a possible connection between the devices and connective-tissue disease is based largely on case reports or studies which lack the power to demonstrate causation because of the very small number of subjects involved," the petition said.

Groups Criticize FDA Analysis

The petition criticized an FDA review, published in the Annals of Internal Medicine earlier this year (B.G. Silverman, et al., Reported Complications of Silicone Gel Breast Implants: An Epidemiologic Review, 124 Ann. Inter. Med. 744 (1996).)

"The agency's primary criticism—the inability of most study designs to detect 'atypical' disorders or rare outcomes—does not detract from the validity of the studies' conclusions that there is no increased risk of systemic connective tissue disease associated with silicone implants," the petition said.

In addition, FDA's statements on the implants has been inconsistent, the petition said.

"The Annals article presents a grim picture of the uncertainty and sufficiency of current scientific information on silicone implants—especially with respect to rupture and breast cancer detection," the petition said.

"In contrast, FDA's recently published patient information booklet on breast implants is much more even-handed in characterizing the risk posed by rupture as a 'known' risk of uncertain magnitude."

The groups signing the petition were the American Cancer Society, American Society of Clinical Oncology, Cancer Care Inc., Candlelighters Childhood Cancer Foundation, National Alliance of Breast Cancer Organizations, National Coalition for Cancer Survivorship, Society of Surgical Oncology, US TOO International, and Y-ME National Breast Cancer Organization.

Professional Societies

ACCC Honors Clinton For Cancer Drug Initiatives

The Association of Community Cancer Centers has awarded its annual National Achievement Award to President Bill Clinton for efforts on behalf of cancer patients.

Assistant Secretary for Health Philip Lee accepted the award for Clinton at the ACCC national meeting in San Francisco on Sept. 20.

ACCC cited the Administration's FDA Cancer Drug Initiatives as the primary reason for naming Clinton to receive the award.

"The changes that the President announced at the White House in March are already speeding new therapies to cancer patients and hold the promise of more new therapies in the months and years ahead," ACCC President John Feldman said in presenting the award.

The association also noted the President's signing of the Kennedy-Kassebaum legislation to assure the portability of health insurance for persons with pre-existing conditions and the Administration's support of the NCI budget.

Publications

Book On Tobacco Industry Documents Available Online

A book based on the internal documents of the Brown & Williamson Tobacco Company has been made available on the World Wide Web.

The Cigarette Papers, the book by Stanton Glantz, professor of medicine at the University of California at San Francisco, and four co-authors publishes 8,000 pages of Brown & Williamson documents.

"The documents provide a unique view into how the tobacco industry has responded over the years to the ever-growing body of scientific evidence proving that its products kill," Glantz said in a statement.

"To this day, despite overwhelming scientific evidence and official government reports to the contrary, the tobacco industry denies that its products are addictive or that they cause any disease at all," Glantz said.

The book was published by the University of California Press last spring.

Includes Links to Documents

The papers reveal the company's research on the addictive nature of nicotine, the cancer causing effects of smoking and the dangers of various cigarette additives.

The documents also show the discrepancy between the industry's public position on the health effects of smoking and the results of its own research, Glantz said.

The Web version of the book includes "hypertext links" which contain connections to related documents.

The internet address to access the book with a subscription is http://www.library.ucsf.edu/tobacco/cigpapers. Without a subscription, readers may use the same address to access a limited version of the book for free. Subscription information may also be found on the website.

The papers themselves have been online since July 1995, when UCSF library staff put them on the World Wide Web to provide the widest possible access to the material.

Since that time, there have been more than 496,000 "hits" to the website.

Coauthors of The Cigarette Papers are Lisa Bero, Peter Hanauer and Deborah Barnes, of UCSF, and John Slade, of St. Peter's Medical Center and the Robert Wood Johnson Medical School in New Brunswick, NJ.

Foundations

Biomedical Foundation Formed To Help Support NIH Projects

The National Foundation for Biomedical Research has been incorporated in Maryland as a 501(c)(3) tax exempt foundation.

The NFBR was created by Congress to support special projects of NIH. The foundation was first authorized by Congress in 1990 and reauthorized in 1993.

The foundation plans to raise money from the private sector to fund adjunct activities within the mission of NIH.

"NFBR will likely concentrate on support of educational activities, making the public aware of the latest research findings which will improve the public health, and supporting fellowships at the graduate and senior level both at NIH and the extramural community," George Galasso, executive director of the foundation, said in a statement. Galasso retired last January as NIH associate director for extramural affairs.

"We are very pleased that the foundation is now up and running," NIH Director Harold Varmus said in a statement. "Public support of medical research has been generous, but the foundation will allow us to undertake some important projects and activities that we are not currently funding.

"We could, for example, enhance our research training activities, conduct some important public education programs, foster collaborations with academic institutions and industry, and improve the environment for conducting research on the NIH campus," Varmus said.

Paul Berg, Cahill Professor of Cancer Research and director of the Beckman Center, Stanford University School of Medicine, is the acting chairman of the foundation's Board of Directors.

"The foundation provides an opportunity for private citizens, private sector institutions, and foundations to enhance the current public investment in biomedical research," Berg said.

A search for a permanent chairman is underway.

Inquiries: National Foundation for Biomedical Research, tel: 301-402-5311, fax: 301-480-2752.

RFPs Available

RFP NCI-CM-77020-10

Title: **Development and production of parenteral dosage forms for clinical studies**

Deadline: Approximately Dec. 6

Description: Develop and produce pharmaceutically acceptable parenteral dosage forms of promising new agents with activity against cancer or the HIV virus. Certain agents selected by NCI, DCTDC, Cancer and AIDS operating committees will be assigned for development and production as parenteral products (primarily sterile freeze dried products). Batch sizes will range from small development batches (less than 100) to intermediate size batches to be used in phase I and II trials; however, escalation to large batch size (10-30,000 or more) for phase III/IV trials and Group C distribution is possible. It is estimated that the successful offerors must be prepared

to supply more than five-hundred thousand parenteral dosage units each year. The capability to develop and manufacture other pharmaceutical dosage form (i.e. large volume parenteral, sterile emulsions, micro-dispersions, etc.) is desirable but not essential. Data obtained from the contract will: 1) be used to support IND applications submitted by NCI to FDA, 2) be provided to other NCI contractors engaged in large scale dosage form manufacture and analytical evaluation of these dosage forms and 3) be provided to physicians, pharmacists, and nurses and other medical personnel handling these products in a clinical setting. It is anticipated that two cost-reimbursement, completion type contracts will be awarded for 3 years with two 1-year options. The offeror must be registered with FDA as a pharmaceutical manufacturing facility for sterile products.

Inquiries: Therese Dick, contracting officer, NCI RCB, TCS, 6120 Executive Blvd, EPS Rm 603, Bethesda, MD 20892-7220, tel: 301-496-8620, fax: 301-402-6699, e-mail: dick@rcb.nci.nih.gov

RFP NCI-CM-77027-30

Title: **Pathology & veterinary support services**

Deadline: Approximately Nov. 22

The NCI Division of Cancer Treatment, Diagnosis and Centers, Developmental Therapeutics Program, anticipates the award of one cost-reimbursement contract for a five-year period beginning on or about July 30, 1997. As a minimum requirement, the contractors must comply with FDA's current Good Laboratory Practice Regulations. The proposed awarded contract will be administrated on a work assignment managed basis. Work assignments will be issued under the proposed, level of effort, contract resulting from this solicitation. DTP is seeking organizations to perform a variety of pathology and veterinary services to support the DTP preclinical toxicology and pharmacology program for anticancer and anti-AIDS drug development. The organization should have the facilities and staff to carry out the requested efforts and the management expertise to respond to the diverse and changing needs of this project. Specifically, the work assignments to be issued will involve the following: operation of a repository to hold the pathology materials and raw data generated in past and future toxicology studies; storage of data on optical medium; performance of an independent verification (peer review) of the pathological findings by the study pathologist especially with respect to individual diagnoses, drug-relatedness, nomenclature and slide quality; provide a pathology support program to prepare blocks and slides and conduct histopathological evaluation of tissues; perform the site visits to conduct necropsies, slide preparation or to assist the project officer in project evaluation. This includes providing expertise in special techniques to assess cardiotoxicity, neurotoxicity, nephrotoxicity, etc.; storage, maintenance and shipment of government infusion equipment to other DTP contractors; development and implementation of new surgical or other procedures for drug administration or sampling; instruction in these procedures; or performance of these procedures in actual animal studies; conduct site visits to the DTP toxicology contractor laboratories to evaluate pathology laboratories, animal care programs or to investigate pathology or animal care problems; and to support the Toxicology and Pharmacology Branch toxicology efforts required through the preparation of study protocols, study monitoring and report evaluation. The principal investigator should be a board certified veterinary pathologist or veterinarian with at least three years of experience with similar programs.

Inquiries: Elsa Carlton, contract specialist, NCI RCB TCS, 6120 Executive Blvd., EPS RM 603, Bethesda, MD 20892-7220, tel: 301-496-8620.

In Brief

ACS Awards Three Grants; Bevers Directs Prevention

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are Francis Kohrs, assistant professor of family practice, University of Kentucky; Andrew Wolf, assistant professor of internal medicine, University of Virginia Health Sciences Center; and Jasit Ahluwalia, assistant professor of medicine and health policy, Emory University School of Medicine. Each will use the three-year, $90,000 award to study issues in cancer control. . . . **THERESE BEVERS** was named medical director for clinical cancer prevention at University of Texas M.D. Anderson Cancer Center. She will oversee a variety of programs including a corporate screening and prevention program, a screening and prevention program for persons at high risk of developing cancer, a breast cancer prevention trial and an ovarian cancer screening program. Bevers was medical director of the MediClinic Corp. . . . **MARGARET KRIPKE**, professor and chair of the Department of Immunology at M.D. Anderson Cancer Center, was selected for a fellowship in the Executive Leadership in Academic Medicine Program for Women. The one-year program, sponsored by the Institute for Women's Health at the Medical College of Pennsylvania and Hahnemann University, is designed to prepare women in academic medicine for senior leadership positions.