CANCER LETTER

P.O. Box 15189 WASHINGTON, D.C. 20003 TELEPHONE 202-543-7665

Vol. 20 No. 1 Jan. 7, 1994

(c) Copyright 1994 The Cancer Letter Inc. Price \$225 Per Year US, Canada \$250 Per Year Elsewhere

Breast Cancer Strategic Plan Underway Following HHS Secretary's Conference

Breast cancer activists are well on their way to getting what they asked for: the Clinton Administration has begun work on a strategic plan against the disease.

Last month, responding to a demand by the National Breast Cancer Coalition, HHS Secretary Donna Shalala held a conference where patient advocates, scientists, government officials, business executives and (Continued to page 2)

In Brief

President OK's Mammography Standards Publication, CDC State Grants Increase

PRESIDENT CLINTON last month signed an amendment to the 1992 Mammography Quality Standards Act authorizing FDA to immediately publish mammography standards in the Federal Register. The new regulations establish quality control standards and a certification system that mammography facilities will have to meet by Oct. 1, 1994. Nearly 60 percent of all mammography facilities are accredited by the American College of Radiology. ACR is expected to apply and receive FDA approval as an accrediting body. FDA plans to establish an advisory panel, the National Mammography Quality Assurance Advisory Committee, to help develop final mammography standards. . . . THE PRESIDENT also signed legislation last month allowing the Centers for Disease Control to increase grants to states for early detection of breast cancer. "Though we don't know what causes breast cancer, how to prevent it or cure it, we do know that broader access to mammograms will make an important medical, personal and economic difference due to increased early detection," Clinton said. . . . SUSAN BLUMENTHAL has been named deputy assistant secretary for women's health, a new post in the Public Health Service. Blumenthal is chief of the behavioral medicine and basic prevention research branch at the National Institute of Mental Health, HHS Assistant Secretary Philip Lee said the new position was created "to demonstrate the Administration's will to advance the health of women through research, education and service." . . . PETER JONES was named director of the Univ. of Southern California Norris Comprehensive Cancer Center. Jones, professor of biochemistry, molecular biology and urology, has been interim director since February 1993, when Brian Henderson left to become director of the Salk Institute. Jones received an Outstanding Investigator Grant from NCI in 1989.

Preliminary Action Plan Seeks Consumer Representation

... Page 5

Mammography Debate "Confused A Whole Generation"--Shalala

... Page 6

Avon To Support Community Programs

. . . Page 7

ODAC Recommends Taxol For Metastatic Breast Cancer

... Page 7

The Cancer Letter Offers FAX Delivery

... Page 8

RFPs Available

Page 8

Shalala Conference To Call For Coordination Of Programs

(Continued from page 1)

politicians offered their recommendations on a "national action plan against breast cancer."

The drafting of the plan has been the coalition's top priority for the past two years.

"We do not want this conference to produce another study," Shalala said to the 250 participants of the Dec. 14 meeting. "I specifically told the team that was pulling together the agenda that we did not need another long term commission report. Or another committee, or another committee task force."

Shalala said the issue had been studied enough and the purpose of the conference was to coordinate existing resources rather than to demand new ones. "We need to build this action plan on the wealth of knowledge that we already have," she said. "Our action plan has to coordinate programs and projects already in place on the federal, state and local level—and the effort of the advocacy groups and non-profits."

A summary of the recommendations of the conference is expected to be completed early this month and the final report is expected early next month.

However, on Dec. 15, a group of conference participants gathered to distill the hundreds of action points proposed the previous day into a dozen recommendations.

The group is still working on a complete summary of recommendations. However, The Cancer Letter has learned that the conference report will call for patient involvement in the planning and implementation of all breast cancer programs, including membership in study sections.

THE CANCER LETTER

Editor: Kirsten Boyd Goldberg
Associate Editor: Paul Goldberg
Founder & Contributing Editor: Jerry D. Boyd

P.O. Box 15189, Washington, D.C. 20003 Tel. (202) 543-7665 Fax: (202) 543-6879

Subscription \$225 per year North America, \$250 elsewhere. ISSN 0096-3917. Published 48 times a year by The Cancer Letter Inc., also publisher of The Clinical Cancer Letter. All rights reserved. None of the content of this publication may be reproduced, stored in a retrieval system, or transmitted in any form (electronic, mechanical, photocopying, facsimile, or otherwise) without prior written permission of the publisher. Violators risk criminal penalties and \$100,000 damages.

Also, the conference is expected to recommend creation of a breast cancer study section in translational research, call for the formation of a national breast cancer tissue bank, request a review of the reasonable pricing clause on the NIH Cooperative Research and Development Agreements and offer educational debt forgiveness as an incentive for young investigators to undertake breast cancer research.

The preliminary report appears on page 5.

Most participants described the conference as a "meeting of the minds." Clearly, scientists have reasons to be impressed by the coalition's track record: in fiscal 1993, NBCC's lobbying put \$210 million in new money into the Department of Defense breast cancer research program.

While breast cancer activists have demonstrated that they can bring in new funds, they have also brought about a redistribution of funds within NIH.

At the conference, several basic scientists, most notably NIH Director Harold Varmus and American Association for Cancer Research President Margaret Kripke warned that the trend toward targeting basic research would impede the advancement of science.

"It is tempting to think that we can predict diseaserelevant outcomes, especially when the work addresses a disease model," Varmus said in his address to the conference. "But in many cases, such predictions are wrong, even though the work itself may have great value in other spheres."

Conference participants appeared to have made a concerted effort to avoid getting bogged down in controversy over breast cancer screening guidelines for younger women. However, the conference is expected to recommend the drafting of new guidelines on breast cancer screening for women of all ages. Patient activists are also seeking a deal under which screening mammography would be available to women under 50 who are willing to make a 20 percent copayment.

In her address to the conference, Shalala admitted that the NCI 's about-face on guidelines did not go smoothly and has "probably confused a whole generation of women." However, Shalala stood by the President's plan and NCI statement that the benefits of mammography for younger women remain unproven (see story on page 6).

Visco: "No Chance" of Inaction

While the Administration clearly needs the support of breast cancer activists in the upcoming

debate over health care reform, securing that support is likely to involve some serious deal-making and the completion of a meaningful strategic plan.

Over its two years as a serious player on the Washington scene, the coalition has made a reputation of not taking no for an answer. "We are an advocacy group," the coalition's president Fran Visco said to The Cancer Letter. "While a scientist or a politician can say that something is not feasible, an advocate doesn't care."

Whenever the coalition's critics claim that its efforts serve to politicize science and create imbalance in the cancer program, the coalition's leaders readily agree that they are a political advocacy group for breast cancer and breast cancer only.

Following the conference, Visco said she was confident that the Administration would not ignore the recommendations of the conference.

"There is no chance of that," she said to The Cancer Letter. "The National Breast Cancer Coalition will not let this happen."

So far, the Administration has been sympathetic to NBCC. Campaigning for Presidency, Bill Clinton came out in support of the coalition's campaign to increase appropriations for breast cancer by \$300 million. After taking office, he appointed Visco to the President's Cancer Panel.

Last fall, when the coalition collected 2.6 million signatures on a petition demanding a strategic plan to combat breast cancer, Clinton received the petition at the White House and asked Shalala to hold a conference that would draft such a plan.

Visco said to The Cancer Letter that the coalition had in effect designed the format of the conference. The participants were divided into 10 smaller groups charged to devise strategy on the various aspects of breast cancer policy.

Each of these smaller panels was co-chaired by one scientist and one patient advocate, to give both groups "an even playing field," Visco said.

"I think one of the things we have already accomplished--and we don't need an action point on it--is that we found out sitting at the table together, consumers, private industry and the scientific community, that we have a great deal in common and we can accomplish so much more when we work together rather than at opposite ends," Visco said at the conference, describing the recommendations of the panel on basic research, which she cochaired with Frances Collins, head of the NIH Human Genome Project.

A Common Ground

In interviews with The Cancer Letter, participants of the conference representing a wide range of interests agreed that there is a common ground for a coordinated plan:

- "I saw indications that the Administration is recognizing that there is a need for additional activity in cancer, in this case, breast cancer," said Harmon Eyre, deputy executive vice president, medical affairs and research, at the American Cancer Society. "The areas of agreement, such as creation of a tissue bank, the funding issues, the need for additional training opportunities are more important than the controversy over mammography."
- "There was a meeting of the minds," said Ross McIntyre, chairman of Cancer and Leukemia Group B. "I didn't hear the activists say, 'Do this or else.' What I did hear was, 'You are telling us that you are having a difficult time attracting patients to your clinical trials. Maybe we can give you advice on how to structure your clinical trials in a way that would attract more patients.'

"I think the people I saw at the meeting would make things go more smoothly," McIntyre said.

- "I got an impression that there is going to be a real earnest effort to formulate a meaningful action plan," said Ellen Stovall, executive director of the National Coalition for Cancer Survivorship. "I hope that the recommendations that come out of a meeting of this magnitude will be used as a template for strategy against all cancers."
- "What I took away from this group is that these people really seemed to focus on what are the impediments to scientists doing good work," said Marc Lippman, director of Georgetown Univ. Vincent Lombardi Cancer Research Center.

Lippman's group, which focused on basic research, recommended that the Department of Defense continue its breast cancer research program.

"This was a totally unexpected gigantic shot in the arm, and it does not seem obvious from where this money will come again," Lippman said. "I think that if the Army wanted to do the same thing for prostate cancer, that wouldn't be a bad thing, either."

• "The program can move forward," said Elin Greenberg, chairman of the board of the Susan G. Komen Foundation, which is not a member of NBCC. "It needs to have someone say, 'It's going to start now.' And it's going to need the will of Congress and the will of the public to start now."

Greenberg said consensus has been building

among the groups represented at the conference. "I think initially everyone came from their own directions," Greenberg said. "But all of us have buried a mutual friend who died of breast cancer, and there is nothing more unifying than burying mutual friends."

• "Despite the diversity of backgrounds of the people present at the conference, there was a tremendous amount of agreement on the objectives of the conference and a tremendous sense of urgency to get on with the work," said **Don Hayden**, vice president and general manager of the Bristol-Myers Oncology Division. "Clearly, there is an opportunity for a partnership between the advocacy groups, private industry, the government and the academia. Until now, there has never been a concerted effort to bring all of these groups together to identify what can be done."

Hayden said communication with physicians is one of the areas where drug companies can help. "A communications capability is a part of our business," Hayden said. "Perhaps we can serve as a channel to make this information available."

Hayden said he was encouraged by the recommendation to reconsider the controversial NIH requirement that drugs developed through the Cooperative Research and Development Agreement program carry a "reasonable" price. The recommendation came from the panel on basic research.

"What it suggested, given the absence of industry participation in that section, was the level of concern that exists about impediments to bringing drugs through the discovery and development process," Hayden said.

• "I think the Secretary gets high marks for arranging this conference," said John Kovach, chairman of the department of oncology at Mayo Comprehensive Cancer Center.

"In our section on basic research there was a certain tension between one group that wanted to be sure not to impair the investigators' freedom in pursuing leads in whatever system, whereas other groups felt that there was ample opportunity to target some of the research.

"We certainly don't want to compromise basic research, but advances in molecular genetics now make it possible to look for clues regarding etiologic factors within breast cancer tissue of populations differing in their risk of developing the disease. There are opportunities to follow up leads that come from epidemiology studies."

Varmus: Caution on Targeted Research

In his remarks to the conference, Varmus drew on his own work to illustrate the hazards of targeting basic research to specific diseases.

"In the early 1970s, I began working with a retrovirus known to cause breast cancer in infected mice," Varmus said. "I hoped, and even presumed, that if we could understand the genetic mechanisms the virus uses to produce a mouse cancer, we would also learn something about human breast cancer, the disease that killed my mother and her mother.

"My laboratory devoted many years to characterizing this virus and its interactions with the genes of infected breast cells. About a dozen years ago, we were proud to have discovered a cellular gene that is switched on by the virus to initiate the cancerous process.

"The gene, however, does not appear to play any role in human breast cancer. Instead, the gene is essential for normal development of the brain—without it, animals are born without a midbrain and cerebellum—and therefore it is of enormous interest to neurobiologists," Varmus said.

Varmus's recommendations to the conference amounted to a plea for flexibility:

- "First, avoid strategies that would impair our ability to pursue the many promising avenues to a fundamental understanding of cancer.
- "Second, define the problem of breast cancer as broadly as possible. This will amplify the prospects for progress with any targeted funds, because it acknowledges the reality that many scientific issues impinge on breast cancer—and vice versa. This was the applauded approach taken by the Institute of Medicine committee that advised the Army last year on plans to spend its 1993 allocation for breast cancer research. [Varmus served on that committee.]
- "Third, attract the best minds—both seasoned and new investigators—to breast cancer research. To do this, it is not always necessary to convince scientists to change fields: often it is enough to induce them to think seriously about the implications of their work for breast cancer. In addition, we should recognize that cancer biology is now a sophisticated field of research, and we should encourage graduate and postdoctoral training programs in it.
- "Fourth, look carefully for impediments to the transfer of new technologies to industry and to the bedside. Novel mechanisms for fostering collaborations between government or academic scientists and the private sector may ultimately be

required to ensure that the findings of basic science are vigorously pursued.

• "Finally, lead the battles against specific diseases by discussion and persuasion, not by formation of committees and offices; in short, by inspiration, not direction."

A view similar to Varmus's was expressed by AACR president Kripke, who said the deliberations of the panel on basic research left her with a sense of frustration.

"Upon reflection, I believe the sense of frustration stems from a conflict between the desire we all share to see rapid progress that will prevent or cure breast cancer... and my conviction as a cancer researcher that there are no 'quick fixes' for the breast cancer problem with our current knowledge," Kripke wrote in a Dec. 28 letter to Visco.

"That is why I strongly support the view expressed by Dr. Varmus that support of untargeted basic biomedical research must be a high priority on the national agenda to address the problem of breast cancer," Kripke wrote. "I regret my inability to champion this idea effectively enough during the panel's deliberations to have it appear as a priority for basic research on breast cancer."

Speaking to reporters, Shalala said Varmus's address raised a philosophical question that can be debated into eternity.

"We are always going to have this discussion, and no conference is going to settle it," Shalala said. "Let me assure you, it's been going on since the beginning of science.

"What both [Varmus and Visco] are saying is exactly correct. Dr. Varmus is saying we must continue to do the basic research so we can catch up with all of you who want us to apply that research. And he is speaking from his shoes. Fran is speaking from her shoes, and luckily, I've put them both in the room today to talk it through," Shalala said.

"And what they will say is we need some of both."

Draft Action Plan: Consumer Participation In All Programs

Following is a preliminary list of recommendations of the HHS Secretary's Conference to Establish a National Action Plan on Breast Cancer.

Sources told The Cancer Letter that other recommendations could be added to this list in the next few days. "Just because something is not on

the list, it does not mean it will not be in the final draft," said a source involved in the drafting of the recommendations. The recommendations are being written by the co-chairs of the 10 conference panels that considered various aspects of the plan.

The final report of the conference is expected to be completed by February.

- 1. Mandate that all relevant programs have consumer participation.
- 2. Request Public Health Service exemption from OMB to permit it to conduct consumer research (research programs, clinical trials) through existing mechanisms.
- 3. Establish a National Resource Bank on breast cancer, to include registries, linked and available online.
- 4. Develop comprehensive plan for individuals carrying breast cancer susceptibility gene.
- 5. Establish a breast cancer study section in translational research to include consumer participation.
- 6. Request a review of the reasonable pricing clause currently in effect through NIH CRADA.
- 7. Assure the availability of ongoing breast cancer clinical trial information to health professionals and consumers, and make widely known and support the establishment of an information clearinghouse.
- 8. Make breast cancer services immediately available in all federally-funded clinics (ensuring that the VA and Indian Health Service are included).
- 9. Legislate debt forgiveness for MDs, PhDs, RNs, etc., who agree to two years of breast cancer research training and two years of breast cancer research.
- 10. Budget new FY95 dollars to extend post-doctoral training two more years for interested researchers (MDs, PhDs).
- 11. Clarify mammography screening guidelines (as well as clinical breast exam guidelines), using consumer appropriate language,
- a) Re-emphasizing that every woman over 50 should have a mammogram every year.
- b) Continue to study the feasibility of additional resources/needs to further clarify mammogram guidelines for women under 50.
- c) Require that women entering all federally funded hospitals and clinics be required to have clinical breast exams and mammograms if they have not had such services.
 - d) Federal agencies and professional societies

should develop consensus on mammography screening of asymptomatic women 50 and over and will engage in a dialogue to identify additional opportunities for consensus regarding women under 50.

12. Ensure that health care reform provides universal access to care and universal coverage that includes mammography screening, eliminates gaps in coverage, eliminates restrictions based on pre-existing conditions and covers participation in clinical trials.

Shalala: "We Tripped Over Ourselves" On Guidelines

HHS Secretary Donna Shalala acknowledged that controversy over NCI's recent decision to pull out of the 1989 consensus guidelines on breast cancer screening has "confused a whole generation of women."

"How can we do something about what happened in the report on mammography in which we tripped over ourselves and probably confused a whole generation of women on what the messages were?" Shalala said at the Dec. 14 conference to establish an action plan on breast cancer.

Asked by a reporter to elaborate on the remark, Shalala said: "I think everybody did the tripping.

"Everybody was predicting what the other group was going to say, and between the scientists and the civic organizations, everybody seemed to have said something slightly different. I think that we should in the future speak more clearly, more carefully. I'd rather take more time to make sure that we are speaking with one voice," she said.

Sources said to The Cancer Letter that Shalala is seeking some form of a consensus that can be presented to the public. At a meeting that followed the conference, Shalala formed a small group of breast cancer activists and scientists to delineate the areas of agreement.

"While we are sorting out how to deal with the controversy, at least we can eliminate uncertainty over what we can agree on," Amy Langer, executive director of the National Alliance of Breast Cancer Organizations, said to The Cancer Letter. Langer is one of the members of the ad hoc group that is expected to report to Shalala by mid-January.

Responding to a reporter's question, Shalala said she was not aware of any pressure by the Administration on NCI to change the mammography screening guidelines. Such pressure would be "improper and inappropriate," she said. "NCI and all of our Institutes have only one thing, and that is their integrity," Shalala said. "And they must act on that integrity. I can assure you that the scientists at this Institute were not motivated by saving anyone money."

Critics of the NCI's new stance of mammography have alleged that the Institute reversed its position on the mammography screening guidelines because widespread screening would be too costly under the Adminstration's proposed universal health care coverage. NCI officials say they based their decision exclusively on scientific evidence.

Defending the mammography benefits contained in the President's health care reform plan, Shalala said, "It looks now like scientific evidence is pretty clear that women who are over 50, plus women who are in high risk groups must get a mammogram once a year. In addition, any other woman who wants a mammogram, and any doctor who thinks it is advisable, should be able to get one.

"Otherwise, it's not as necessary, according to scientific evidence," Shalala said. "There is some concern by women that we ought to go beyond the science, but that's where the science is. And HHS cannot go beyond that and keep our integrity."

Shalala said she expected that the Human Genome Project would soon yield an alternative to mammography.

"We expect within a year, hopefully as a result of some of the efforts [at NIH] and some of our scientific efforts to have some other detecting strategies," Shalala said.

The Human Genome Project is expected to isolate the BRCA-1 gene on chromosome 17, a discovery that may help identify familial breast cancer, which accounts for a small number of cancers. However, speaking at Shalala's conference, NIH Director Harold Varmus said the implications of the discovery remain unclear.

"With the exception of genetic risk assessment with the BRCA-1 gene in certain families, it is still difficult to say exactly what needs to be done to cross the barriers to applicability—that is, to prevention, detection, and treatment," Varmus said.

Patient advocates say the Administration is placing undue emphasis on the BRCA-1 discovery.

"It's disturbing to me that the Administration is trying to focus on women with a predisposition to breast cancer in an attempt to narrow down the number of women to whom screening will be made available," NABCO's Langer said to The Cancer Letter. "In fact, fewer than 20 percent of women diagnosed with breast cancer have a known risk factor, such as a first degree relative with a history of the disease."

One possible solution currently discussed by patient advocates and the Administration is offering mammography screening to all women regardless of their risk of developing the disease, but requiring a 20 percent copayment for the procedure, sources said.

Shalala said NIH is unlikely to get a windfall of new funds to fight the disease. The purpose of the conference was to shape existing programs into a single action plan, she said.

"We have a lot of money now," Shalala said to reporters. "I don't know what decisions the President will make on the 1995 budget in relation to NIH. But there are other places where there are resources. In the CDC, the FDA. And it's not just HHS. The Veterans Administration, the Defense Department. There are lots of efforts going on, and there are efforts in the private sector, with private foundations."

Asked whether biomedical researchers could count on being pleasantly surprised by the 1995 budget, Shalala said, "I expect, no. Because we could never invest enough in biomedical research."

Avon To Fund Community Breast Cancer Programs

Avon Products Inc. has created the Avon Breast Health Access Fund to support new and established community-based breast cancer programs that improve women's access to education and early detection services.

The fund will be administered by the National Alliance of Breast Cancer Organizations and will distribute \$250,000 in March and additional money in September. The money is part of the \$5 million raised by Avon through ribbon pin sales.

Most grants will be in the range of \$5,000 to \$20,000, with several "supergrants" to be made available at the \$25,000 to \$75,000 level. Grants are for one year, and will not fund medical services directly. Avon sales representatives will be encouraged to volunteer to help grant recipients publicize their programs in their communities.

The application deadline is Jan. 31, 1994. Application forms may be requested by FAX to NABCO, 212/768-8828, or by writing to NABCO and the Avon Breast Health Access Fund, 9 West 57th St., New York, NY 10019.

ODAC Recommends Taxol For Metastatic Breast Cancer

FDA's Oncologic Drugs Advisory Committee recommended approval of Taxol for treatment of metastatic breast cancer in previously treated patients who have relapsed within six months after adjuvant therapy or failed to respond or relapsed after treatment for metastatic disease.

Prior therapy, the committee said, should have involved an anthracycline chemotherapy regimen.

The unanimous decision at the committee's Dec. 15 meeting was based on the results of five phase II trials presented by Bristol-Myers Squibb Co. and NCI's Treatment Referal Center program.

Response rates in the trials ranged from 22 percent with a median duration of five months in the NCI study to 57 percent, with a median duration of 5.8 months in a study by Memorial Sloan-Kettering Cancer Center.

Bristol presented data it said showed that patients' quality of life improved while taking Taxol (paclitaxel). FDA considered this information important to the committee's recommendation, since the agency said it expects to receive several New Drug Applications this year for drugs to treat advanced breast cancer.

"This will be precedent setting for breast cancer," FDA reviewer Grant Williams said.

The committee agreed with FDA that for drugs with moderate to severe toxicity for treatment of patients with metastatic breast cancer who have relapsed prior chemotherapy, "a response rate of 20-30 percent accompanied by sufficient evidence of relief of tumor specific symptoms may be sufficient basis for marketing approval."

Navelbine Recommended For Approval

The committee also voted unanimously to recommend Navelbine (vinorelbine tartrate, Burroughs Wellcome Co.) in combination with cisplatin for the treatment of advanced non-small cell lung cancer.

The committee voted 6-4 in favor of recommending that Navelbine be approved as a single agent for the treatment of unresectable advanced NSCLC in ambulatory patients.

In a European multicenter study with 612 patients, the median survival of the Nabelbine/cisplatin regimen was 40 weeks versus 31 weeks for those who received Nabelbine alone and 32 weeks for those who received vindesine plus cisplatin.

The Cancer Letter Begins Weekly Facsimile Delivery

The Cancer Letter Inc. has begun facsimile delivery of The Cancer Letter.

The Cancer Letter FAX, the new service, is an upgrade to the regular subscription. For an additional \$274 per year, subscribers can receive the complete text of The Cancer Letter via facsimile on the Wednesday of the week in which the newsletter is published.

The Cancer Letter FAX subscription upgrade also provides the monthly supplement, Cancer Economics, by facsimile.

The price is applicable to the continental U.S. only. Subscribers in other locations are encouraged to call or FAX for a price estimate.

"Many of our readers have told us that they need the news immediately. The Cancer Letter FAX is for them," said Kirsten Goldberg, editor and publisher of The Cancer Letter. "Our Canadian and overseas subscribers also may want to look into the service. Since foreign phone charges and FAX machines vary greatly, we will work with individual subscribers on pricing."

For additional information, contact The Cancer Letter: Tel. 202/543-7665 FAX: 202/543-6879.

E-mail us: The Cancer Letter welcomes electronic mail from readers, through CompuServe. Contact Editor Kirsten Goldberg, Washington, DC, ID# 73322,2044.

RFPs Available

Requests for proposals described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. Address requests for NCI RFPs to the individual named, Executive Plaza South room number shown, NCI, Bethesda, MD 20892. Proposals may be hand delivered to the Executive Plaza South Building, 6130 Executive Blvd., Rockville, MD.

RFP NCI-CB-40502-60

Title: Biomedical computing software services in support of the Cancer Diagnosis program

Deadline: Approximately Feb. 18

NCI is soliciting proposals from offerors with the capability to establish databases and tracking systems, assist in the development of forms for data collection, enter data from forms into the database using appropriate quality control measures, and prepare statistical summary reports using available statistical software for projects initiated by components of NCI. This is a 100% Small Business Set-Aside, Standard

Industrial Classification Code 7379, size standard \$14.5 million. Specific duties include: 1) Data Management Support for Research Projects, 2) Data Management Support for Tracking NCI Supported Resources, 3) Data Management Support for Ad Hoc System Analysis and Programming Services, 4) Use of Government Computer System, and, 5) Preparation of Reports. These duties require the application of existing software or the development of specialized software for data organization, maintenance, and analysis. Use of the system provided by the Div. of Computer Research and Technology located at the NIH campus in Bethesda, MD, is required.

Contract specialist: Barbara Birnman, Tel. 301/496-8611, RCB, Cancer Etiology Contracts Section, Executive Plaza South, Rm 620.

RFP NCI-CN-45585-32

Title: Centralized chemoprevention agent repository and drug regulatory support

Deadline: Approximately Feb. 14

The Chemoprevention Investigational Studies Branch of the NCI Div. of Cancer Prevention & Control is seeking a contractor who will provide a centralized source of agents for use in preclinical and clinical studies and to perform certain agent-related drug regulatory activities. The contractor shall: identify sources and procure bulk reagent chemical substances, receive agents from suppliers, store reagents, and provide administrative support as needed for dosage formulation, encapsulation, calendar packing and labeling, including shipment to final destination. The contractor shall also provide long term storage of sera.

Procurement assistant: Desiree Sylver-Foust, RCB, PCCS, Executive Plaza South Rm 635, Tel. 301/496-8603.

MAA NCI-CN-45580-63

Title: Early detection research network Deadline: Approximately Jan. 28

NCI's Div. of Cancer Prevention & Control is soliciting proposals for the Early Detection Research Network to increase the number of master agreement holders originally awarded under MAA No. NCI-CN-15340-04. Current MA holders for this program are not required to submit a proposal. The MAA is issued to solicit master agreement holders who have knowledge in establishing a biorepository of normal premalignant and malignant tissues by the collection and storage of tissues and associated fluids in order to identify potential cellular and molecular markers for early detection. The project will focus on tissues of the colon and rectum, lung, prostate and urinary bladder. There will be an associated database with demographic information, exposure to potential carcinogens and risk factors on the subjects from whom specimens have been obtained; and expertise in conducting cellular and molecular studies on these

Contract specialist: Tina Huyck, RCB, PCCS, Executive Plaza South Rm 635, Tel. 301/496-8603.