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Wyden Asks Bristol For Documentation To Prove That Taxol Price Is Not 'Gouging' Taxpayers

It is unlikely that Rep. Ron Wyden (D-OR) expects a van laden with documents on the pricing of taxol to pull up to the loading dock of Rayburn House Office Building.

Still, at his hearing on pricing of drugs produced through Cooperative Research and Development Agreements, the Congressman asked over and over whether the drug's manufacturer, Bristol-Myers Squibb, would be willing to turn over the information on the drug's price.

The company declined to provide the documents, citing its contract

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In Brief

NCI, EPA Award Contracts For Farmers Study To Iowa, North Carolina; NIAID's Hoth To Resign

EPIDEMIOLOGIC STUDY of farmers and their families was announced this week by NCI, the Environmental Protection Agency and the National Institute of Environmental Health Sciences. The joint Agricultural Health Study will identify and assess factors that may account for previously reported cancer excesses among farmers. About 100,000 farmers, spouses, and pesticide applicators will be involved in the $15 million, 10-year study. The research also will assess non-cancer health endpoints that may be associated with farm practices and lifestyles. Farmers tend to have higher than normal rates of leukemia, multiple myeloma, non-Hodgkin's lymphoma, and cancers of the brain, prostate, stomach, skin and lip. **Five-year contracts** were awarded to Univ. of Iowa College of Medicine and Survey Research Associates of Durham, NC. Iowa and North Carolina were chosen as field sites. NCI's **Michael Alavanja** and EPA's **Elaine Grose** will direct the study. . . . **DANIEL HOTH**, director of the Div. of AIDS, National Institute of Allergy & Infections Diseases, has announced plans to resign in a few months. Hoth, an oncologist, moved to NIAID from NCI in 1987 to lead the AIDS research effort through a phenomenal and controversial growth phase. Hoth said he has accomplished what he set out to do at NIH. He said he revealed his plans prior to finding a new job in order to avoid rumors while he was looking. NIAID will conduct a wide search for a replacement for the high-pressure job, NIAID Director Anthony Fauci said. . . . **KENNETH FOON** was named director of the Univ. of Kentucky's Lucille Parker Markey Cancer Center and professor of medicine, UK College of Medicine. Foon was associate director for clinical research, Green Cancer Center, Scripps Clinic and Research Foundation. From 1981-85, he was a section head in NCI's Biological Response Modifiers Program.

Wyden To Bristol: If NCI Did 'Heavy Lifting' On Taxol, Is Price Fair?

(Continued from page 1)

with NIH, which does not call for an audit of its books.

Wyden's concern: the government has no way of judging whether its collaborators in technology-transfer agreements have lived up to their contractual obligations to price CRADA drugs fairly.

His frustration: representatives of the drug industry as well as government officials have stated repeatedly that regulatory scrutiny of prices of CRADA drugs would deter companies from taking part in such deals.

"American consumers who have funded drug development through the gift of corporate tax credits and federal lab research should not be bludgeoned by price gouging," Wyden said at a Jan. 25 hearing of his Subcommittee on Regulation, Business Opportunities and Energy.

"Americans should not be held political hostage to drug companies who threaten to walk away from cures if Congress requires reasonable price justification," said Wyden, the subcommitte's chairman.

Wyden's accusations, his prosecutorial tone and his liberal use of the word "gouging," appeared to cause discomfort in several of his witnesses.

"I think it's very unfortunate that the word 'gouging' is being used here," said Bruce Chabner, Director of NCI's Div. of Cancer Treatment. "I don't think there is any evidence that there is gouging going on."

Another witness, Reid Adler, Director of the NIH Office of Technology Transfer, expressed a similar sentiment.

"I appreciate very much the chance to work with you and your staff on these issues, but these are not simple issues, and acting imprudently may be ultimately to the detriment of technology transfer," Adler said to Wyden.

Mandate to Provoke

While Wyden's critics at NIH and in the industry frequently wonder out loud whether the Congressman is at all interested in establishing the truth, his allies on Capitol Hill counter that a legislator's mandate includes the mandate to provoke.

"Dr. Chabner, I don't know if you are referring to me," said Wyden, responding to the NCI official's objection to the word "gouging."

"The issue here is whether it's acceptable to keep the public in the dark on pricing issues when the public has done so much of the heavy lifting to get these drugs to market.

"It may well be that the price of this drug is justified, but until we get some accurate information with respect to costs and the potential for profit, I don't see how you can come to this committee and say that the public is being treated fairly. You don't know that."

The "reasonable" pricing clause was added to the standard language of the NIH CRADAs in 1989, as a result of political pressure over the high price of AZT.

According to Adler, the provision was intentionally broad. The specifics were to be worked out later. However, the speed with which Bristol developed taxol created something of a bureaucrat's nightmare.

The product hit the market before NIH was able to arrive at uniform criteria for the assessment of the prices of such drugs.

Last month, the advisory committee to the NIH Director was asked to provide guidance on the NIH role in assessment of pricing of CRADA drugs (**Cancer Economics**, December 1992).

"Mr. Adler, we've got to move," said Wyden, responding to Adler's remark that drug pricing is not a simple issue.

"We don't want to move imprudently, but we've got to move. We've asked to work with you 14 months ago, and I am not convinced that there has been a lot of progress made," Wyden said.

Fear In The Industry

"NCI believes that the pricing strategy announced by Bristol meets any reasonable test of fairness," said Chabner, whose division had to come up with its own approach for judging the fairness of the drug's price.

"We chose to measure the fairness and reasonableness of taxol's price by comparison with other products marketed for the same indication," he said.

THE CANCER LETTER

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NCI requested that the company set the price below the median of other recently approved cancer drugs.

As a result, the drug's weighted average price, $695, is close to the price of cisplatin. Its average wholesale price, $986, is below the price of carboplatin (**The Cancer Letter**, Jan. 8).

Chabner said the production costs of taxol are at least 10 times higher than those of cisplatin.

According to his estimate, the production cost of taxol account for about 25 to 35% of its selling price. By comparison, the production cost of cisplatin accounts for 5 to 10% of that drug's selling price.

Considering this comparison of production costs, Bristol's price for taxol indicates that the company did not seek to maximize its gains, Chabner said.

In recent months, the prospect of a stricter pricing language being inserted in a standard CRADA has had a chilling effect on the companies' willingness to pursue such agreements, Chabner said.

According to Chabner, two companies have refused to accept fair pricing clauses for their drugs. A third discontinued its collaboration with NCI, citing fears of potential price restraints. A fourth suspended negotiations for two cancer drugs pending the outcome of the taxol pricing hearings.

"Other companies have simply refused to become involved with NCI in early drug development, and although the reasons were not stated openly, fears about price control play a significant role," Chabner said.

"NCI has no doubt that companies will not accept the risks of investing large sums in the development of a government product if their freedom to realize a profit could be restricted.

"These companies are not willing to put their corporate fate in the hands of a government-appointed committee of experts. There are less risky ways for companies to make a profit," he said.

Bristol: The Price Is Fair

According to Congressional sources, Wyden had been under considerable pressure to cancel the CRADA drug pricing hearing, or at least to moderate his stance.

Sources said Wyden was contacted on behalf of the Senate Labor and Human Resources Committee as well as by Rep. Rosa DeLauro (D-CT). Sen. Bennett Johnson (D-LA) wrote a letter to NIH Director Bernadine Healy, complimenting Bristol and NCI on the success of their "Manhattan-like" project to produce taxol. Similarly, the Oregon Society of Medical Oncology and the National Coalition for Cancer Survivorship submitted letters cautioning Wyden against weakening the CRADA program.

At the hearing, Wyden cited a 1991 letter from Samuel Broder, in which the NCI Director wrote that taxol was "discovered and developed within the NCI's comprehensive anticancer drug development program."

The letter, according to Wyden, indicated that the taxpayer-funded NCI did most of the "heavy lifting" to produce the drug, while Bristol may have done little more than put the drug in a "pretty package."

"Do you disagree with that statement that Dr. Broder made?" Wyden asked Zola Horovitz, Bristol's vice president, business development and planning.

"Certainly, NCI did a fantastic job of bringing taxol at least to a point where there was some enthusiasm to go further," Horovitz said. "However, they stalled. They stalled because they weren't able to get material. They weren't able to get enough taxol to prove whether it was a unique compound.

"There had to be a large capital investment to scale up so we could produce kilograms, not just grams, of material," he said. Along with complying with the good manufacturing practices standards, obtaining regulatory approvals and engaging in marketing, the company needed to make a fair return on its investment, Horovitz said.

"A company needs a return on its investment not only for itself, but to continue to have a basis of research and development expertise, so that when something like taxol comes along, there is an infrastructure that is immediately put to work so that the drug could be developed," he said.

While NCI spent $32 million to develop the drug, Bristol spent well over the minimum of $114 million it was required to invest under the CRADA, Horovitz said.

Asked by Wyden to break down the costs, Horovitz declined.

"You note that the price [finances] the company's ongoing research," Wyden said. "Now, that's done for defense contractors as well. The government purchases a number of their goods on a cost-plus basis. Is your company willing to look at that kind of cost-plus pricing?"

HOROVITZ: "I can't comment on that. It's never been discussed in my company."

WYDEN: "Has anything been discussed in your company other than stonewalling the public? Because there are a number of alternatives, all of which are worth debating. But your only position is that the American people don't get to know. We charge them, they pay the price; if they don't pay the price, they get sick. Is there any kind of alternatives that you might be willing to look at?"

HOROVITZ: "We take the position that the price of taxol is fair, based on the CRADA. Taxol would ordinarily have commanded a premium price. It is unique, it comes in for possibly life saving, or life prolonging, activity, and normally, another company not working with the government would have priced it at a premium to what was there already."

The Alternatives

Wyden's list of potential approaches to determining the fairness of pricing of CRADA drugs follows:

▶Before entering into a CRADA, the drug price would be negotiated based on a formula that estimates the cost and profits of the new drug.

▶The NIH could commission an informal panel of experts to assess the price proposed by a company. The panel would work on a confidential basis, but with access to proprietary cost and investment data held by the company.

▶On a more formal basis, NIH or HHS could form a permanent secretariat on pricing, including expertise in appropriate areas of analysis. The secretariat would give a yea or nay as to whether the minimal threshold for fair and reasonable pricing specified in the CRADA has been met.

▶Paralleling arrangements used for defense contractors, agreements could include stipulations for cost-plus charging, allowing the manufacturer to recover investment and a guaranteed rate of return.

▶The Industrial Biotechnology Association suggests that rather than focusing on fair pricing arrangements, a richer profit sharing arrangement for the federal labs should be agreed to by the NIH and its industry partners.

"The Chair is not wedded to any one of these proposals, but I want to note that the drug companies seem to be against every one of them," Wyden said. "I believe strongly that this issue is too important to get lost in the Congressional fog."

Bristol-Myers No Longer Needs Yew From Public Lands, Will Use Needles

Bristol-Myers Squibb announced that it would not be harvesting yew trees on public lands during the 1993 season that begins this spring.

The announcement was made by Zola Horovitz, vice president, business development and planning, at a hearing of the House Small Business Committee's Subcommittee on Regulation, Business Opportunities and Energy.

Federal lands yielded about half of the bark used by the company to produce taxol.

According to company sources, Bristol no longer needs to harvest the yew trees on public land because it has constructed a manufacturing facility that will use a semisynthetic process to extract taxol from the trees' needles.

Environmental Impact Statement Released

The U.S. Forest Service, the Bureau of Land Management, and the Food and Drug Administration released a draft environmental impact statement for the Pacific yew last week.

The statement describes different ways of harvesting "anywhere from one million to 30 million dry pounds of yew bark over five years."

The Forest Service and the BLM will use the impact statement to decide on yew harvesting programs for national forests and for BLM districts.

The agencies' preferred harvesting plan would allow cutting of 100% of the yew in timber sale units (clearcutting) and 50% of the yew in partial-cut sale units (partial cutting) and non-sale areas (areas in a national forest or BLM district where no timber sales are scheduled, but where yew harvest is allowed).

This method would provide three to five million yew trees available for harvest on 1 to 2 million acres over the next five years, and yield 15 to 23 million pounds of dry bark. It would allow for yew to regenerate and provide for "moderate protection" of the ecosystem in the yew harvest areas, the agencies said.

Comments on the draft statement will be received until March 15 by Sally Campbell, Pacific Yew EIS Team Leader, USDA Forest Service, Pacific Northwest Region, 333 SW First Ave., PO Box 3623, Portland, OR 97208, phone 503/326-7755.

Healy Had Boxes Packed When Word Came That She Could Stay

NIH Director Bernadine Healy had packed her office to return to Cleveland on Jan. 15, only to be notified early last week (past **The Cancer Letter's** presstime) that President Bush, with only hours left in office, had reversed himself and decided not to accept her resignation.

Bush last week agreed to a request from the Clinton transition team to keep about 40 Bush appointees--including Healy and FDA Commissioner David Kessler--in their positions. The former president asked about 650 appointees to resign on Jan. 20.

Healy's staff expressed relief at Bush's last-minute reversal. "She had taken the resignation seriously and

had packed everything," Healy spokesman Anita Greene said to **The Cancer Letter.** "It would have been a shame for her to leave so suddenly. She is back now on her usual schedule."

The Clinton Administration has not said whether the new President would ask Healy and Kessler to remain in their jobs permanently.

"I certainly think Dr. Healy would accept that if President Clinton decides," Greene said.

Shalala Confirmed At HHS Secretary

In other developments in Washington last week:

▶The Senate confirmed Donna Shalala as Secretary of the Dept. of Health & Human Services.

▶President Clinton moved last week to lift the former Administration's ban on research using fetal tissue, and signed executive orders removing the Reagan-Bush era restriction on abortion counseling at federally-funded clinics.

▶Clinton appointed his wife, Hillary Rodham Clinton, to head a committee to develop plans for health care reform.

FDA Requires Safety Data On Saline Breast, Silicone Testicular Implants

Manufacturers planning to continue marketing saline implants will be required to submit Premarket Approval Applications demonstrating the safety and effectiveness of these devices as a condition of keeping them on the market, the Food and Drug Administration announced this month.

The proposal, published in the Jan. 8 "Federal Register," requires manufacturers to submit evidence of the safety and effectiveness of saline implants to keep them on the market.

"We are proposing that manufacturers collect and present all relevant data in support of the safety and efficacy of these implants," Kessler said. "In the meantime, women should carefully read the patient information sheets that accompany the implants and discuss the risks with their doctors before undergoing implant surgery."

In 1991, FDA required manufacturers of silicone breast implants to submit safety and efficacy data.

Among the issues to be addressed by manufacturers, FDA said, are infection, capsular contracture and interference with mammography. The implants can also rupture and rapidly deflate, requiring further surgery, FDA said. The agency said it has received "numerous reports" of rupture, leakage and deflation associated with saline implants.

Although the safety and effectiveness of the saline implants have not been proven, leakage or rupture would release only salt water, which is not thought to be harmful, FDA said. Nevertheless, like silicone gel-filled implants, saline implants have a silicone rubber envelope and therefore may not be entirely without risk, the agency said.

Also Seeking Data On Testicular Implants

FDA this month also proposed that manufacturers of testicular implants be required to submit scientific data to show that these products are safe and effective.

Testicular implants, which are made of silicone, are intended for cosmetic purposes. They are commonly used to correct congenital abnormalities in infants and toddlers who are born without one or both testicles, FDA said. They are also used in men who have had one or both testicles removed because of cancer or other diseases or through injury. An estimated 1,000 are implanted yearly.

"We need to make sure these devices are safe and effective," FDA Commissioner David Kessler said. "Therefore, we are proposing that companies submit data, just as we did for breast implants."

These implants were on the market prior to the Medical Device Amendments of 1976, which gave FDA regulatory authority over devices. Like other pre-amendment devices, testicular implants were allowed, under the law, to remain on the market with the understanding that FDA would later require manufacturers to demonstrate their safety and effectiveness.

Although some information on the risks and benefits of testicular implants is available, there is not enough scientific evidence to determine whether the benefits outweigh the risks, FDA said.

The agency's safety concerns regarding the implants involve the lack of adequate information on:

--The incidence of leakage, hardening of surrounding tissue and rupture. The silicone gel in these implants may leak into adjacent tissue, causing problems similar to those seen with breast implants.

--The long-term effectiveness of the implants. Reported problems of unknown frequency and origin include infection, pain, discomfort, erosion of the device and its migration to other parts of the scrotum and abdomen. It is also not known how often these complications require corrective surgery.

--The potential for long-term adverse effects, such as cancer, immune-related connective tissue disorders and reproductive problems. This type of information is particularly important because many of the implant users are young, FDA said.

--The immediate and long-term psychological benefits of the implants, such as patient satisfaction and improved self-image and psychological outlook.

If FDA's proposal, published in the Jan. 13 "Federal Register," is made final, manufacturers planning to continue marketing testicular implants will be required to submit a Premarket Approval Application demonstrating the safety and effectiveness of these products as a condition for keeping them on the market.

FDA also plans to call soon for safety and effectiveness data on inflatable penile implants, heart bypass blood pumps and cranial electrotherapy stimulators.

Publishes Rules To Speed Drug Approval

In another development at FDA, the agency has published new rules to speed the approval of drugs for patients with serious or life-threatening illnesses, such as AIDS, cancer and Alzheimer's disease.

These rules establish procedures for FDA to approve a drug based on "surrogate endpoints" or markers. They apply when the drug provides a meaningful benefit over currently available therapies. Such endpoints could include laboratory tests or physical signs that do not in themselves constitute a clinical effect but that are judged by qualified scientists to be likely to correspond to real benefits to the patient.

Use of surrogate endpoints for measurement of drug efficacy permits approval earlier than if traditional endpoints--such as relief of disease symptoms or prevention of disability and death from the disease--are used, FDA said.

The impetus for using surrogate endpoints came from NIH officials and advocates for patients with cancer and AIDS who had been long been frustrated by FDA requirements for approval of new therapies.

The new rules provide for therapies to be approved as soon as safety and effectiveness, based on surrogate endpoints, can be reasonably established, FDA said. The drug's sponsor will be required to agree to continue or conduct postmarketing human studies to confirm that the drug's effect on the surrogate endpoint is an indicator of its clinical effectiveness.

The anti-AIDS drug zalcitabine (ddC) was approved last June uding a model of this process.

FDA said accelerated approval can also be used when the agency determines that a drug, judged to be effective for the treatment of a disease, can be used safely only under a restricted distribution plan.

"The new rules will help streamline the drug development and review process without sacrificing good science and rigorous FDA oversight," Kessler said. "While drug approval will be accomplished faster, these drugs and biological products must still meet safety and effectiveness standards required by law."

The new procedures also allow for a streamlined withdrawal process if the postmarketing studies do not verify the drug's clinical benefit, if there is new evidence that the drug product is not shown to be safe and effective, or if other specified circumstances arise that necessitate expeditious withdrawal of the drug or biologic.

Final Food Labeling Regulations

HHS last month announced agreement on final regulations to provide for consistent, scientifically based labeling for nearly all processed foods.

Under the agreement, consumers will find a single nutrition label format on virtually all processed foods. Foods regulated by FDA will be required to provide the label under the HHS rules; processed foods regulated by the U.S. Dept. of Agriculture will bear the same nutrition label.

The new labels could appear on some foods by the middle of this year. They will be required under the final regulations in 1994.

In one key change, the nutrition panel on the label will have a new format. The panel will include not only nutrient contents of the specific food product, but also information on the relationship of the ingredients to an average daily caloric intake.

Other new provisions include consistency in the presentation of serving sizes, definitions for nine core descriptive terms such as "light," "low fat," "high fiber," and provisions for health claims which may be made by prepared foods containing specific nutrients.

Permitted health claims are those that cite relationships between calcium and osteoporosis; sodium and hypertension; fat and cancer; fat and heart disease; fiber-containing foods and cancer; fiber-containing foods and heart disease; and foods such as fruits, vegetables and whole grains that are high in antioxidant vitamins (including vitamin C) and cancer.

Asks Fertility Drug Makers To Add Risk Info

FDA is requesting that drug firms add the potential risk of ovarian cancer to the adverse drug reaction section of fertility drug labels because recent data and studies indicate that such drugs may have a stronger association with the disease than previously believed. However, this labeling change is being made only in one section of the label without a conclusion about causality; no change is being made in prescribing directions.

At least 12.5 million courses of fertility drugs have been prescribed since the drugs have been marketed. Six cases of ovarian cancer have been reported to FDA as being associated with these drugs, the agency said.

In addition to these reports received by FDA, a recent article published in the "American Journal of Epidemiology" suggests a possible relationship between use of fertility-enhancing drugs and ovarian cancer.

According to FDA, the article provides no information about the fertility drugs prescribed, reasons for the infertility, tumor size or stage of disease at diagnosis, making it difficult to interpret the findings. A 1987 article in the same publication found no association between these drugs and ovarian cancer.

The article combines data from a number of studies in which women with ovarian cancer were compared to women without ovarian cancer. The report also looks at a number of other factors, such as the number of pregnancies, the use of oral contraceptives and breast feeding, all of which were found to protect against ovarian cancer.

Only three of the 12 studies contained data about the use of fertility drugs and the risk of ovarian cancer.

The report concluded that, in women who had experienced one pregnancy, the use of fertility drugs was not appreciably related to ovarian cancer. However, it did find a risk of ovarian cancer among women who had never been pregnant, had been diagnosed as infertile and had been treated with fertility drugs.

Komen Foundation Offers Grants For Fellowships, Education, Screening

The Susan G. Komen Breast Cancer Foundation seeks applicants with MD or PhD degrees for is postdoctoral fellowship grants. Application deadline is March 20.

The three-year program offers an experienced breast cancer investigator the opportunity to select a fellow to train in his/her laboratory. The stipend is $35,000 per year. No indirect costs are allowed.

The foundation also offers education and screening project grants for innovative projects in breast cancer education, screening and early detection, education concerning breast cancer treatment, and support programs. Application deadline is March 20.

Applications and information may be obtained from the Susan G. Komen Breast Cancer Foundation, 5005 LBJ Freeway, Suite 370, Dallas, TX 75244, phone 214/450-1777, fax 214/450-1710.

RFAs Available

RFA AI-93-04

Title: **National cooperative vaccine development groups for Acquired Immunodeficiency Syndrome**

Letter of Intent Receipt Date: Feb. 26

Application Receipt Date: April 22

The National Institute of Allergy and Infectious Diseases announces the availability of an RFA for funding of the National Cooperative Vaccine Development Groups for AIDS (NCVDGs). It is the purpose of this RFA to invite applications aimed at the conceptualization, development, and evaluation of vaccines designed to effectively prevent AIDS. This research should stress creative, novel approaches to the development of effective AIDS vaccines and should have the capacity to rapidly translate these concepts into improved candidate vaccines.

The NCVDG can be focused in one or more vaccine areas and may pursue studies of HIV-based vaccines or studies of relevant model viruses (e.g., the Simian Immunodeficiency Viruses (SIV)). The Group must possess the expertise necessary to conduct adequate evaluation of the proposed approach(s) in preclinical situations. Further studies required for development of identified new vaccines to clinical trial may be a part of the work proposed by an applicant. Alternatively, an NCVDG may request that the NIAID conduct these developmental tasks using contracts now in place (SIV Evaluation Units, Chimpanzee Access via Interagency Agreement with the National Cancer Institute, and AIDS Resources and Reagents Contract). An NCVDG must form a cohesive team, and is encouraged to include scientists from a combination of academic, non-profit research, and commercial organizations. Applications which include research projects from the private sector (e.g., pharmaceutical, chemical, or biotechnological companies) are encouraged.

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private. Applications from minority individuals and women are encouraged.

Awards will be made as cooperative agreements (U01s). Applications with first-year budgets in excess of $1,000,000 total (direct and indirect) should contact the program staff for written approval.

NIAID anticipates making four to eight awards, based on highest program priorities, for project periods of up to four years. NIAID has set aside $4.2 million total (direct and indirect) costs for first year funding.

The NCVDGs will provide assistance to talented scientists to interact, with NIAID support, as a unit to carry out the research essential to development of safe and effective AIDS vaccines. NIAID has awarded 13 NCVDGs; two have already expired and four are expiring in fiscal 1993. This initiative will maintain the total NCVDG network at 10 groups.

Applications for funding as an NCVDG should stress creative, novel approaches to the development of effective AIDS vaccines. Applications for research on novel vaccine vectors, immunogen processing and presentation, mucosal immunity, and creative methods to enhance immunogenicity are encouraged.

Inquiries may be directed to: Dr. Alan Schultz, Vaccine Research and Development Branch, BRDP, NIAID, Solar Bldg Rm 2B-01, Bethesda, MD 20892, phone 301/496-8200.

RFA CA-93-17
Title: **Breast cancer education summits**
Application Receipt Date: May 7

The purpose of this RFA is to provide support for the planning, implementation, and evaluation of Breast Cancer Education Summits. The summits are intended to convey information and educational materials about breast cancer to community organizations and businesses and to stimulate these organizations and businesses to establish breast cancer education and screening programs in the community. The aim is to motivate these organizations and businesses to reach women in the community, to inform them about the risks of breast cancer and the methods to achieve early detection, and how to seek the best treatment. The summits are intended ultimately to reach all women in the community, placing special emphasis on women at high risk of breast cancer and populations that are medically underserved and/or hard-to-reach. Special attention should be given to encouraging the establishment of readily available, low-cost, high-quality mammograms for underserved populations, such as at the worksite, or off-site with accommodations made for time and cost considerations.

These regional summits should follow the model of the national and regional summits, including educational sessions and panel discussions featuring successful community-based programs and worksite screening efforts.

It is expected that grants awarded under this RFA will be used to partially fund planning, implementation and evaluation of the summit conference. The summits will be sponsored by the National Cancer Institute and non-profit organizations. Centers are encouraged to obtain additional funding from local sources for any costs not met by this grant.

Eligibility is limited to institutions with NCI P30 Cancer Center Support Grants, institutions with NCI P20 planning grants for prospective cancer centers and other institutions with a broad base of grant-supported research in basic, clinical and prevention and control science. NCI-designated comprehensive cancer centers that received awards, or co-hosted summits with awardees in 1992 from applications in response to RFA CA-91-27 are not eligible to apply under this RFA, but are encouraged to apply for RFA CA-93-18, Breast Cancer Education Mini-Summits.

The mechanism to support these summits will be the conference grant award (R13). The total project period may not exceed one year. No more than $20,000 in direct costs will be awarded to a single institution. The anticipated award date is July 30.

Approximately $140,000 in total costs will be committed to fund applications. It is anticipated that seven to eight awards will be made.

The institutions that receive grants will be asked to coordinate their meeting dates to ensure that the summits are well-spaced within the time frame of October 1993 to July 1994.

Applications will be selected for funding based primarily on their technical merit. However, location of the cancer centers will also be considered to assure balanced geographic distribution.

Inquiries may be directed to: Linda Muul, Special Assistant to OCC Program Director, Cancer Centers Branch, Div. of Cancer Biology, Diagnosis and Centers, NCI, Executive Plaza North Rm 308, Bethesda, MD 20892, phone 301/496-8531.

RFA CA-93-18
Title: **Breast cancer education mini-summits**
Application Receipt Date: May 7

The purpose of this RFA is to provide support for the planning, implementation, and evaluation of Breast Cancer Education Mini-Summits. These mini-summits are intended as follow-up to other breast cancer education programs designed to educate and encourage leaders of community organizations, businesses, and/or health organizations to establish breast cancer education screening programs, such as the Breast Cancer Education Summits funded under RFA CA-91-27. The present RFA provides applicant institutions opportunities to develop and conduct focused programs that are tailored to the needs of more defined target audiences, as opposed to the large-scale summits that will be funded under a different RFA and will provide a comprehensive introduction to screening and education programs aimed at a broad audience.

The mini-summits are to provide information about the importance of early detection of breast cancer and practical experience, advice, and skill-building in the development and operation of education and screening programs and on effectively reaching women with these services. They are also to provide information on ways in which women can obtain information on state-of-the-art treatment and on referral to treatment services if a problem is found in screening. Both education and workshop sessions should be included in the program. Attention should be given to defining the target audience, determining their needs and obstacles to establishing education and screening programs and to utilization of these services (e.g., cultural, social, economic concerns), and to developing a program that addresses these needs and obstacles.

The grants awarded under this RFA will be used to partially fund planning, implementation, and evaluation of the mini-summit. The mini-summits will be sponsored by NCI and other non-profit organizations. Centers are encouraged to obtain additional funding from local sources for any costs not met by this grant.

Eligibility is limited to institutions with NCI P30 Cancer Center Support Grants, institutions with NCI P20 planning grants for prospective cancer centers, and other institutions with a broad base of grant-supported research in basic, clinical and prevention and control science. Applicants must show clear evidence of prior experience in planning and conducting major breast cancer education programs within the last three years for one or more of the audiences that are the focus of this RFA.

Eligible institutions may apply for a grant under both this RFA and RFA CA-93-17 to host a large-scale summit.

The mechanism to support these summits will be the conference grant award (R13). The total project period may not exceed one year. No more than $7,500 in direct costs will be awarded to a single institution. The anticipated award date is July 30.

Approximately $60,000 in total costs will be committed to fund applications submitted in response to this RFA. It is anticipated that seven to eight awards will be made.

Inquiries may be directed to: Linda Muul, Special Assistant to OCC Program Director, Cancer Centers Branch, Div. of Cancer Biology, Diagnosis and Centers, NCI, Executive Plaza North Rm 308, Bethesda, MD 20892, phone 301/496-8531.