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When Screening Mammography Meets Health Care Reform, Opinions Proliferate

When the House Subcommittee on Health and the Environment attempted to examine the controversy over screening mammography last week, the number of views presented appeared to be equal to the number of witnesses.

The Jan. 26 hearing gave Congress its first opportunity to consider screening mammography in the context of health care reform. But instead

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In Brief

AMA Issues Guidelines For HIV Infection, Smoking Cessation; MDA Appointment

AMERICAN MEDICAL ASSN. has released new guidelines for the treatment of nicotine addiction and the treatment of HIV. The guidelines are intended to provide primary care physicians with new scientific data and strategies for treating smokers and HIV patients during routine office visits. The new smoking cessation guidelines give physicians a step-by-step approach to implement a "stop smoking" program for patients. The HIV guidelines will help physicians diagnose HIV infection, determine the disease stage, monitor and treat the early stages of infection and assist patients in modifying behavior than can transmit HIV. . . . **MARK SCHUSTERMAN** has been named chairman of the Dept. of Reconstructive and Plastic Surgery at the Univ. of Texas M.D. Anderson Cancer Center. Schusterman, formerly deputy chairman of the department, joined M.D. Anderson in 1988. He established the center's Reconstructive Microsurgery Service. The department conducted 718 surgical procedures during the past fiscal year, and 4,656 outpatient visits. . . . **ONCOLOGY NURSING SOCIETY** has revised its position statement, "Rehabilitation of Persons With Cancer." The statement proposes that rehabilitation services be available to address the individual's physical, psychological, spiritual, social, vocational, and educational potential. The position paper includes a list of recommendations to facilitate the rehabilitation of cancer survivors. The position paper was written by **Deborah Mayer**, Ontario Cancer Institute, Princess Margaret Hospital, Toronto, and a member of the National Cancer Advisory Board. The paper is available for \$2 (ONS members, \$3 non-members), from ONS, 501 Holiday Dr., Pittsburgh, PA 15220, Tel. 412/921-7373.

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No Agreement At Hearing On Screening Mammography

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of presenting a coordinated case, testimony by the advocacy groups and the Administration pointed to a multitude of disagreements over who should be screened when.

The Administration has been trying to work out some of the differences with the advocacy groups. However, the breast cancer action plan being drafted following a conference held by HHS Secretary Donna Shalala was not completed by the target date of Feb. 1 and is continuing to wind its way through the Administration.

Attempts To Forge Consensus

Another effort by the Administration to emphasize consensus rather than disagreement—a statement that would outline the areas where NCI and the advocacy groups agree on screening mammography—is also a few weeks from completion, sources said.

The Congressional Caucus for Women's Issues, too, has been trying to forge consensus between advocacy groups and the Administration. However, even the caucus members are not in complete agreement over the fine points of recommendations on screening mammography.

What sort of screening mammography benefit should the new health care plan offer?

• “I think we should adopt [screening mammography] standards that are consistent with those of the American Cancer Society,” Olympia Snowe (R-ME), cochair of the caucus, testified at the Jan. 26 hearing.

• “The President's legislation allows some flexibility on the frequency of mammograms, but with the current confusion in this area, we would prefer the plan explicitly assure coverage of mammograms when recommended by a health professional,” Pat Schroeder (D-CO), the other cochair of the caucus, said at the same hearing. “Women want doctors to make that decision, not policymakers.”

NCI Decision Examined

The hearing also gave Congress its first opportunity to examine the NCI decision to withdraw from the 1989 consensus guidelines on mammography screening, drafting instead a “statement of scientific fact” (*The Cancer Letter*, Dec. 10, 1993). The Institute's statement, issued two months ago, reads:

“There is a general consensus among experts that routine screening every one or two years with mammography and clinical breast examination can reduce breast cancer mortality by about one-third for women ages 50 and over.

“Experts do not agree on the role of routine screening mammography for women ages 40 to 49. To date, randomized clinical trials have not shown a statistically significant reduction in mortality for women under the age of 50.”

“NCAB: Ten Scientists, Twelve Opinions...”

Critics say the change of guidelines was brought about by pressure from the Administration as it sought ways to contain costs under the proposed health reform plan.

“There is no political imperative or momentum to what we were doing,” NCI Director Samuel Broder said at the hearing. “This process has been slow and deliberate and it started in 1991.”

Questioning Broder, Rep. Henry Waxman (D-CA), chairman of the subcommittee, asked why NCI chose to ignore the recommendation of the National Cancer Advisory Board, which opposed the change of guidelines (*The Cancer Letter*, Nov. 26, 1993)

“I think it's important to stress that there is more than one advisory board involved here,” said Broder. “The Div. of Cancer Prevention and Control board enthusiastically supports the gist and substance of where we are going.

“NCAB normally does not get involved in this kind of specific issue, but in this particular case, it did. There are times when the NCAB makes a recommendation that we feel is not consistent with

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the facts and realities, and we simply can't agree to that. In this case, we believe that the facts and the science of it provided the rationale for proceeding.

"The larger question is what did NCAB mean when they said what they said. And you have to recognize that when you put ten scientists in a room, sometimes you get twelve opinions, and that, in fact, is one of the issues that we have.

"The chairman of NCAB, Dr. Paul Calabresi, said in a document, 'I am extremely pleased by the nature and substance of the NCI statement. I think the recommendations are both accurate and appropriate. NCI is a science-based organization and the statement represents an excellent summary of scientific fact.'" (The Cancer Letter, Dec. 10, 1993).

What's 'One Or Two Years'?

Turning to another issue, Waxman asked Broder to interpret the NCI "Summary of Scientific Fact" which states that women under 50 should undergo screening mammography every "one or two years." Where does the survival benefit occur?

"We know that a statistically significant benefit occurs," said Broder. "We can't say that it occurs in one year versus two years."

Judith Feder, HHS principal deputy assistant secretary for planning and evaluation, said HHS decided to reimburse screening mammography every two years under the proposed health care reform plan.

"We took two years as the appropriate interval, taking a more conservative approach," Feder said at the hearing.

Under the Clinton plan, a woman would be able to get a screening mammogram annually after making a copayment.

WAXMAN: "Dr. Broder, do you believe that there would be significant increase in mortality because lower income women get mammograms every two years?"

BRODER: "No. And I also think there would be a sea change when we start providing the benefits of technology to women who would otherwise not get such technology."

(See related story, page 4.)

Visco: "Spend The Money, Get The Answers"

The next round of controversy is likely to center around the demand by the National Breast Cancer Coalition that the federal government conduct a clinical trial to determine whether mammography would reduce breast cancer mortality among women under 50.

"Let's stop the debate, and spend the money, and get the answers," Fran Visco, president of the National Breast Cancer Coalition and member of the President's Cancer Panel said at the hearing.

"The coalition wants every woman [between ages 40 and 49] put into a national system of randomized clinical trials, testing different modalities of screening, to determine what does work best for this age group. As new techniques are developed, they can be folded into the trial design," Visco said.

International Study?

The American Cancer Society and the International Union Against Cancer, too, asked for a large, international, randomized study to determine the efficacy of mammography for younger women.

That study is proposed to enroll 1.5 million women ages 40 to 42 and follow them until they turn 50. The U.S. branch of the study would include 1 million women (The Cancer Letter, Oct. 15, 1993).

"The Administration should aggressively support standards that examine the efficacy of mammography in the 40 to 49 age group and the interval of screening in women over 50," said Katherine Alley, a surgeon at George Washington Univ., testifying for ACS.

"Until we have the answers, however, access to mammography should not be limited," Alley said.

Hearing Feb. 10 On Proposed Trial

NCI has not taken a public stance on the feasibility of a trial of mammography in younger women, though several NCI officials said their concerns about the trial include its astronomical cost as well as the possibility that by the time the definitive answers are obtained mammography will be replaced by other screening tools.

The trial will be the subject of a hearing by Rep. Edolphus Towns(D-NY). The hearing is scheduled for Feb. 10.

"There are times when the NCAB makes a recommendation that we feel is not consistent with the facts and realities, and we simply can't agree to that."

*—Samuel Broder
to Rep. Henry Waxman*

Waxman To Broder: What Would You Tell A 45-Year-Old?

The following is the transcript of an exchange between Rep. Henry Waxman (D-CA), chairman of the Subcommittee on Health and the Environment, and NCI Director Samuel Broder. Broder testified at the subcommittee hearing Jan. 26.

WAXMAN: "Dr. Broder, assume you have a patient, who is a woman 45 years old. She has no symptoms of breast cancer. She has no family history of breast cancer. She is at no known risk for breast cancer. She has read about breast cancer and is concerned about whether to get a mammogram. In your professional judgment, would you recommend that this patient have a mammogram every two years?"

BRODER: "I think I will answer it two ways. Speaking only for myself, I believe in the sanctity of the doctor-patient relationship. And I believe that this has to exist and has to be uninhibited.

"I cannot sit here, inside the Beltway, making this kind of judgment and interpose myself into ongoing doctor-patient relationships.

"I would say, however, that it would be wrong for the health care provider to attempt to induce the woman to obtain mammography or to say the basis of the decision is informed by the fact that mammography in that age group has been shown to save lives.

"There is a duty for the health care provider to give the full disclosure of the science as best as one knows it, and then allow an informed process to go on. But patients, and consumers, are part of the process, not just on the receiving end.

"But the facts have to be clear. I would object if a doctor said I am going to ask for mammography because it's been proven to work in your situation. I also think the doctor would have the duty to discuss issues such as the false negative rate, the false positive rate, the probability that there might be an unnecessary biopsy or other procedures, or what exactly does it mean to undergo screening mammography in that age group and to [obtain] a fair and informed consent to that process."

WAXMAN: "After you have gone through all that analysis of the statistics and related ramifications, she turns to you and says, 'Dr. Broder what should I do?'"

BRODER: "I don't mean to evade your question, but I can't answer it in the abstract. Each doctor-patient relationship would be different. There are a number of factors that might be informing that

woman's concerns.

"Having given a long lecture about science and the scientific method, I will contradict myself. I believe that sometimes patients will know things about themselves. Even though they may not be able to articulate it. I am a strong believer in that.

"I believe a [patient] is the best person to know that something is wrong, even if they can't bring it to consciousness, or—occasionally—even when they know that something, they have identified it, and for a variety of reasons, a man or a woman doesn't choose to bring that to the attention of the doctor.

"As a physician I can tell you I have seen that happen and what the patient is really doing is asking for a further inquiry and further questioning.

"For example, to counter your theoretical situation, I might in that situation ask more acute questions. Is there really a lump there? Is there something that you are not telling me? I might ask another health care provider, like a nurse or someone with more sensitivity than me, to ask that woman if there is a lump inside her breast that she found. Or she is anxious, but anxious on an informed basis."

Covered As Diagnostic Services

WAXMAN (Addressing Judith Feder, HHS principal deputy assistant secretary, planning and evaluation): "Okay, then Dr. Feder, under those circumstances, if the doctor and the patient decide to have a mammogram, should there be cost-sharing?"

FEDER: "In those circumstances that Dr. Broder is laying out, the [services] are covered as diagnostic services."

WAXMAN: "No cost-sharing."

FEDER: "That's correct."

BRODER: "But speaking as a physician-scientist, if the doctor and the patient are in a situation where there might be something wrong, I don't want to hear from anybody that mammography is not a tool that one would use in the diagnostic evaluation in the practice of the art of medicine.

"I don't know how to say that any clearer than what I've just said. That's a different area. I don't have the standing to tell you what the reimbursement scheme is, what that part of the equation is, that's not my expertise. But I do believe that nobody should say that [diagnostic] mammography isn't a useful tool. That's a different category altogether from what we are talking about today.

FEDER: "And it's covered as such."

Capitol Notes

Senate Urges Clinical Study Section In Letter To Varmus

NIH should form a study section to review clinical cancer research grant applications, several Senate members wrote in a letter to NIH Director Harold Varmus.

The letter was circulated by Sens. Connie Mack (R-FL) and Daniel Inouye (D-HI) and was expected to be sent to Varmus Feb. 2, sources said to *The Cancer Letter*. The letter was expected to be signed by at least 10 Senate members, sources said.

The text of the letter follows:

"We are writing to express our serious concerns regarding the absence of a specific study section for the review of clinical cancer research project grant applications

"You indicated during your confirmation hearing that you intend to examine the peer review process, and you have also commented recently on the need to bring scientific advances from the bench to the bedside. We commend your attention to these related issues. We believe a review of the peer review system is timely. Furthermore, we believe the current system places clinical cancer researchers at a significant competitive disadvantage and discourages young scientists who might consider clinical research fields.

"We understand that none of the NIH study sections is dedicated to clinical research which has direct relevance to cancer patient care. Moreover, the study section currently used for review of clinical cancer research applications is, in fact, dominated by applications for basic and clinical research projects. The current system does not ensure that clinical cancer researchers' proposals are evaluated by scientists who are their peers.

"In May 1993, the National Cancer Advisory Board concluded that the current peer review system is contributing to a 'crisis in clinical research' and recommended the creation of a specific study section to review project grant applications for clinical cancer research.

"We urge you to complete your evaluation as soon as possible, giving fair consideration to the recommendations of the NCAB and clinical cancer researchers. The clinical research structure nurtured by NIH must not be jeopardized by lack of appropriate mechanism for review of clinical research grant proposals."

The letter was the result of advocacy by the American Society of Clinical Oncology, sources said. The goal was to make it clear that clinical researchers are not seeking a special earmark, or set-aside of funds, but an opportunity to compete for existing grants funding.

"Our feeling was that there needed to be a new level of attention to this issue," Stacey Beckhardt, ASCO director of government affairs, said to *The Cancer Letter*. "Dr. [Samuel] Broder has been urging clinical researchers to submit R01 grants, but it is hard to encourage that if there isn't a level playing field."

Clinical Research Needs Payment Mechanism: Kerrey

Any plan to reform the health care system should include a bureaucratic mechanism to ensure that the government, private insurers and pharmaceutical companies continue to bear the costs of clinical cancer research, said Sen. Bob Kerrey (D-NE).

"We need a collaborative environment where all the payors can come together [to set priorities for clinical research]," Kerrey said at a forum on the role of clinical research in health care reform. "It seems to me if we can connect that decisionmaking with the clinical research that is being done, then we can come out of health care reform with a dramatically improved environment for doing clinical research."

Kerrey said he held the forum as a result of his friendship with James Armitage, chairman of the Dept. of Internal Medicine at Univ. of Nebraska Medical Center.

"Most of the public discourse on health care reform has focused on the important needs of patients and providers," Kerrey said. "But researchers are the vital link which allows the provider to treat the patient, and we must ensure that health care reform perpetuates an already top-notch American research effort."

Plans To Support Research

In his opening statement, Kerrey said he had the support of Sen. Edward Kennedy (D-MA) and Sen. Tom Harkin (D-IA), chairman of the Senate Appropriations Subcommittee on Labor, HHS, Education.

"In the health care debate, I'm going to carve out this one area," Kerrey said to the clinical

investigators, patients, and NCI officials attending the forum. "Regardless of the recent irrelevant arguments whether we do or do not have a crisis in health care, we will pass legislation in 1994 and I intend to use the product of your testimony to influence my own arguments, in the Finance Committee, the Labor Committee, and on the floor itself."

Administration Needs To Strengthen Act

Harkin, who attended the forum briefly, said the health care reform package must contain a stronger provision covering the costs of patient care in clinical trials.

Under the Clinton Administration's Health Security Act, such costs "may" be covered in life-threatening situations, wording that is too limiting, Harkin said.

Harkin said he is continuing to seek support for a health research fund that would raise \$5 billion a year for medical research through a levy on health insurance policies. The proposal is co-sponsored by Sen. Mark Hatfield.

Assistant Secretary for Health Philip Lee acknowledged that the Act needs refinement. "We haven't sufficiently clarified and spelled out in detail" how clinical research would continue under health reform, he said.

"We believe it is entirely appropriate for insurers to cover patient care costs of clinical trials, and this would be corrected in the plan," Lee said. HHS is conducting a survey to determine to what extent patients are participating in clinical trials, he said. "Clinical trials will be covered by the comprehensive health benefits package." Research sponsors would continue to bear the costs of research, he said.

Under the Act, health plans would contract with academic health centers to care for patients requiring specialized care, Lee said. "We could include cancer centers" in that provision, he said.

Another goal of the Administration, Lee said, is to increase funding for NIH research and to increase outcomes research sponsored by the Agency for Health Care Policy & Research.

Testing New Procedures Sooner, Faster

Participants in the forum used autologous bone marrow transplants for advanced breast cancer as an example of a new, expensive, and controversial procedure which has challenged clinical investigators, patients and insurance companies.

Though the procedure has not been proven in a large randomized study to extend survival in advanced breast cancer, as compared to standard therapies, patients desperate to try bone marrow transplantation have won lawsuits against insurers reluctant to pay for the experimental procedure.

In 1990, Blue Cross/Blue Shield agreed to pay patient care costs for women enrolled in NCI-supported clinical trials testing the efficacy of ABMT for advanced breast cancer.

Insurance companies have in the past paid for much of the patient care involved in the evaluation of new treatments, said Craig Henderson, chief of medical oncology, Univ. of California, San Francisco.

"However, as the cost of developing new therapies has increased, insurers have gradually become less willing to provide this support, especially for very expensive therapies, such as bone marrow transplant for breast cancer," Henderson said. "This is in spite of the fact that insurers have, during the same time period, become one of the major consumers of the data generated by such clinical trials, since these are the data that many of them use to decide whether a therapy should be offered routinely to their customers."

Turning To Other Countries

A consequence of the lack of support from insurers is increased pressure by clinical investigators to get the federal government and the pharmaceutical industry to pay more of the costs. Many companies turn to other countries to test new treatments, since research often can be conducted overseas less expensively than in the U.S., Henderson said.

"Clearly, if we do not provide the means to conduct clinical research, our progress against breast cancer and many other diseases will stagnate," Henderson said. "At the same time, ineffective but very costly therapies will find a place in the health care package only because they have not been adequately assessed but seem promising on the basis of limited evidence."

Jane Reese-Coburn, a chemical engineer, described the treatment she received for stage III breast cancer through a research protocol at NIH. Though her doctor recommended the experimental protocol over standard therapy, her insurance company refused to pay \$20,000 in hospital costs she incurred. Standard therapy, Coburn said, would have cost her insurance company \$100,000. She has

filed suit against the insurance company, she said.

If patient care costs are not covered under health care reform, Coburn said, "clinical trials will only be available for those who can afford it."

Require Randomized, Controlled Trials

Susan Love, director of the Univ. of California, Los Angeles, Breast Center, said controlled clinical trials have formed the basis for all the recent advances in the treatment of breast cancer. "The fact that the mortality rate for young women with breast cancer has improved by 11 percent is due to the use of chemotherapy which was devised and tested in a series of randomized controlled clinical trials," Love said.

The drug DES should have been tested in controlled trials prior to its widespread use as a fertility treatment, she said.

"All new treatments should be subjected to the test of a randomized controlled clinical trial before they are accepted as standard practice," Love said. "The current morass regarding silicone implants could have been avoided if they had been required to be tested first. We would know the value of bone marrow transplant in breast cancer by now if we had required it only to be used in a randomized controlled clinical trial. I would say the same thing about shark cartilage or laetrile.

"The only way to move beyond the empathetic use of treatments with questionable value is to subject them to careful study," Love continued. "Proponents argue this is too expensive. It can't be. In fact, it has been stated that the cost of health care could be cut in half if we stopped paying for any treatment which had not been proven to work."

Third-party payors should be required to pay for the patient care costs of phase III trials, Love said. "All new treatments and techniques should only be paid for as part of a clinical trial, preferably randomized," she said. A trial should be approved by the institutional review board and some other body, such as a national health board, NCI or a state review board.

This was one area of agreement reached during the HHS Secretary's planning meeting for a national strategy for breast cancer, Love said.

Karen Antman, chief of the medical oncology division, Columbia Univ., and president-elect of the American Society of Clinical Oncology, said she agreed that coverage for patient care costs of clinical trials must be mandated in health care reform.

NIH, the Institute of Medicine, and a special committee under the President's Cancer Panel reviewed the problem and agreed, Antman said, that "cancer patients enrolled in high-quality peer-reviewed clinical trials are receiving the best available patient care, which should be covered by third-party payors."

Also, health reform should address Medicare coverage of patient costs in approved trials, Antman said. Medicare beneficiaries are denied coverage for care costs of investigational therapy.

In addition, Antman urged increased support for NIH appropriations and a balanced research portfolio, as well as a study section for clinical research.

Stephen Carter, senior vice president, worldwide clinical research and development, Bristol-Myers Squibb Co., cautioned that health care reform must not reduce the incentives for the pharmaceutical industry to undertake high-risk medical research. Companies conduct expensive, long-term research and development for a return on their investment, he said.

"We need to make sure nothing in the health care plan increases the risks or costs of cancer research," Carter said. "No one sector has all the resources necessary" to develop new therapies.

Bruce Chabner, director of NCI's Div. of Cancer Treatment, testified that tremendous opportunities exist in cancer research, at the same time that it is more difficult to attract young people to the field.

Insurance Industry View

Susan Gleeson, executive director of medical and quality management, Blue Cross Blue Shield Association, said the association is paying 40 institutions \$62,000 to provide for patient care costs associated with clinical trials of ABMT for advanced breast cancer.

"There is no way insurers could fund all patient care costs no matter how efficient [trials] are," Gleeson said.

Under health care reform, she said, a national research council should be formed to assess priorities, establish a budget for clinical research, and come up with a funding source such as a tax on insurance premiums and on drug companies.

"We need to create a separate mechanism, and someone needs to step forward to prioritize research," Gleeson said.

Joseph Simone, physician-in-chief, Memorial Sloan-Kettering Cancer Center, said the difficulty

would be establishing the budget for clinical research. "What if there is no better treatment than that offered in a clinical trial?"

Simone's institution last fall filed suit against Empire Blue Cross and Blue Shield over denial of reimbursement for care.

Medical care costs should be covered if clinical trials have been approved by appropriate oversight bodies such as NCI, NCI-designated cancer centers, cooperative groups or community clinical oncology programs, FDA, the Dept. of Veteran's Affairs, or a qualified non-governmental research entity as identified in the guidelines for NCI cancer center support grants.

Program Announcement

PAR-94-029

Title: HIV, AIDS and related illnesses: collaboration award

The Fogarty International Center (FIC) is expanding its AIDS International Research and Training Program to provide small individual research grants for collaboration between U.S. and foreign scientists in any country, consistent with U.S. foreign policy considerations. Support is available for research on human immunodeficiency virus (HIV) infection, acquired immunodeficiency syndrome (AIDS), and for research related to AIDS. Up to \$20,000 per year for a maximum of three years is available for U.S. investigators and their foreign collaborators to conduct research mainly at the foreign site. U.S. investigators holding currently active NIH grants for research related to HIV infections, AIDS, and other related health problems are eligible to apply with their foreign collaborator for the AIDS Fogarty International Research Collaboration Award (AIDS-FIRCA).

Grants will provide funds to the foreign collaborator, through the U.S. grantee institution, for supplies at the foreign institution; for expenses incurred at the U.S. institution to support the collaboration; and for research-related travel and subsistence expenses for both the U.S. and foreign investigators. If the foreign collaborator is in a developing country, applicants may also request funds for small pieces of equipment necessary to the AIDS-FIRCA project at the foreign site.

For the purpose of this program, developing countries are considered to include those in the following regions: Africa, Asia (except Hong Kong, Japan, Singapore, South Korea and Taiwan), Central and Eastern Europe, Latin America, the Middle East (except Israel and the Persian Gulf states), and the Pacific Ocean Islands (except Australia and New Zealand).

To be eligible for the AIDS-FIRCA program, the following conditions must be met:

- o The proposed U.S. Principal Investigator must be the Principal Investigator (Project Director) of an NIH-sponsored AIDS or AIDS-related research grant project (R, P, or U01 series) that will be active and funded during the proposed grant award period (up to three years). Under exceptional circumstances, after consultation with program officials, some research contracts (N01 series) may be eligible "parent" funding for the AIDS-FIRCA. On submission of an application, at least 19 months of active research support must remain on the listed parent grant. Investigators may request the full three years of support in the FIRCA application in cases where less than three future years remain on the parent grant, presuming that the renewal application will be submitted and awarded.

- o The foreign collaborator must hold a position at an institution in a foreign country that will allow him or her adequate time and provide appropriate facilities to conduct the proposed research.

- o The application must demonstrate that the award will enhance the scientific contributions of both the U.S. and foreign scientists and will enhance or expand the contribution of the NIH-sponsored research project (parent grant).

The small grants (R03) will provide up to \$20,000 per year in direct costs for up to three years. Funds may be used for materials and supplies necessary to conduct the collaborative research in the foreign scientist's research laboratory or site, and for costs related to the AIDS-FIRCA project at the U.S. institution. Equipment requests are limited to items for use in the AIDS-FIRCA project at foreign institutions in developing countries.

Travel and subsistence-related expenses may be requested for the U.S. Principal Investigator, the foreign collaborator, and/or their colleagues for visits directly related to the subject of the collaborative research. All proposed expenditures must be well justified and clearly related to the research objectives of the proposed project.

The awards will be made to U.S. institutions, which will be responsible for the expenditures. The minimum FIRCA project period will be for one year, the maximum will be for three years, and depends on the continuation of appropriate NIH support of the Principal Investigator's AIDS-related research. If the related NIH research project (parent) grant expires in less than three years' time it may, upon renewal, reestablish eligibility for a continuation of the AIDS-FIRCA award for the full award period. Since the research supported under this award is mainly to occur at the foreign site, indirect costs will be calculated on the basis of the off-site rate of the U.S. sponsoring institution.

Direct inquiries to: Dr. Mirilee Pearl, International Research and Awards Branch, Fogarty International Center, Building 31, Room B2C39, Bethesda, MD 20892, Tel: 301/496-1653, FAX: 301/402-0779.