THE CANCER LETTER

Vol. 21 No. 37
Sept. 29, 1995

Price $255 Per Year US
$280 Per Year Elsewhere

P.O. Box 15189 Washington, D.C. 20003 Telephone 202-543-7665

In Surprising Result, Survey Of Centers Finds Little "Crisis" In Clinical Research

Is the onslaught of managed care strangling clinical research at the NCI-designated cancer centers?

Robert Day, president of the Fred Hutchinson Cancer Center and a member of the National Cancer Advisory Board, asked the question directly, in a poll of directors of the NCI-designated clinical and comprehensive cancer centers.

When Day presented the survey results to NCAB earlier this month,

(Continued to page 2)

In Brief

Radiologists Elect Officers, Award Medals; FDA Advisors Okay Test For Breast Cancer

NEW OFFICERS of the American College of Radiology were elected at the group's annual meeting earlier this month in Boston. They are: chairman of the Board of Chancellors, **Emmett Templeton**, Baptist Medical Center-Montclair, Birmingham, AL; vice chairman, **Ronald Evens**, Washington Univ.; president, **Murray Janower**, St. Vincent Hospital, Worcester, MA; vice-president, **Barbara Gosink**, Univ. of California, San Diego; and secretary-treasurer, **Abner Landry**, Mercy Hospital, New Orleans. . . . **ACR GOLD MEDALS**, the society's highest honor, were awarded to Joseph Marasco Jr., chairman emeritus of radiology, St. Francis Medical Center, Pittsburgh; Theodore Keats, professor of radiology and orthopedics, Univ. of Virginia; and Seymour Levitt, professor and head, department of therapeutic radiology/radiation oncology, Univ. of Minnesota Hospital. . . . **FDA ADVISORS** last week recommended marketing approval of a new test to help detect whether a woman's breast cancer has returned. The blood test, manufactured by Canada's Biomira Inc., measures the CA15-3 antigen. Biomira showed the FDA advisory committee evidence that adding the antigen test helped physicians diagnose the recurrence of breast cancer about five months earlier than under normal circumstances. . . . **ONS FATIGUE** Initiative developmental grants have been awarded to **Marcia L.M. Grant**, director of nursing education, City of Hope National Medical Center; **Victoria Mock**, director of nursing research, Johns Hopkins Oncology Center; and **Lillian Nail**, associate professor, Univ. of Utah College of Nursing. The grants are designed to stimulate multi-institutional research projects to explain fatigue mechanisms and to design intervention strategies.

GAO Report Finds Hydrazine Sulfate Trials Were Accurate . . . Page 5

Oncology Nursing Foundation Offers Research Fellowship, Clinical Scholar Award . . . Page 6

NCI Contract Awards . . . Page 6

RFP, RFAs Available; SBIR Proposals Sought . . . Page 7

A Crisis In Clinical Research? Survey Says Centers Coping

(Continued from page 1)

the results caused surprise and dismay among board members and top NCI officials and raised profound questions about what the Institute can do to avert the crisis.

At a time when clinical cancer researchers are confronting a nearly universal sense of doom, Day's five-question survey conducted with the help of the staff of the NCI Cancer Centers Program concluded that the crisis has not begun—at least not yet.

"We don't have a picture of a crisis by any means," Day said to the board. While the responses varied by region, with California and Arizona hit particularly hard, "most places are certainly coping in this new environment," Day said.

Unexpected Statement: A Positive Effect?

In a statement board members found particularly unexpected, Day saw a positive effect in the drive toward greater cost-consciousness at the cancer centers.

Cancer centers are reaching out for new strategies by establishing networks, doing cancer carveout deals with insurers and establishing multidisciplinary clinics.

"Multidisciplinary clinics, for example, appeal to patients, and, probably, provide better care for patients. They may indeed provide a better platform for research into specific conditions."

Day noted that this first attempt to determine whether the crisis has, in fact, set in is nothing more than a snapshot in time. "We do not have the degree of crisis that people anticipated a year or two ago, [but] there is the anticipation that this is going to get a lot tighter in the future," Day said.

Its conclusions notwithstanding, Day's survey may have accomplished a great deal more than a portrayal of universal doom ever could: it provided an urgent, fundamental, dramatic challenge to adopt strategies for tracking the effect of managed care and shoring up the damage at academic cancer centers.

As board members and NCI officials lunged to point out the survey's limitations and challenge Day's interpretations, the risk that the issue would be studied to death in a detached way was greatly diminished.

● "If this doesn't show crisis, then this is wrong," said Frederck Becker, NCAB member and vice president and scientific director at M. D. Anderson Cancer Center. "The crisis has hit some of us, and I predict that a year from now these same data will show a desperate crisis in clinical research."

● "I have some concern about the accuracy of the data," said board member Ellen Sigal. "It doesn't seem consistent with what hospitals are producing. When you look at the centers seeing no change in reimbursement, it doesn't seem real."

● "It is very important that if we are going to be accumulating data about this, I think we have to do it in a very serious way," said NCI Director Richard Klausner. "In essence, you've just announced that there is no crisis.

"We need to step back and make the time to decide how the data should be collected, how it should be analyzed, exactly what the data is going to look like, what the questions are going to look like."

● "I think that we collect more data until we are blue in the face, and if we do it very carefully, I think that what we will do is document very carefully the destruction of the clinical trials system and of clinical research," said Robert Wittes, director-designate of the NCI Div. of Cancer Treatment, Diagnosis and Centers.

● "I think it's important that if the firestorm of managed care is moving as quickly as everyone says, and the crisis really is there six months from now or nine months from now, then by the time we get the data we won't have any time to do anything about it," said Brian Kimes, director of the NCI Centers, Training and Resources Program.

Hence, the clash over Day's data led the Institute and the board to confront a series of strategic questions: Should NCI and clinical researchers devote their efforts to documenting the approach of the crisis

THE CANCER LETTER

Editors: **Kirsten Boyd Goldberg**
Paul Goldberg
Founder & Contributing Editor: **Jerry D. Boyd**
P.O. Box 15189, Washington, D.C. 20003
Tel. (202) 543-7665 Fax: (202) 543-6879
E-Mail: 73322.2044@compuserve.com
Subscription $255 per year US, $280 elsewhere. ISSN 0096-3917. Published 48 times a year by The Cancer Letter Inc., also publisher of The Clinical Cancer Letter.

or should they concentrate on efforts to avert it?

"It's an issue of action vs. data," said Klausner. However, with data being a prerequisite of action, NCI doesn't have the luxury to choose.

"The reality is that we cannot simply sit down with people and explain that medical technology is good," Klausner said. "If you are going to go to Congress and say there is a crisis, they are going to ask you, What crisis? Is there a crisis? What is it going to cost us? Why?"

Survey Results

Day's survey was sent to the directors of 42 clinical and comprehensive cancer centers.

Responses were received from 33 of those directors, a response rate of 79%. Telephone follow-up in the survey was conducted by Kimes's staff.

The questions and the results follow:

Question 1: *"Has there been a change in the cancer center population served by your center? Do you see fewer or more patients, patients with different diagnoses or from different geographic areas?*

All the centers reported that the demographics and the diagnoses remained unchanged.

Answering the second part of the question, 18 cancer centers said they are seeing an increase of patients; 3 centers reported a decrease and 12 said they observed no change.

"Now this isn't quantified," said Day. "This is a qualitative answer, and we hope in subsequent surveys to get more quantitative information."

Question 2: *Can you quantify any of the above, including patients eligible for clinical trials and patients placed on clinical trials?*

Seven centers reported increased accrual; three reported decreases; nine reported no change, and eleven said no data were available.

"There is certainly not a disaster represented in these data," said Day. "In fact, it looks like a fairly steady state. Again, these are qualitative responses."

Question 3: *Has there been a change in denials of reimbursement for patients on clinical trials? Please document.*

No change in denials was reported by 15 cancer centers; an increase in denials was documented by 10. One center reported a decrease in denials, and seven said no data were available.

"In many cases, these are only partial denials," Day said. "In other words, there will not be reimbursement for certain tests or certain drugs, but not necessarily for the entire episode of care. Again, we will get this information quantitatively in the future."

Question 4: *Have there been changes in the reimbursement for care of cancer patients in your programs? Can you describe and quantify that impact? What effects have you noticed?*

Responding, 13 cancer centers said they had seen no change in reimbursement and 20 said their reimbursement had decreased. None of the centers reported an increase.

"Here you see a rather preponderate answer that there is a decrease in reimbursement," said Day. "I think most of us have expected that. No one has received an increase, which may be the more telling figure."

Question 5: *Are there any other areas of your cancer center which have been, or are likely to be positively or negatively affected by the current changes and/or trends in the financing and delivery of cancer care?*

In their responses, the centers said they were devoting more time to resolving reimbursement problems and development of strategies to cope with the changing health care environment.

"[Negotiations] with insurers for patients who come for specialized care take a long time," said Day. "The number of staff people involved, the amount of effort that an attending physician has to give in justification for care is a major cost.

"And it's not a cost that shows up in the cost of medical care. The costs of a patient going home earlier following a procedure, or having an outpatient procedure and going home rather than spending the night at the hospital don't show up as health care costs," said Day.

"They are costs that the institution, the provider or the patients bear."

Day's Conclusions

Day offered the following conclusions:

- Quality of care may be compromised.
- Managed care has not yet resulted in a crisis for clinical research. Most centers are coping, but it is work-intensive. Successful strategies may be developed for the future.
- Long-term prognosis for clinical research includes declining discretionary revenue for institutional studies; less time for academic research and changes in training opportunities."

●Managed care benefits to centers include greater efficiency encouraged by cost-containment and a benefits to prevention and clinical research stemming from proliferation of networks with community hospitals.

"Now, [NCAB member] Fred [Becker] is, of course, predicting doom and gloom in the future, and he may be right, or he may not be right," Day said after his report drew criticism. "As there are trends in one direction, there are trends in other directions.

"I think the one thing that comes through from all of this, is the profit margins have gone out of the practice of medicine," Day said. "I would comment about were they've gone. [Since] the cost of health care hasn't come down, they've gone into the industry in a very different way than they had before.

"The take-home message is: There is no flexibility to support training and research," Day said.

Quantifying a Crisis

To keep track of the state of affairs at the cancer centers, NCI needs to sharpen the questionnaire and develop methods for quantifying the data, and integrate the data with the data collected on the number of patients eligible for trials and the number of patients on trials by organ site, Day said.

Collecting the data will not be an easy task, Day said.

"Most teaching hospitals have very elaborate financial systems," he said. "They don't necessarily have data systems. How successful we will be in getting that kind of quantitative information will depend a lot on the data system at a particular setting."

NCI's Kimes agreed.

"It's not easy to get clean data that's equally clean for all centers," he said. "That's always been one of the problems we've had in our clinical database, and that's why we've never actually stood by it as one that we can rely on entirely."

Thus, as his office polled the cancer centers, some of the responses were complete while others easily fit on one page.

"I think we have to consider the survey a very preliminary one," Kimes said. "Every time you develop a survey, you have to ask questions in the best way possible to get the best information. And I don't think this survey was considered as carefully as it should have been. We didn't have the time. Perhaps we can do a better job."

More importantly, NCI will have to decide whether cancer center directors are in fact the appropriate people to survey, Kimes said.

"I am not certain that we are going to get a lot better data from the center directors," Kimes said. "Talking to deans, who oversee the economics of their institutions in a much more significant way, we will have a different perspective on this."

Becker: Measure the Income Margin

"There is another [cost] you can add: the amount of time you spend with consultants and the amount of money you are paying them to tell you how in God's name to get out of this," said Becker.

"While Houston has had only 25% penetration by managed care, in 14 months the income of our center dropped by 34%.

"The prediction of every group that we know is that the slope of penetration [of managed care] is accelerating, and that it's going to be multiplied by predatory price practices, in which companies will force hospitals to literally bid the lowest price per patient per day to get the contract.

"And this will make this conversation obsolete in 6 to 9 months.

"I think we should focus not on the overall impact of managed care but focus perhaps only on the impact of managed care on the money available for clinical research.

"A change in income for a given organization may not tell you that story.

"The question that has to be asked is either in dollars or percentage of income or margin what they devoted to clinical research in the past and what they envision they'll be able to devote in the future."

What is to be Done?

Addressing the problem, several NCAB members and NCI suggested lobbying HHS agencies to reimburse clinical trials through Medicare, Medicaid and other programs as well as engineering meetings with leading insurers.

"The insurers have not been uniformly unwilling over the last decade or so to join a partnership with the clinical research community and support certain kinds of trials," said DCT's Wittes. "The breast cancer bone marrow transplant example shows that the Blues and some others are willing to do their part to support the medical care costs."

Fran Visco, president of the National Breast Cancer Coalition and a member of the President's

Cancer Panel, said that any deal with insurers should also address the issue of reimbursement of experimental treatments provided outside clinical trials.

"I think the most egregious example of that is the bone marrow transplants, where we do have insurance carriers who are willing to work with us to accrue the patients into reimbursed clinical trials at the same time that physicians are supporting lawsuits to get reimbursement for [treatment provided] outside clinical trials," Visco said.

In the past, insurance executives have said that an alliance between academic cancer centers and managed care companies is entirely possible.

In one such statement, at the annual meeting of the American Society of Clinical Oncology earlier this year, Aetna official William McGivney said that while academic cancer may not be the lowest cost providers, the care they provide is appropriate (**The Cancer Letter**, June 2).

"I think there is a natural alliance [between academic cancer centers and managed care companies], beacause of our orientation to outcomes-based decision making," McGivney, medical director of the Aetna Health Plan, said at the ASCO meeting. "Our problem with patient selection criteria is not with the academic institutions; it's with the community cancer centers out there, which are not keeping up with the data in certain areas."

Klausner: Data Needed To Convince Congress

"I don't think this is going to be solved by sitting down with HCFA or Medicare and convincing them that clinical trials are good," said Klausner. "I think we are going to be much more [convincing] having information about the collapse or the non-collapse of academic health centers.

"I don't think that Congress, White House, major insurers would be sanguine about the complete destruction of academic health centers.

"[However] we do have to demonstrate the extent to which academic health centers are threatened, and in what ways and on what time scale.

"And I don't think we are going to get this issue by asking the question, `Are you at this time period continuing to accrue patients to trials in the cancer centers?'"

◆ ◆ ◆

Has managed care indeed precipitated a crisis in clinical cancer research? How is your institution or your practice affected? Whether you are an office-based physician, a director of an academic cancer center or a patient activist, **The Cancer Letter** *invites your accounts and opinions of what is taking place. Write to us or call us. See box on page 2 for address, phone and e-mail address.*

Hydrazine Sulfate Trials Were Accurate, GAO Finds

An audit by the General Accounting Office said three NCI sponsored trials of hydrazine sulfate were accurate in their principal conclusion that the drug is ineffective in extending the survival of cancer patients.

However, GAO said the Cancer and Leukemia Group B had failed to maintain complete and accurate records of the patients' use of alcohol and tranquilizers that were prescribed for their antiemetic properties.

According to advocates, hydrazine sulfate is ineffective when used in conjunction with alcohol and antiemetic agents that contain barbiturates.

GAO's audit disagreed with that assertion.

"Retrospective analyses...found no evidence that the use of allegedly incompatible agents adversely affected NCI's clinical trial results," the agency said in a report titled "Cancer Drug Research: Contrary to Allegation, NIH Hydrazine Sulfate Studies Were Not Flawed."

"Although our work did not support the allegation that the studies were flawed, NCI should have made sure that complete, accurate records were kept during CALGB's clinical trials regarding concurrent medications and possible alcohol use," the report said.

Commenting on a draft report, NCI said the data on the use of concomitant medications were, in fact, kept by CALGB and the North Central Cancer Treatment Group which conducted two trials of the drug.

"The data were clearly available, either on the patient research forms or on the patient medical records, as demonstrated by the fact that the analysis of the effects of concomitant use of the supposedly incompatible agents on the alleged effectiveness of hydrazine sulfate has been done," NCI said in comments on the GAO draft report.

The GAO audit was requested last year by Rep. Edolphus Towns (D-NY) after his office received a large number of telephone calls from listeners to a

Washington area radio program. The calls were prompted by talk show host Jeff Kamen, who is also the author of Penthouse magazine articles that assert that hydrazine sulfate is an effective cancer treatment (**The Cancer Letter**, May 27, 1994).

Kamen was out of the country and could not be reached by **The Cancer Letter**.

The report is available from GAO. Tel.: 202/512-6000. The document's call number is GAO/HEHS-95-141 Hydrazine Sulfate.

ONF Seeks Applicants For Research Fellowship

The Oncology Nursing Foundation is seeking applicants for the 1995 Research Fellowship Awards.

The purpose of the program is to support short-term oncology research training.

The fellowships may be used to support a variety of activities including, but not limited to the following:

- Learn a new methodology or laboratory procedure
- Develop a program of research or refine an existing program
- Switch to a new area of research or enter oncology for the first time
- Develop a relationship with a mentor as a springboard to another source of research funding
- Attend an advanced or specialized research training program
- Work with a multicultural expert on the translation of research tools into another language.

The award is funded by Chiron Therapeutics. The applicant must be a registered nurse with an interest in oncology and with a completed doctoral degree in nursing or a related discipline. Membership in the Oncology Nursing Society is preferred but not required.

Total award is $13,700. The fellow receives $10,000 to cover transportation, lodging, tuition, salary support, and other research-related expenses. The mentor and/or the mentor's institution will receive a $2,000 award in the form of an unrestricted honorarium to cover the mentor's consultative or research-related expenses.

Proposals are due by Dec. 1. To receive an application, contact ONS Research Dept., 501 Holiday Dr., Pittsburgh, PA 15220-2749, tel: 412/921-7373 ext. 257.

ONF Seeks Applicants For Clinical Research Award

The Oncology Nursing Foundation has announced a call for the 1996 Clinical Research Scholars Program.

The program, which is a component of the Fatigue Initiative through Research and Education project, is designed to facilitate fatigue research by nurse researchers in clinical settings, promote the scholar's own fatigue research, link clinical and academic researchers and promote the dissemination and ultilization of findings.

The scholar's program of activities should emphasize the development of a cancer-related fatigue research program. Scholars are expected to provide opportunities for other nurses to become involved in fatigue-related research.

Applicant must be a registered nurse and an established oncology nurse researcher, have an earned doctorate in nursing science or related discipline with an emphasis in oncology, have a staff scientist or similar appointment in a clinical setting or faculty/ research appointment in a school of nursing, be in an organizational climate that promotes interdisciplinary collaboration, and institutional resources dedicated to supporting the program of activities.

Amount of award is $35,000 per year for a term of two years. Application deadline is June 1, 1996. To receive an application, contact ONS Research Dept., 501 Holiday Dr., Pittsburgh, PA 15220-2749, tel: 412/921-7373, ext. 257.

NCI Contract Awards

Title: Phase I single and multiple dose safety and pharmacokinetic clinical study of indole-3-carbinol. Contractor: Univ. of Kansas Medical Center, $838,340.

Title: Survey of compounds which have been tested for carcinogenic activity. Contractor: CCS Associates, Mountain View, CA; $971,241.

RFP Available

RFP NCI-CP-61004-60

Title: **Synthesis of Derivatives of Polynuclear Aromatic Hydrocarbons**

Deadline: Approximately Nov. 15

The Chemical and Physical Carcinogenesis Branch

of the NCI Div. of Cancer Etiology has a requirement for the synthesis of labeled and unlabeled derivatives of polynuclear aromatic hydrocarbons. This acquisition involves two tasks.

Task I involves the synthesis of primarily unlabeled polycyclic aromatic hydrocarbon derivatives, some labeled synthesis may also be done under Task I, and offerors must possess this capability. Task II involves the operation of a labeled chemical repository which includes the resynthesis of compounds currently in the repository. The operation of the repository requires regular resynthesis, repurification, and analysis skills thus requiring linkage with a synthesis facility.

Two awards are anticipated, one award for Task I only and one award for Task I plus Task II. In order to bid on Task II, an offeror must also bid on Task I. Each award is expected to be for a five-year period.

Contract specialist: Barbara Birnman, RCB NCI, Executive Plaza South Suite 620, 6120 Executive Blvd. MSC 7224, Bethesda, MD 20892-7224, tel: 301/496-8611, fax: 301/480-0241.

RFAs Available

RFA CA-95-020

Title: **National Cooperative Drug Discovery Groups**

Letter of Intent Receipt Date: Oct. 1

Application Receipt Date: Dec. 20

This is a notice of availability of an RFA from the Developmental Therapeutics Program, NCI Div. of Cancer Treatment, for the continuance of the National Cooperative Drug Discovery Group (NCDDG) and the National Cooperative Natural Products Drug Discovery Group (NCNPDDG) Programs.

The RFA will support innovative, multidisciplinary approaches to the discovery of new anticancer agents and therapeutic strategies. A multi-institutional approach involving academic, non-profit, and/or industrial institutions is envisioned. The biological or molecular targets for attack will be selected by the applicant.

NCI has set aside approximately $3.5 million total costs (direct plus indirect costs) for the first year of funding. It is anticipated that three or four NCDDG and one or two NCNPDDG cooperative agreement (U19) awards will be made for periods of up to five years.

Inquiries: The RFA may be obtained electronically through the NIH Grant Line (data line 301-402-2221) and the NIH Gopher (gopher.nih.gov) and by mail and e-mail from: George Johnson,

DCT, NCI, Executive Plaza North Suite 832, Bethesda, MD 20892-7450, tel: 301/496-8783, fax: 301/496-8333, e-mail: johnsongpax2.ncifcrf.gov

RFA CA-95-017

Title: **Cancer Therapy With Biological Response Modifiers**

Letter of Intent Receipt Date: Oct. 30

Application Receipt Date: Jan. 4

The Biological Response Modifiers Program in NCI's Div. of Cancer Treatment announces the availability of an RFA to establish cooperative agreements (U01) for clinical trials of cancer therapy with biological response modifiers (CATBRMs).

These cooperative agreements are designed to foster innovative translational research with BRMs by peer-reviewed groups of clinical and preclinical investigators. Each CATBRM group will consist of a Principal Investigator; one or more clinical programs, each with a Program Leader; one or more laboratory programs, each with a Program Leader; and the NCI Program Director. Applicants must propose a plan for early clinical development of a BRM agent or approach, including a detailed plan for an initial clinical trial. Applications must include evidence that the agent(s) to be studied are available for development to a clinical trial, and a statement of the assistance sought from NCI (e.g., regulatory affairs assistance, or production of clinical-grade agents).

This RFA is a reissuance of RFAs CA-92-01 and CA-92-28, which were issued under the title, "Clinical Trials of Cancer Therapy With Biological Response Modifiers (CATBRMs)." Applicants who did not apply to the previous announcements, who applied but did not receive an award or those applicants who have received an award, are encouraged to respond to this RFA. However, this reissued RFA is a one-time solicitation. Future unsolicited competing renewal applications will compete as research project applications with all other investigator-initiated applications.

Applicants who are past recipients of CATBRM awards should include results of work with those awards, including scientific progress and how they have met the Terms and Conditions of Award.

NCI plans to make up to four awards for project periods up to four years, and has set aside $1.0 million total costs for the initial year funding.

Inquiries: The RFA may be obtained electronically through the NIH Grant Line (data line 301-402-2221) and the NIH GOPHER (gopher.nih.gov) or by mail and e-mail from: Jon Holmlund, DCT, NCI, NCI-FCRDC Building 1052 Room 253, Frederick, MD 21702-1201, tel: 301/846-1098, fax: 301/846-5429, e-mail: HOLMLUND@NCIFCRF.GOV

Program Announcement

PAR-95-091

Title: **Cancer Prevention And Control Research Small Grant Program**

NCI invites applications for Small Research Grants (R03) in cancer prevention and control.

This program is designed to aid and facilitate the growth of a nationwide cohort of scientists with a high level of research expertise in the field of human cancer control intervention research.

New, as well as experienced, investigators in relevant fields and disciplines (e.g., disease prevention and control, medicine, public health, health promotion, epidemiology, social work, nursing research, nutrition, health policy, health services research, and behavioral sciences, such as psychology, health education, sociology, and community organization) may apply for small grants to test ideas or do pilot studies.

Inquiries: The PA may be obtained electronically through the NIH Grant Line (data line 301-402-2221) and the NIH GOPHER (gopher.nih.gov), and by mail and e-mail from: Helen Meissner, DCPC, NCI, Executive Plaza North Room 330, 6130 Executive Blvd, MSC 7346, Bethesda, MD 20892-7346, tel: 301/496-8520, e-mail: meissneh@dcpceps.nci.nih.gov

Small Business Innovation Research Proposals Due Dec. 5

Small Business Innovation Research Program
Contract Proposal Receipt Date: Dec. 5, 1995

Innovative technologies and methodologies fuel progress in biomedical and behavioral research and represent an increasingly important area of the economy. The Small Business Innovation Research (SBIR) program provides support for research and development of new technologies and methodologies which have the potential to succeed as commercial products.

The purpose of this notice is to (1) announce the issuance of the solicitation of the Public Health Service for Small Business Innovation Research Contract Proposals with a due date for receipt of proposals of Dec. 5; and (2) inform the public about the opportunities that the SBIR program offers to small business concerns as well as to scientists at research institutions, including colleges and universities.

Public Law 102-564 requires the PHS and certain other federal agencies to reserve a specified amount of their extramural research or R&D budgets for an SBIR program through fiscal year 2000. In FY 1996, 2 percent of the PHS extramural budget will be reserved for the SBIR program, amounting to $180-$185 million (estimated); and in FYs 1997 and beyond, the set-aside requirement will be 2.5 percent.

The offeror organization must be a small business concern, and the primary employment of the principal investigator must be with the small business concern at the time of award and during the conduct of the proposed project. In accord with the intent of the SBIR program to increase private sector commercialization of innovations derived from federal R&D, scientists at research institutions can play an important role in an SBIR project by serving as consultants and/or subcontractors to the small business concern. Normally, up to one-third of the Phase I budget may be spent on consultant and/or subcontractual costs, and up to one-half of the Phase II budget may be spent on such costs. In this manner, a small business concern with limited expertise and/or research facilities may benefit from teaming with a scientist(s) at a research institution; for the scientist(s) at a research institution, this team effort provides support for R&D not otherwise obtained.

The SBIR program consists of the following three phases:

PHASE I: The objective of this phase is to determine the scientific and technical merit and feasibility and potential for commercialization of the proposed research or R&D efforts and the quality of performance of the small business concern, before consideration of further Federal support in Phase II.

PHASE II: The objective of this phase is to continue the research or R&D efforts initiated in Phase I. Funding shall be based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II proposal. Only Phase I contractors are eligible to apply for Phase II funding, and Phase II proposals may be submitted upon the request of the Contracting Officer only.

PHASE III: The objective of this phase, where appropriate, is for the small business concern to pursue, with non-SBIR funds, the commercialization of the results of the research or R&D funded in Phases I and II.

The amount and period of support for SBIR awards are as follows:

PHASE I: Awards may not exceed $100,000 for direct costs, indirect costs, and negotiated fixed fee for a period normally not to exceed six months.

PHASE II: Awards may not exceed $750,000 for direct costs, indirect costs, and negotiated fixed fee for a period normally not to exceed two years, that is, generally, a two-year Phase II project may not cost more than $750,000 for that project. Only one Phase II award may be made for any SBIR project.

Inquiries: Eligibility requirements, definitions, submission procedures, review considerations, contract proposal forms and instructions, and other pertinent information are contained in the Solicitation of the PHS for Small Business Innovation Research contract proposals, available from: PHS SBIR/STTR Solicitation Office, 13687 Baltimore Ave., Laurel, MD 20707-5096, tel: 301/206-9385, fax: 301/206-9722, e-mail: a2y@cu.nih.gov