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NCI NEEDS 100 SBIR CONTRACTS BY APRIL 1 TO AVOID LOSING $5 MILLION; NIH OBJECTS TO DCT COMMENTS

NCI will have to fund 100 contracts in the Small Business Innovation Research Program out of those proposals submitted by the April 1 deadline or suffer the cruelest of April Fool's Day pranks—lose back to the U.S. Treasury a substantial sum of money, possibly as much as $5 million. At the moment, the entire $5 million

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In Brief

MOORHEAD HEADS ACCC; ANDERSON PRESIDENT ELECT; SEGALOFF DIES; RAAF CLEVELAND CLINIC DIRECTOR

EDWARD MOORHEAD, Grand Rapids medical oncologist and PI for the Community Clinical Oncology Program there, assumed the presidency of the Assn. of Community Cancer Centers at the organization's annual meeting last week. Paul Anderson, director of Pensrose Cancer Hospital in Colorado Springs, was elected president elect. Robert Enck, Binghamton, was elected secretary, and Ann Welch, Cincinnati, was reelected treasurer. Ralph Scott was elected to the Board of Trustees; reelected were Nancy Agee, Irving Fleming and Rodger Winn.... **ALBERT SEGALOFF,** head of the oncology program and director of endocrine research at Ochsner Cancer Institute and long a major figure in cancer research, died after suffering a heart attack last month. He was 69. Segaloff had been at Ochsner for 40 years... **JOHN RAAF,** currently at Memorial Sloan-Kettering Cancer Center, will become director of the Cleveland Clinic Cancer Center April 1. James Montie, chairman of the Dept. of Urology at Cleveland Clinic Foundation, has been acting director.... **CHARLES BALCH,** chief of surgical oncology and professor of surgery and immunology at the Univ. of Alabama Comprehensive Cancer Center, will become chief of surgery at M.D. Anderson Hospital & Tumor Institute July 1. He will be head of the Div. of Surgery and chairman of the Dept. of General Surgery at MDA and will hold the position of associate chairman of the Dept. of Surgery at the Univ. of Texas. Balch has been at the Univ. of Alabama for 15 years.... **WILLIAM HRUSHESKY,** Univ. of Minnesota assistant professor of medicine, was disappointed at not being included in the "honor roll" of investigators whose grants in normal years would be funded by NCI but who will be left unfunded because of OMB's budget cuts (**The Cancer Letter,** March 8). Hrushesky received a priority score of 175 in competing for renewal of his grant on the clinical applications of chronobiology to cancer, a study in which he has demonstrated that individual timing of medication can influence response.... **FDA'S ONCOLOGIC** Drugs Advisory Committee will consider NDAs for mitoxantrone and epirubicin at its meeting March 28-29.

NIH SAYS SBIR NOT AN APPROPRIATE ALTERNATIVE FOR MOST UNPAID GRANTS

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appears to be at risk, since only one contract proposal had been received as of last Friday.

"We'll need an overwhelming response in contract applications by April 1, or NCI will lose money," Gregory Curt, Div. of Cancer Treatment deputy director commended. Curt is in charge of the program for DCT.

While NCI has been desperately trying to stimulate grant and contract applications from cancer investigators employed by small business firms or allied with them, NIH executives objected to what they felt were inappropriate and misleading statements emanating from NCI and reported in **The Cancer Letter** Feb. 22. The differences led to barbed exchanges between NIH SBIR program officials and NCI staff members. The quarrel appears to have been patched up this week, with NIH withdrawing its demand that DCT send out a retraction of a letter widely distributed to investigators urging them to consider competing for SBIR awards.

Details to follow. First, here's how the money situation stands:

*NCI had to set aside $9.2 million of its FY 1985 appropriation for SBIR. Any of that amount not awarded through the program will revert to the Treasury. Congress deliberately included that provision in the law (PL 97-219) to discourage NIH and other federal agencies subject to the program from dragging their feet on awards to small business in order to save as much of that money as they could for their traditional constituents.

*Grants funded through the February meeting of the National Cancer Advisory Board totaled $1.75 million. At present, 86 phase 1 grants are being reviewed. If the usual NIH percentage of approved applications prevails, about 40 of those will be eligible for funding (never mind priority scores—the law says all those approved have to be funded until the money runs out). At $50,000 each, the new phase 1 grants will consume $2 million. Finally, seven phase 2 grant applications are in review. If four of them are funded, that will soak up, at $250,000 each, a total of $1 million. Phase 2 awards are up to $500,000, spread out over two years.

Thus it seems likely that at best, SBIR grants will take only $4.75 million from the $9.2 million available, leaving $4.45 million headed back to the Treasury unless enough contracts can be awarded to put a dent in it.

This round is the first for contracts, so phase 1 awards are all that can be made.

April 15 is the deadline for the next round of SBIR grant applications, but those probably will not be funded with FY 1985 money, at least by NCI. The National Cancer Advisory Board, which must approve the grants before they are awarded, meets in October, its first meeting after review of the April 15 grants will have been completed. The 1985 fiscal year ends Sept. 30, the date the unspent SBIR money will revert to the Treasury. The NCAB review could be accomplished by mail, but that then would deprive the FY 1986 budget of one round of SBIR awards, probably making it even more difficult then to expend all the reserved funds than it is this year. That's what happened this year—the NCAB met in September last year, earlier than usual. The SBIR grants it approved then were funded with FY 1984 money, which helped use up most of the reserved funds then. But it exacerbated the problem this year.

NCI staff has exhorted the division boards of scientific counselors to help stir up interest in the program. At the February meeting of the DCT Board, Director Bruce Chabner said, "I don't understand why grantees, who are in such dire straits, aren't flocking to this. I want to emphasize that a small business can be an individual, he can be a post doctoral fellow in your lab. If he affiliates with a company, through a subcontract he can do a substantial portion of the work."

That comment reported in **The Cancer Letter,** plus the tone of the article encouraging unfunded grantees to consider working out arrangements which would permit them to compete for SBIR grants or contracts, and the DCT letter combined to create considerable discomfort at Building 1 (NIH headquarters). William Raub, NIH deputy director for extramural research and training, wrote to the editor:

"... There are some statements in the article that are so misleading or erroneous that I feel compelled to comment on behalf of NIH and ask your assistance in providing additional information to your readers.

"The Small Business Innovation Development Act of 1982 (PL 97-219) was enacted by Congress and signed by the President expressly for the purpose of helping small businesses carry out research and development that will result in products or processes of commerical significance. The impetus for the legislation came from recognition that in the past two decades a significant share of technological innovations having near term commercial promise came from small research companies and that, despite this fact, less than five per cent of federal R&D funds awarded to research organizations went to small business.

"SBIR funds, set aside by law for small businesses, are not intended as an alternate source

of funding for university based research. Rather, they are earmarked for supporting research oriented, for profit organizations that want to bring the fruits of new science and technology to the market place. In other words, the SBIR Program targets organizations that are commercially oriented, not organizations that are oriented principally toward education and/or research per se.

"Funds set aside as a result of PL 97-219 do not constitute replacement funding for scientists in universities or other not for profit organizations who have been unsuccessful in obtaining traditional research grants from NIH. While I am keenly sensitive and sympathetic to the plight of those investigators whose meritorious grant applications will go unfunded this year, I think we would simultaneously distort the objectives of PL 97-219 and render these investigators a disservice if we were to portray the SBIR Program as their panacea. Your account of the NCI meeting suggests that you went away with precisely that impression.

"Four examples should suffice to illustrate the basis for my concern. First, while it is true that the definition of a small business includes a sole proprietorship, the latter term is not synonymous with 'individual.' A sole proprietorship simply means a business owned by a single individual. Most of the sole proprietorships that have received SBIR awards have a staff of several persons, i.e., the owner has a payroll of more than one individual for which he/she is responsible. Thus, it would be erroneous to assume that NIH makes SBIR awards to individuals; they are made to for profit organizations, some of which have a single owner.

"Second, there are other SBIR Program eligibility requirements that must be met, e.g., the individual proposed as the principal investigator of an SBIR project must be in the employ of the small business more than one half of his or her time. That is to say, the small business, not the university, must be the primary employer of the PI. This requirement will obviously present difficulties for a number of academic scientists because reduction of their time to less than 50 per cent employment with the university usually will mean a material as well as professional change in their relationships with the university. For example, most universities will eliminate fringe benefits from those individuals who are less than half time faculty members. Also, since the SBIR Program is intended to benefit small research oriented companies, any copyrights or patents resulting from an SBIR project are retained by the small business, not the university.

"Third, there is the matter of discontinuity of support. While regular NIH research project grants are usually awarded for three years with continuous funding, this is not true of SBIR grants. Under the strict structure defined by PL 97-219 and the Small Business Administration, phase 1 awards are made for a six month period. An application for phase 2 support can be submitted only after the phase 1 period has ended. Since phase 2 applications to NIH must also undergo peer review, there will be a hiatus in funding between phase 1 and phase 2 that could range from six to 10 months, assuming that the application is one that will be funded. Those investigators who choose to form their own companies or establish a relationship with an existing one must develop a contingency for this programmed discontinuity of funding.

"Fourth, simple affiliation with a small business does not mean the assurance of adequate grant income for an academic investigator. Under the rules of the SBIR Program, only one third (or $16,500) of a phase 1 grant ($50,000 in total costs) can be used for consultant fees and contractual arrangements with a third party for services to be performed in support of the SBIR research project. The remaining two thirds must be expended by the small business for in house activities. Only at the phase 2 stage (awards of up to $500,000 for total costs over a one-three year period) does SBIR funding rival the options for salary support that are inherent in traditional NIH grants.

"Finally, since the issues of priority scores and award rates apparently were prominent during the NCI meeting, I think your readers might find a broader perspective helpful. The experience of NCI within the SBIR Program is essentially as you reported but is not indicative of the experience of other institutes at NIH. For example, in the latest round of review, which included all grant applications brought to the January and February council meetings, the mean score of SBIR applications assigned to the National Institute of Neurological & Communicative Disorders & Stroke was 198, the cutoff score for SBIR applications awarded by the National Eye Institute was 203, and the average score of SBIR applications across all institutes was 265. Moreover, the figure of $1.75 million cited in your article as representing the total dollar amount that would be spent by NCI if no additional SBIR grants or contracts are awarded is misleading. There is one round of contract proposals and two more rounds of grant applications yet to be funded this fiscal year.

"PL 97-219 was passed by Congress to stimulate technological innovation in the small business community and increase commercialization of research and development conducted by small firms. The NIH SBIR Program is pursuing these objectives faithfully. Among other things, we strive to do everything possible to ensure that those scientists

who leave traditional academic pursuits to form or affiliate with small companies do so for the right reasons and with full knowledge of the tradeoffs they face. More and stronger research oriented small businesses clearly are in the national interest; premature or ill considered attempts to form such companies are not."

Raub, of course, was not aware that NCI intends to have only one more round of grants awarded in FY 1985. Neither was he aware, apparently, that the number of grant applications presently being reviewed makes it highly unlikely that NCI will be able to expend more than $4.75 million, except for what it can fund in phase 1 contracts.

The issue is whether unfunded NCI grantees should be encouraged to go after the $4.5 million left on the table.

"I don't see anything wrong with telling scientists who may have good ideas with potential commercial value to consider appropriate affiliations with small business and take part in this program," Curt said. He acknowledged that to be the principal investigator, the investigator would have to be employed 51 per cent of his time by the small business. But "the easiest way to do this would be to arrange with the company for one of its employees to be the PI and contract some of the work back to your lab."

That could amount to only $16,500 for phase 1, as Raub noted. But in phase 2, that could be as much as 50 per cent of $250,000 a year for two years. The program permits that much for subcontracts or consultants.

Neither would Curt back down on the suggestion by Chabner that awards could be made to one person firms. Many such SBIR awards have in fact been made, he said.

Many NCI grantees already have affiliated in one way or another with commercial organizations, most of which probably qualify as small businesses (no more than 500 employees). "Many of them didn't know about SBIR," Curt said.

Curt feels strongly that encouraging scientists to develop relationships with small business firms meets both the spirit and letter of the law and would help strengthen the scientific base of small business. He and Raub agreed on that point, and Raub withdrew the demand for a letter of retraction to all those who received the DCT letter.

As if losing nearly $5 million wasn't painfull enough, NCI (and NIH) has been told that SBIR grants will be counted against the ceiling imposed by the Office of Management & Budget.

For NCI, that will reduce the number of RO1s and PO1s it can award in FY 1985 by as much as 10 per cent, from the total of 790 that was its share of the 5,000 new and competing grants permitted NIH. That will further rankle the scientific community. The very likely prospect exists that while some outstanding scientists with RO1s or PO1s won't be funded, even with scores as high as 159, a wacky SBIR proposal with the worst possible score of 500 could be.

Counting SBIR grants against the maximum permitted NIH definitely is another case of OMB (which means the White House) ignoring the intent of Congress.

Atlhough the time is short, those considering submitting SBIR contract proposals by the April 1 deadline should contact NCI immediately; likewise for those planning to submit SBIR grant applications by the April 15 deadline. Here again are the contacts:

Dr. Vincent Oliverio, Div. of Extramural Activities, 301-496-4218. He is the overall NCI SBIR coordinator. Others who may be contacted at the divisions are Louis Greenberg, Div. of Cancer Biology & Diagnosis, 301-496-5307; Dr. John Cooper, Div. of Cancer Etiology, 301-496-1882; Dr. Gregory Curt, Div. of Cancer Treatment, 301-496-6711; and Dr. Richard Costlow, Div. of Cancer Prevention & Control, 301-427-8648.

The NIH SBIR Program coordinator is Lily Engstrom, 301-496-1968.

NSABP SEGMENTAL STUDY PUBLISHED, AT LAST, CONFIRMS LESS IS AS GOOD

The National Surgical Adjuvant Breast Project's segmental mastectomy study results have finally been published, more than a year after submission to the "New England Journal of Medicine." They confirm in general what NSABP Chairman Bernard Fisher has been saying informally—and what was learned from occasional leaks—for the past year: for many women with early stage breast cancer, conserving the breast is at least as effective as removing it entirely, in recurrence and in survival.

The results also demonstrated the value of breast irradiation, with a remarkable difference in recurrence. They also provided interesting evidence that radiation and chemotherapy combined add even more to prevention of recurrence.

Fisher held a press conference at NIH the day prior to the NEJ publication, the first occasion on which he spoke to the news media on the study since it was closed in December, 1983. Among his comments:

*He is confident that the five year data presented now will hold up at 10 years, since the previous NSABP study comparing radical with total mastectomy (no difference) now has 10 years of

followup (also published in the same issue of NEJ), and they confirm the five year results.

*The study was limited to stage 1 and 2 disease, with tumors no larger than 4 cm, located in such a way that removal did not materially affect cosmetic results. The fact that for the most part, patients with those factors present are the only ones who benefit from breast conservation or for whom it is feasible "provides a great advantage for early detection. It is a very tangible reward for getting it when the tumor is smaller."

*Asked if he would advise women to ask their doctors up front if they are candidates for the conservative procedure: "Absolutely."

*"The next horizon (in the treatment of breast cancer) is in systemic therapy. We've been talking here about local and regional therapy. The next advances will come in systemic therapy, from chemotherapy, immunotherapy, hormonal treatment, monoclonal antibodies."

*Are there enough radiation therapists in the country to handle the demand if all the women who are candidates for segmental (or lumpectomy) treatment demand it? NCI Director Vincent DeVita estimated that would be 50 to 60 per cent of the 119,000 women who will get breast cancer this year. "That could be a problem," Fisher said. It also could be a problem training enough surgeons "to do a proper lumpectomy."

*Why did it take so long to get the study published? "I can't say. The peer review process sometimes takes a long time." But reporters would not let it go at that. What about the ethics of waiting a year to publicize the results?

"We're used to waiting a long time. Fourteen months is normal for some journals," Fisher answered.

"This study cost taxpayers $5.5 million," a reporter insisted. "During that year, 100,000 of them got breast cancer, and 35,000 of them may have had mastectomies unnecessarily (DeVita had estimated that about 15 per cent of patients underwent surgical procedures less than total mastectomy). One man, Arnold Relman, held it up." Relman is editor of NEJ.

"It had to have peer review," Fisher said. "I would have liked to see it published sooner. It's not something to be engaged in a polemic about."

Relman told the "Washington Post" that the delay was necessary for revisions and accumulation of more data. The study was "the most exhaustive and definitive to date... But I think before one can say with complete confidence there really isn't any difference in quality or quantity of life, we'll have to wait a bit longer," the Post quoted him as saying.

For the record, and for those who may have been on the moon or otherwise without access to the barrage of details in the media (including the March issue of **The Clinical Cancer Letter**), major findings of the study were:

—Preservation of the breast with or without radiation has not resulted in an adverse effect on recurrence of disease in the area of the breast or elsewhere, or in patients' survival at five years (calculated by life table analysis).

—Recurrence of tumor in the breast with segmental mastectomy is inhibited by external radiation; 92.3 per cent of patients with segmental mastectomy and radiation remain free of tumor in the breast at five years compared to 72.1 per cent of those receiving no radiation. In patients with positive lymph nodes, 97.9 per cent of the irradiated and 63.8 per cent of those without radiation remained tumor free, although both received the same chemotherapy (melphalan and 5-FU).

—Tumors occurring in the breast after segmental mastectomy and radiation were fewer in patients with positive lymph nodes, all of whom received chemotherapy, than in negative node patients, none of whom received chemotherapy. The suggestion that the two modalities may be additive, if not synergistic, could have important implications in development of new therapeutic strategies.

Although Fisher displayed a slide which showed survival at five years as 76 per cent for the total mastectomy group and 85 per cent each for the two segmental groups (one received irradiation, the other did not; all in all three groups with positive nodes received chemotherapy), he insisted at the press conference that survival for the three groups has to be considered equal. The difference in favor of the segmental groups is not statistically significant, he insisted.

The article, of which Fisher was the primary author, was not quite so reluctant about claiming an advantage for the lesser surgery. "Among both patients with negative nodes and those with positive nodes, survival was higher for patients treated by segmental mastectomy; the advantage for patients with negative nodes was significant (P=0.05)."

And again, "Disease free survival was higher (P=0.04) and distant disease free survival was slightly higher (P not significant) in patients undergoing segmental mastectomy plus radiation. The observed survival benefit in this group approached significance (P=0.07). A similar analysis of patients according to their nodal status indicated that at five years there were no significant differences between the two treatment groups. However, among patients with negative nodes, the group treated with segmental surgery and radiation had 10 per cent higher overall survival and disease

free survival rates—differences that approached significance (P=0.09 and 0.1, respectively)."

The abstract preceding the article called attention to the better results for the segmental plus radiation group compared to the total mastectomy group.

If those figures hold up and statistically significant survival rates for lesser surgery are demonstrated eventually, the implications are mind boggling to consider.

"We conclude," the authors state in the abstract, "that segmental mastectomy, followed by breast irradiation in all patients and adjuvant chemotherapy in women with positive nodes, is appropriate therapy for stage 1 and 2 breast tumors <4 cm, provided that margins of resected specimens are free of tumor."

Some other aspects of the study, which Fisher has called the most important clinical trial ever conducted and which may turn out to be the most analyzed, dissected, pondered over and praised/condemned:

*Patients in the segmental groups who were found by pathological examination of specimens to have tumor in the margins received an immediate total mastectomy. But they remained in the segmental groups for analysis. Likewise, if the tumor later recurred in the breast, they remained in the segmental group for analysis. Patients refusing the therapy of the group to which they were randomized nevertheless were continued in that group for analysis.

*Radiation consisted of a minimum of 5,000 rads, 200 per day five days a week, started no less than six weeks after surgery for those with negative nodes and eight weeks for those with positive nodes, the latter schedule to permit completion of the first course of chemotherapy. Supplemental boosts of radiation to the operative area (use of external beam or interstitial implantation) and radiation of regional nodes were not employed.

The article notes that the results demonstrated by the study's radiation protocol "approximate the incidence of recurrence observed by proponents of such additive radiation," and cites J.R. Harris and Samuel Hellman, who have conducted extensive lumpectomy studies in which irridium implants are used after external radiation. "Thus, the findings fail to indicate the need for a radiation boost to the excision site," the article continues. "Whether a boost of a particular type would contribute an additional advantage cannot readily be determined. Since some tumors recur in areas of the breast that are distant from the excision site, they are not likely to be prevented by a boost. Thus, the difference between results obtained with and without a particular type of boost is apt to be small. The size of the sample that would be required to conduct a clinical trial to settle this issue hinders its undertaking. Further evaluation of our data with respect to the characteristics associated with tumor recurrence after radiation may indicate which patients would benefit from a boost."

As might be expected, surgeons and possibly others are not exactly jumping on the bandwagon. They are reluctant to abandon a procedure which they have seen to be effective, for one which merely offers a cosmetic benefit. The critics all are calling for the world to wait for 10 year data.

Fisher suggested at the press conference that the lumpectomy will not come into general use until patients demand it.

Fisher's comment that saving the breast is a "tangible reward for early detection" touched on what may be the key issue in considering whether a woman should consider the surgery that offers the cosmetic benefit. If the availability of a breast conserving procedure, practical only for early stage disease, encourages more women to practice breast self examination and to have regular professional examinations, the trend toward diagnosis at earlier stages could be dramatically stimulated, with possible significant reduction in mortality. That could be the most important legacy of the NSABP study.

Fisher expressed appreciation to the physicians and others who were involved in carrying out the studies, and gave special recognition to the patients who participated. "At the top of the list for accolades are the 3,928 patients who quietly consented to be randomized into the two studies. Each of those women made a personal decision which in most instances must have been an agonizing one, to participate in a study which stood to have more of an effect on future patients with breast cancer than on themselves. Their courage is unparalleled in history. Next in line are the physicians who broke with the dogma of the time and who enrolled patients into one or both of the studies. It took great courage for some to enter even one such patient. Without the nurses who often played more of an influential role than the physicians, the trials would have floundered."

NIH PLANS CONSENSUS CONFERENCE ON BREAST CANCER ADJUVANT CHEMOTHERAPY

The segmental study will not be the only breast cancer topic of controversy this year. NIH has scheduled a consensus development conference on "Adjuvant Chemotherapy for Breast Cancer" for Sept. 9-11 at Masur Auditorium in the Clinical Center.

A consensus conference in 1980 concluded that

adjuvant chemotherapy might be of benefit to premenopausal patients but in a highly disputed decision suggested that it might not be for postmenopausal patients. The conferees called for further studies. NCI's Div. of Cancer Treatment has decided that it is time to take a look at the issues again and is sponsoring the conference along with the NIH Office of Medical Applications of Research.

The conference will address these questions:

*Have adjuvant chemotherapy trials in breast cancer demonstrated an increase in survival in any group of patients?

*Are there significant adverse effects of adjuvant therapy?

*What is the role of endocrine treatment in the adjuvant therapy of breast cancer?

*When should women with histologically negative axillary lymph nodes receive adjuvant therapy?

*What directions for future research are indicated?

Members of the conference panel will include biomedical investigators, practicing physicians, consumers, and represents of public interest groups. The conference will be open, but those who expect to attend should register by contacting Peter Murphy, Prospect Associates, Suite 401, 2115 E. Jefferson St., Rockville, Md. 20852, phone 301-468-6555.

NCI DIRECTORY OF FREQUENTLY CALLED NUMBERS AVAILABLE TO SUBSCRIBERS

Mailed with this issue of **The Cancer Letter** is the 1985 edition of our "NCI Directory of Frequently Called Numbers," published as a service to our subscribers.

This edition is a little late—there was no 1984 edition because NCI was still in the throes of the massive reorganization instigated by Director Vincent DeVita. Scores of staff members trading offices between the Blair and Landow Buildings were in limbo while NIH and NCI thrashed out problems with the Landow landlord. A directory published then would not have had a long shelf life.

Most of the moves have been completed, although the bureaucracy is never still, and the room and phone numbers listed here are not guaranteed.

In addition to providing addresses, phone numbers and (we hope) accurate spelling of names, the directory provides an NCI "table of organization" with the various branches and labs listed under their appropriate offices or programs—a look at who reports to whom.

Program directors, project officers and other staff members not included here usually may be contacted by calling the branch to which they are assigned. The directory is available only to subscribers of **The Cancer Letter.**

NATCHER SAYS MULTIPLE YEAR FUNDING WOULD NOT BE APPROVED BY COMMITTEE

Congressman William Natcher, chairman of the House Labor-HHS Appropriations Subcommittee, said last week that if the White House proposal to fund 1986 and 1987 renewals of 1985 grants with money from the 1985 fiscal year budget were presented to the subcommittee as a reprogramming request, it would not be approved.

"I believe that multiple year funding constitutes a reprogramming request," Natcher said at the hearing on the NCI budget. "If it is brought to this committee as a reprogramming request, I think we would not approve it."

The bills which include NIH appropriations generally leave most of the money undesignated, except for those amounts assigned to programs which have line item authorization. But the Appropriations Committees accompany their legislation with reports which spell out how much of the money should be spent. In the FY 1985 committee reports, NIH was directed to use enough of the additional money Congress appropriated above the President's request to fund about 6,500 grants.

The little trick being attempted by the Office of Management & Budget to reduce that number to 5,000 through multiple year funding amounts to reprogramming, Natcher argued. It has been the practice of Administrations in the past to request approval of House and Senate Appropriations Committees before deviating from the spending directives in the committee reports.

Whether that practice is enforceable remains to be seen. So far, no legal actions have been taken. The only congressional effort in that direction so far has been the resolution introduce by Congressman Henry Waxman (D.-Calif.), calling on the Administration to drop the multiple year funding scheme.

The Natcher subcommittee referred to objections by NCI scientific advisors, the latest of which was a letter from the Div. of Cancer Etiology Board of Scientific Counselors (copies of which also went to the Senate Labor-HHS Subcommittee, chaired by Lowell Weicker, the White House, NIH and the President's Cancer Panel). The letter said in part that OMB's "abrupt action will withdraw funding from extremely good research projects all around the country at a time when the pace of progress in cancer research and in other components of the NIH program has never been greater and when public expectations are appropriately very high. The judgment by Congress that many more than 5,000 grants should be supported should not be subverted by a fiscal maneuver... OMB's action reveals dangerous instability in our basic research investment and is extremely

discouraging to young peopole considering careers in biomedical research."

Individual members of the scientific community have been weighing in with their own efforts. Typical of the letters that have been inundating Congress and Administration officials is one from Herbert Kerman, director of the Regional Oncology Center in Daytona Beach. He called OMB's ploy "a devious device to circumvent the anti-impoundment laws... It will make it nigh impossible to reach the Year 2000 goals."

RFPs AVAILABLE

Requests for proposal described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs, citing the RFP number, to the individual named, the Blair building room number shown, National Cancer Institute, NIH, Bethesda, MD. 20205. Proposals may be hand delivered to the Blair building, 8300 Colesville Rd., Silver Spring, Md., but the U.S. Postal Service will not deliver there. RFP announcements from other agencies will include the complete mailing address at the end of each.

RFP NCI-CP-EB-51022-13
Title: Epidemiologic investigations of rare reproductive cancers
Deadline: Approximately May 23

The Environmental Epidemiology Branch of NCI's Div. of Cancer Etiology is soliciting proposals from qualified organizations to perform research and support type activities involving the initiation, supervision and coordination of case control investigations of cancers of the vulva and vagina. The objectives of this acquisition are to (1) identify environmental exposures of women that predict the risk of developing vulvar and vaginal cancers; (2) attempt to define possible mechanisms of carcinogenesis through serologic indicators.

A maximum of four contracts may be awarded to those organizations possessing the capabilities for locating appropriate vulvar and vaginal cancer cases and controls and soliciting their cooperation for interviewing and obtaining biologic specimens. In order to obtain a total sample size of approximately 300 cases of vulvar cancer and 150 cases of vaginal cancer diagnosed over a 30 month period (and 600 appropriate controls), it is anticipated that several contracts will be awarded to separate area centers, which might be specialized cancer centers, large referral hospitals, cancer registries or any other facilities where sufficient numbers of patients are diagnosed and/or treated.

Selected area centers will be required to accrue a minimum of 75 incident cases of insitu and invasive vulvar cancer diagnosed over a 30 month period and 35 comparable cases of vaginal cancer. In addition, one award will be to a coordinating center which will ensure that standardized study approaches are being taken at each of the area centers. The organizations selected as area centers will be involved in both research and support activities; the organization selected as the coordinating center will be involved in only resource activities.

The primary activities of the area centers will be (1) liaison with study institutions; (2) identification of study subjects; (3) development of study procedures; (4) data abstracting and interviewing; (5) obtaining biologic specimens; and (6) providing quality control throughout the study.

The coordinating center will have primary responsibility for (1) developing data collection forms and associated manuals; (2) training field personnel; (3) coding collected data; (4) entering data into computer readable form; and (5) editing data and producing preliminary analyses.

The concept from which this RFP was derived was approved by the DCE Board of Scientific Counselors last fall and was reported in The Cancer Letter, Nov. 9, page 2.

Contract Specialist: Sharon Miller
RCB Blair Bldg Rm 114
301-427-8888

RFP NCI-CO-54052-36
Title: Div. of Extramural Activities program support
Deadline: Approximately May 10

The services required will be definitized by work orders issued during the period of performance. The work orders will be issued under the following four areas: (1) National Cancer Advisory Board and President's Cancer Panel support; (2) quick turnaround assistance; (3) ad hoc technical assistance; and (4) task order development and administration.

These services will be provided under a level of effort, cost plus fixed fee contract for 37,867 person hours. Offerors will not be considered eligible for award unless they can demonstrate their ability to meet with the project officer in Bethesda and then provide certain deliverables, such as slides or charts, to Bethesda within 24 hours.

The proposed contract described here will be a 100 per cent small business set aside.

The concept from which this RFP was derived was approved by the National Cancer Advisory Board Committee on the Office of the Director last fall and reported in The Cancer Letter Dec. 7, page 5.

Contracting Officer: Patricia Rainey
RCB Blair Bldg Rm 314
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The Cancer Letter _Editor Jerry D. Boyd
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