

THE

CANCER LETTER

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POST STARTS SERIES WITH HORROR STORIES ON DRUG TESTING; DEVITA SAYS THEY ARE "SLANTED, DISTORTED"

The long developing *Washington Post* investigation of the National Cancer Program broke into print this week with the expected attack on clinical testing of experimental anticancer drugs. The consequences for clinical research could be devastating.

Two crack *Post* reporters, Ted Gup and Jonathan Neumann, have
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In Brief

ADAMSON'S APPOINTMENT OFFICIAL AS DCCP DIRECTOR; NCI HOLDS CURRENT SPENDING TO 12 PERCENT LEVEL

RICHARD ADAMSON'S appointment as director of NCI's Div. of Cancer Cause & Prevention has now been made official. HHS Secretary Richard Schweiker approved the appointment this week. Adamson has been acting director of the division for more than a year. Adamson, 44, received a PhD in pharmacology from Iowa State Univ. in 1961 and joined NCI in 1963 as senior investigator in the Laboratory of Chemical Pharmacology. He became chief of that lab in 1973. During 1979-80 he was on leave from NCI to work as a senior policy analyst in the White House Office of Science & Technology Policy. . . . FY 1982 BUDGET picture for NCI and the rest of HHS remains bleak, with the Administration determined to extract a 12 percent reduction from its original proposal. NCI presently is operating at the continuing resolution level established by Congress in which spending is limited to the 1981 level of \$989 million, prorated for the Oct. 1 to Nov. 20 period, when the resolution expires. Anticipating the possibility that the 12 percent cut will be imposed, NCI is holding its spending through Nov. 20 to the \$902 million level, prorated—12 percent under the President's request of \$1.026 billion. Congress is balking at the severe reductions in health and social programs, probably will settle on an appropriations bill with more money in it than the President wants, risking a veto. Congress is likely to sustain a veto, requiring more continuing resolutions, and the President still has the deferral and rescission options. The House has completed action on the bill, which would give NCI \$1.030 billion. The Senate HHS Appropriations Subcommittee marked up its bill, with NCI at \$1.034 billion, but the full committee has yet to act, and no date has been scheduled for it to do so. The pinch on NCI will not be felt until early 1982 when grant funding demands require more outlays. . . . MEANWHILE, NCI is bringing its advisors into the process of determining where the cuts will be made, if cuts there must be. Members of the National Cancer Advisory Board will receive lists of the Institute's programs and will be asked to rank them by priority. The four Boards of Scientific Counselors will receive similar lists of programs in their respective divisions.

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WASHINGTON POST SERIES DWELLS ON DRUG DEATHS, ADVERSE REACTIONS

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spent nearly a year investigating the Cancer Program. They told *The Cancer Letter* last November that they were taking on the project with "open minds, no preconceived ideas on the direction the investigation will take. We'll let the chips fall where they may."

The chips fell this week in the form of a series of horror stories in which Gup and Neumann claimed to have documented 620 instances where experimental drugs were implicated in the deaths of cancer patients. They selected some of the more gruesome and heart rending to describe in detail.

The four part series on testing of experimental drugs was scheduled to end Oct. 21. The *Post* said that in coming months, other areas of what it called the "War on Cancer" will be examined, including "the psychology of cancer doctors and patients, the causes of cancer and possible methods of prevention, basic scientific research in cell biology and genetics, and the politics of cancer."

The *Post* in its Oct. 19 issue used a rebuttal by NCI Director Vincent DeVita to the opening article. DeVita submitted another response the following day to the second article, which was not used, and planned to follow with others.

The series opened with a set of statements by the reporters describing conditions which, while it may have been news to the two reporters, certainly was not to clinical investigators:

"While all anticancer drugs can cause side effects among some of those who take them, the experimental drugs—in addition to leading to hundreds of deaths—have elicited a nightmarish list of serious adverse reactions, including kidney failure, liver failure, heart failure, respiratory distress, destruction of bone marrow so the body can no longer make blood, brain damage, seizure, coma, and visual hallucinations.

"So little is known about many of these chemicals that doctors have found these ironic results: In some cases the experimental drug actually stimulated tumor growth rather than stopped the cancer; and in other tests, doctors and researchers found that the experimental drugs themselves caused cancer.

"In many cases, the experimental drugs have been given to patients even years after studies failed to show that they were of use in the fight against cancer. The first phase of the experimental drug program, in fact, is primarily designed not to combat cancer but to find out how toxic the drugs are."

The first article went on to claim that evidence of mismanagement of patient records at leading hospitals and cancer centers, miscalculation of doses with fatal results, administration of drugs not approved by the FDA for human use and not authorized by NCI.

"The litany of death and suffering from experi-

mental drugs has become an accepted part of life at some hospitals around the nation," the article said.

The opening article included a couple of quotes by Robert S.K. Young, the former FDA oncology group leader who appears to have dedicated his career to opposing anticancer drug development and testing. About five years ago, investigators found one IND application after another blocked by Young, sometimes for nitpicking technical reasons, sometimes for no apparent reason at all. He fiercely opposed the new toxicology protocol which substantially reduced the cost and time of getting drugs into the clinic. When the protocol was approved by FDA's own Oncologic Drugs Advisory Committee (after being approved by the Board of Scientific Counselors of NCI's Div. of Cancer Treatment), and then was approved by the director of FDA's Bureau of Drugs, Young resigned as group leader and carried on his fight. The FDA commissioner recently threw out Young's citizen's petition against the new protocol.

Nevertheless, Gup and Neumann selected a man whose views had been disavowed by the scientific advisors to both NCI and FDA and by his own superiors to feature in their lead article. Young did provide them with some grabby statements:

—"Sometimes there is little regard for people's lives. In Boston a hospital tested a new NCI drug on children. Their kidneys were lost within days. This was no big deal, because NCI new drugs are routinely given out with literally no safeguards for people who will receive them."

—"There are so many analogies between the 'War on Cancer' and the war in Vietnam. It's scary. You've got the generals, the NCI. And you have this attitude among the generals: 'We have to burn the village to save it.'"

That set the tone for the series. There followed case histories, with patients, their physicians, and sometimes family members and nurses, all being named. Most ended with the patients' deaths, usually caused by the drugs, always after enduring agonies from drug effects.

The articles have dwelled on repeated use of the same drugs in phase 1 studies despite the severe side effects and despite lack of beneficial effects for the patients.

The *Post* so far has used two positive sidebars by Gup and Neumann. One dealt with the development of cisplatin as a successful anticancer agent. The article noted that the drug was almost abandoned because of severe kidney toxicity but that a method was developed to overcome that problem and cisplatin is now one of the most successful drugs against some forms of cancer.

The other positive article reported on a 13 year old Maryland girl treated at Johns Hopkins Oncology Center for neuroblastoma. After surgery and chemotherapy failed to keep her in remission, her physi-

cians—Brigid Leventhal, Herbert Kaiser, and David Hall—proposed using high doses of adriamycin and cytoxan with autologous bone marrow transplant. That worked, and the girl has been free of disease for two years.

In several of the case histories reported in the first article, Gup and Neumann cited drugs as failures which appeared on the high priority list of drugs going through NCI's Drug Development Program in 1979. Each time, they pointed out this was one of the "high priority drugs listed by DeVita in 1979."

The Washington Post-Los Angeles Times News Service distributes articles from the two newspapers to other subscriber newspapers around the country. The Gup-Neumann articles have appeared in other papers, although not (as of *The Cancer Letter's* press time) in the *Los Angeles Times*. DeVita's first response apparently has not appeared in many, if any, of the papers. The *Post* series also is being distributed, summarized, by the Associated Press.

As a service to Cancer Program advocates who may wish to combat the negative aspects of the *Post* series, *The Cancer Letter* will publish each of DeVita's responses. Following is the first, which may be clipped and reproduced without further authorization:

The article by Ted Gup and Jonathan Neumann in the *Post* Oct. 18 presented a tragic lack of understanding of cancer treatment and the national program to develop drugs that are effective in treating cancer.

It bears repeating that cancer patients—and the doctors treating them—have as their first goal the successful treatment of the disease. In this context, many patients feel that it is worthwhile putting up with side effects of treatment knowing that the treatment may prolong their lives or provide a cure. All of us who work on the cancer problem wish there were no side effects related to treatment, and much of our work now is to develop treatments that are effective without causing side effects.

It also bears repeating that, contrary to the impression left by the article, much progress has been made in treating cancer. Of the 785,000 patients diagnosed with serious cancers in 1980, 356,000—45 percent—are potentially curable. This includes 220,000 patients curable with the oldest treatment, surgery; 90,000 patients curable by surgery combined with radiation therapy, a treatment that has come into its own only since 1947; and about 46,000 curable as the result of adding chemotherapy, the newest form of cancer treatment.

The article did not mention that cancer mortality rates are falling in the age group under 45 years old. It did not mention that survival rates have increased significantly for seven of the 10 major forms of cancer in whites and six of the 10 in blacks. These major gains are among cancers of the breast, colon, rectum, bladder and prostate, to mention some. In addition, survival gains for cancers striking young Americans are even more substantial. These cancers include childhood leukemia, Hodgkin's disease, testicular cancer and others. Unfortunately, not all patients with any type of cancer are cured so it is essential to continue research to develop better treatments.

Several points need to be made about the distortions in the article:

One, Gup and Neumann totally missed the concept that anticancer drugs are meant to be used in combination with other forms of treatment, such as surgery and radiation, and

that they are expected to be most effective in treating early cancers. For ethical reasons, all drugs are first tested against advanced cancers afflicting patients for whom no other hope exists. Even a few responses against advanced cancers can mean major effect against early cancers, particularly when the drugs are used in conjunction with surgery and radiation therapy.

Two, the writers state that they have documented 620 cases where experimental drugs were implicated in the deaths of cancer patients. Any death associated with treatment causes anguish to the family of the patient, to those who were providing the care, and to those of us who are working to help all cancer patients. The fact remains, however, that such cases are unusual. Gup and Neumann did not mention that hundreds of thousands of patients have participated in our research programs to develop anticancer drugs. Remember also that 46,000 patients are cured every year because of anticancer drugs. The contrast between lives saved and risks taken is striking.

Three, the article did not make clear that most drugs side effects are temporary, predictable, and manageable with standard techniques. Different patients experience different effects, and some experience no side effects at all. As I noted above, much research now is devoted to reducing side effects and developing new drugs with few side effects.

Four, the article implied that studies of particular anticancer agents are carried on long after the compounds have been shown to be toxic and after they were shown to have little effect in treating particular types of cancer. Again, Gup and Neumann missed or are ignoring the fact that specific anticancer drugs often work only against a specific type of tumor. When a drug is tested in patients it is done at many different dose levels, schedules of administration, and against a variety of different cancers. If a drug proves to be ineffective against one or more types of cancer, it does not mean it will not be effective against other cancers. Cisplatin, a drug whose success the writers described, is not effective against all cancers. In other words, early discouraging results do not mean an experimental drug will not be effective against another tumor yet to be tested.

Five, Gup and Neumann repeatedly referred to my 1979 list of high priority drugs. But they twisted the meaning of that list, implying that I was predicting these drugs would have great beneficial effect in patients. My 1979 list was of drugs that had performed well in animal tests, and therefore had high priority for human testing. There were no predictions that any of those compounds would become miracle drugs for treating people.

Six, in discussing particular anticancer drugs, such as MeCCNU, Gup and Neumann point to side effects of renal failure and acute leukemia. These are delayed side effects that develop slowly and are difficult to detect and difficult to predict with any animal testing. The kidney problems with MeCCNU, for example, showed up as an acute, or immediate, effect in the animals, but did not show up as an immediate problem among patients who received the experimental drug. The first case in humans was not detected until more than a year after the patient had stopped receiving the drug and after several years of use with patients. Under such circumstances, the development of kidney damage in a cancer patient with a long history of the disease and many treatments can be difficult to link with any one drug when the observation is made for the first time.

Seven, Gup and Neumann imply and quote a cancer expert as saying that Phase 1 studies provide patients no potential for cure. This is clearly a distortion of what occurs. Phase 1 studies do sometimes result in significant responses, and the drug vincristine provides a striking example. Potential for beneficial effect exists and is an important part of the ethical

base for conducting such studies.

Eight, Gup and Neumann consistently make the point that only six drugs are effective in treating cancer. That, too, is just plain wrong. There are more than 40.

In summary, it is unfortunate that the *Post*, particularly now that Washington is a one-newspaper city, has chosen to present such a slanted and distorted view of cancer research. Gup and Neumann should keep in mind one important point: cancer is lethal if left untreated. The possibility of treatment side effects and the small but real chance of drug-related death has to be balanced against the nearly 100 percent chance of death if experimental therapy is not attempted for the advanced cancer patients who participate in our studies. All cancer patients experience anxieties and doubts at one time or another during treatment. It would be tragic if cancer patients who read this article, and those that will follow, turn away from their treatment.

Solomon Garb has seen the cancer problem from both sides. A clinical pharmacologist who dedicated his career to finding better treatments for cancer, he has been a cancer patient himself now for almost a year. He has been battling stomach cancer, first with extensive surgery, and then with chemotherapy. So far, there has been no recurrence, but he has paid the price with severe side effects from the drugs. He almost died from reaction to treatment last April.

"I don't mind," Garb said Monday. "I'm just glad to be alive. It's been tough, but I'll take treatment over the alternative any time."

Five year survival with stomach cancer is 10-15 percent, with most recurrences coming within the first 18 months. Garb figures he is within sight of beating it.

Garb was dismayed by the *Post* articles. He sees it not only as a threat to progress by discouraging patients from participating in clinical trials, but also as a threat to the entire National Cancer Program. As chairman of the Citizens Committee for the Conquest of Cancer, Garb was a leader in the movement which led to the National Cancer Act of 1971. Much of his time in the years since has been spent fighting to keep the Act intact, and fighting for the money to properly implement it.

Garb had a suggestion for Cancer Program advocates for action they might take if their local newspapers use the *Post* series or any part of it: "Go see the editor and take Vince DeVita's statement with you." Local AP bureau chiefs also might be interested in DeVita's response, he said.

Garb said he agreed with one aspect of the series. "A lot of us have argued for years against phase 1 studies. We don't think they are necessary. They can be combined with phase 2. The argument there is not with us (clinical investigators) or NCI, but with FDA."

The opening article included statements from DeVita and others. His was the only one which could be considered positive.

"I believe sincerely that patients want those therapies, they want to go into phase 1 studies," DeVita

was quoted as saying. "Patients do not want to go out of this world without trying in the majority of cases. You stop putting cancer drugs out there and there will be an avalanche of people clamoring for drugs."

Michael Hensley, who the *Post* said was an FDA investigator, reportedly said, "Cancer chemotherapy is off limits for FDA investigators. The rule book is thrown out when it comes to cancer chemotherapy. I don't know if it's written in as many words, but there's absolutely no question about it. Ask anyone around here. I have been told many times that NCI was off limits."

All NCI has asked of FDA is that prospective anti-cancer drugs not be considered in the same category as new headache pills. Because so many cancer patients will die without some new therapy, NCI staff and cancer investigators feel it is not logical to demand as many safeguards as would be required for a new medicine designed to treat non-life threatening ailments. If Hensley was told NCI is "off limits," (whatever that may mean), it was because his superiors were overreacting to NCI opposition to the type of nitpicking they endured from Young.

Linus Pauling was quoted as saying, "Why make the patient miserable for his last few days. I don't think the terminal cancer patients should be used as guinea pigs. You have to carry out human experiments to make progress, but you must be careful that you don't sacrifice human beings."

Charles Moertel, director of the Mayo Comprehensive Cancer Center, was quoted as saying, "The state of the art, generally, it's awfully rudimentary. We have hit on some areas more or less by luck. We have accomplished a lot but it's been like swatting flies with a sledge hammer. It's been rather blind. I suppose as far as end products are concerned it's been a bust, but then so is the overall treatment of cancer."

Vincent Bono, who until earlier this year was chief of the Investigational Drug Branch in NCI's Div. of Cancer Treatment, was quoted as saying, "In phase 1 or phase 2, human beings are actually being used as guinea pigs. Phase 1 is like donating your body to science while you are still alive."

The *Post* series gives more ammunition for Sen. Paula Hawkins (R.-Fla.) to shoot at DeVita in the hearing scheduled for her Labor & Human Resources Subcommittee on Investigations & Oversight Nov. 3. Hawkins took the floor of the Senate this week to quote from the articles and to say she has found "dangerous deficiencies" in NCI's Drug Development Program.

The hearing will start at 9 a.m. in the Dirksen Senate Office Building, Room 4232.

**NIH SAYS ITS PROBE FOUND CHARGES
OF DOUBLE PAYMENT "BASICALLY CORRECT"**

The NIH Div. of Management Survey & Review has reported that its investigation of charges involving double payment from two cancer center core grants to a Bowman Gray scientist has found the allegations "basically correct" (*The Cancer Letter*, Sept. 4).

The double payment allegedly occurred during a two and a half month period last year when the scientist, Edward Modest, left his position at Sidney Farber Cancer Institute for a new one at Bowman

Sept. 14, 1980.

On June 2, 1980, Dr. Modest sent a letter of resignation to his supervisor, Dr. Emil Frei, principal investigator on the Sidney Farber Cancer Core Grant, CA-06516. He stated that, "... in connection with my move to Bowman Gray, I should like to inform you that my last working day at the Sidney Farber Cancer Institute will be 30 November 1980 and to request they I be granted the usual termination pay for the period 1 Dec. 1980 through 31 Jan. 1981." Also, Dr. Modest stated that it would be necessary for him to continue his laboratory operation at Sidney Farber through Nov. 30, 1980, since his laboratory space at Bowman Gray would not be ready as anticipated. Further, Dr. Modest requested that his research grant be relocated to Bowman Gray effective Dec. 1.

ber until Nov. 30. Also, Dr. Charles Spurr, principal investigator on the Bowman Gray Cancer Core Grant, CA-12197, said that he knew Dr. Modest's laboratory was not completed yet but that he had thought Dr. Modest had been provided office space on July 1, 1980, and he had assumed that Dr. Modest had begun to work at Bowman Gray on that date.

After we completed our review at Bowman Gray, the comptroller of the Bowman Gray Cancer Center informed us that the salary charges to grant CA-12197 for Dr. Modest for the period from Sept. 15, 1980 through Nov. 30, 1980, would be removed from the grant. He said that, even though Dr. Modest's personnel papers showed he was to be charged 80 percent to the grant for that period, the salary charges to the grant would be removed because his time and effort report showed that 100 percent of his effort should have been charged to a university account. The comptroller said this is in accord with their normal practice. He said that Bowman Gray routinely reviews their time and effort reports and compares them to their employees' personnel papers. When they find discrepancies between them, they adjust their accounts to reflect the information shown on the time and effort reports.

NCAB SUBCOMMITTEE APPROVES CONCEPTS FOR RECOMPETITION OF FIVE CONTRACTS

The National Cancer Advisory Board Subcommittee for Review of Contracts & Budget of the NCI director's office has given concept approval to the recompetition of five contracts at an estimated total cost of more than \$10 million.

The subcommittee also approved the concept of sole source renewal of two contracts supporting activities of the International Cancer Research Data Bank, totaling an estimated \$2.5 million over three years.

Contracts approved for recompetition were:

Technical writing, publication distribution, and telephone answering services in response to cancer related inquiries. Current contractor is Biospherics Inc. Estimated first year award, \$1.4 million, total for three years, \$4.6 million. Narrative description of the program:

The National Cancer Act and its amendments state that the director of NCI "shall provide and contract for a program to disseminate and interpret on a current basis, for practitioners and other health professionals, scientists and the general public, scientific and other information respecting the cause, prevention, diagnosis and treatment of cancer."

This project will provide contractor support to the Office of Cancer Communications for dissemination of current cancer information in response to inquiries from the general public, patients, persons at high risk of cancer, health professionals, and those who work with them.

OCC was responsible for responding to a total of 308,313 inquiries in 1980. More than 90 percent of these inquiries were answered by a contractor. The volume of inquiries varies greatly from day to day, and month to month, because of items in the news media and information dissemination projects of OCC.

More than 60,000 inquiries were received during the most active month; about 500 telephone inquiries were received during the most active day. It would be difficult for the government to staff a unit adequately for such a varying workload. A government staff sufficient for average workloads could not handle peak periods, leading to public frustration. A contractor on the other hand, can offer flexibility both in staffing and office space. The contract mechanism will permit

this project to be carried out with close direction and surveillance by OCC.

The contractor should be prepared to write answers for up to 10,000 personal letters and 500 congressional/controlled inquiries per year, answer up to 48,000 telephone inquiries per year, store 18 million publications requiring up to 380,000 cubic feet of storage space, fill up to 250,000 publication orders per year, and distribute up to 22 million publications per year in response to orders and as enclosures in letters. Also the contractor should be prepared to write, edit, or otherwise process and distribute materials related to the communication and education activities of NCI.

Support services of the office of the director. Current contractor is JRB Associates Inc. Estimated first year award, \$495,000, total for three years, \$1.6 million. The narrative:

A variety of support services is provided to the office of the director by this contract. These include quick response graphics and other materials required for congressional and other presentations, assistance to the Office of Program Planning & Analysis in connection with preparation of review drafts of the director's report/annual plan, some limited conference support, and special projects. Included in the latter category have been initiatives required by the secretary, HHS (the asbestos awareness campaign), and the massive task of reviewing and summarizing the archive of PHS documents relating to the effects of atomic weapons testing on health.

The three year contract awarded to JRB Associates covered the period from 9/30/77 to 9/29/80. For several reasons (primarily because of the difficulty in projecting future assignments and work loads), the contractor has expended funds more slowly than had been anticipated. The contractor's most recent estimates indicate that the contract could be extended through February, 1983 if expenditures continue at their present rate, using funds originally budgeted for the first three years.

Analytical services in support of the Div. of Extramural Activities. Current contractor is Capital Systems Group Inc. Estimated first year award, \$300,000, total for three years, \$955,000.

This project will provide the following type of support: (1) Technical analyses, including the collection and analysis of quantitative technical data (e.g. fiscal, programmatic, resource, administrative, technical) and the development of methods, techniques, formats, etc., for technical analyses and guidance for their use; (2) Science analyses, including the collection and analysis of qualitative science information (e.g. scientific activities, findings, accomplishments, literature, state of the art) and the development of methods, techniques, formats, etc., for science analyses and guidance for their use; (3) Operations support, including a) policy analyses, b) operations analyses, c) development of processes, procedures, and systems, d) development of analysis/collection methods, techniques, formats, etc., e) quick-reaction capabilities, and f) special projects; (4) Documentation coordination including a) the design and writing of a wide range of books, booklets, manuals, handbooks and other similar documents; b) providing briefing materials, i.e., charts, slides, view graphs, etc., for conferences, workshops, the NCAB, President's Cancer Panel, etc., and c) editing, proofreading, typing, transcription and other similar services, and (5) conference coordination to assist DEA, GAB, and/or GFDAB in the planning, development and conduct of conferences, workshops, business meetings, etc. This task also includes providing DEA with assistance in managing regularly scheduled meetings as well as ad hoc or new working groups. The scheduled meetings include the NCAB and its subcommittee meetings, the President's Cancer Panel, and grant and contract review committees of NCI.

Preparation and updating of clinical protocol summaries.

Current contractor is Informatics Inc. Estimated first year award, \$265,000, total over four years, \$1.3 million.

The International Cancer Research Data Bank Program was established in response to a congressional mandate to collect, catalog, store, and disseminate cancer research information. This project provides a unique, comprehensive and detailed source of both current awareness and retrospective information about some 2,600 clinical cancer therapy protocols active since 1976 (about 1,250 are currently open to patient accrual; the rest are now closed).

This information is prepared from original/updated protocols by specialists who carefully extract critical data elements including protocol title; name, address and telephone number of the protocol coordinator; all identification numbers; protocol objectives; entry criteria; protocol outline; stratification criteria; special study parameters; end points; current patient accrual; dosage schedules and dosage forms; multiple index terms; and supporting agency information.

The resulting summaries of protocols represent a comprehensive and unique file of current and retrospective data covering the entire spectrum of clinical trials carried on in the U.S. and other countries over the past six years. The data are available through two sources:

1. A database called CLINPROT (for CLINical PROTOcols) which is available through the MEDLARS system of the National Library of Medicine. This database can be searched by type of tumor treated or by type of agent or combination of agents used. Such searches are available at 1,500 locations in the U.S. and 13 other countries.

2. In addition, currently open protocols are published each year in a Compilation of Experimental Cancer Therapy Protocol Summaries which lists the major data elements for each protocol. Indexes permit easy searching of the protocols by type of tumor treated (subdivided by type of agents used), agents tested (subdivided by types of tumors treated by each agent), and all protocol identification numbers.

Current Cancer Research Project Analysis Center (CCRESPAC). Current contractor is the Smithsonian Science Information Exchange which probably will go out of business at the end of this month. If it does, NCI intends to offer the contract for competitive award. Estimated first year cost, \$570,000, total for three years, \$1.9 million. The narrative:

CCRESPAC provides a unique and comprehensive source of descriptions of current cancer research projects carried out in the U.S. as well as in 85 other countries. This data is designed to promote the exchange of ideas and information about cancer research projects currently under way before the results are published. CCRESPAC also identifies principal investigators who are the prime users of ICRDB services and provides invaluable data for program analysis and program planning. A worldwide network of influential scientists and administrators at cancer centers and funding agencies has been established to facilitate the input of project descriptions from researchers and administrators from countries around the world.

The data at CCRESPAC is available to health professionals through two sources:

1. A database called CANCERPROJ (for CANCER PROJects), which is available through the MEDLARS system of the National Library of Medicine. Specific descriptions can be retrieved by investigator, research topics, hierarchical and subject codes, country and several other data elements. CANCERPROJ searches are available at 1,500 locations in the U.S. and 13 other countries.

2. Project descriptions are included in one or more issues of an annually updated series of 55 technical documents known as Special Listings, each covering a major area of cancer research. Investigators automatically receive specific

Special Listing(s) with descriptions of projects related to their current research. This easy access to knowledge about areas of ongoing research fosters communication among the investigators and avoids unnecessary duplication of effort.

This project supports the collection and processing of project descriptions, preparation of Special Listings, provision of computer tapes for the CANCERPROJ database and performance of special searches in response to requests for information from scientists, clinicians and administrators. Concept approval is requested for the period of October 1981 through October 1985.

The cost estimates listed with each contract included in concept review are not firm figures established for those projects and should not be used as the basis for developing proposals. Those wishing to participate in any competition for a contract should obtain copies of the RFP before writing their proposals. Those who rely on the cost estimates in concept reviews do so at their own risk. When RFPs are available, announcement of their availability will be published in *The Cancer Letter*.

The two noncompetitive renewals sought for the ICRDB include printing and other services for production and distribution of CANCERGRAMS, Special Listings, and Oncology Overviews; and funds for the Scientist to Scientist Information Exchange Program.

Document printing, dissemination and announcement services. Contractor is the National Technical Information Service. Estimated first year award, \$695,000, total for three years, \$2.2 million.

International Scientist to Scientist Information Exchange Program. Contractor is Union Internationale Contre le Cancer. Estimated first year award, \$150,000, total for two years, \$300,000.

RFPs AVAILABLE

Requests for proposal described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. Write to the Contracting Officer or Contract Specialist for copies of the RFP, citing the RFP number. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs to the individual named, the Blair Building room number shown, National Cancer Institute, 8300 Colesville Rd., Silver Spring, Md. 20910. RFP announcements from other agencies reported here will include the complete mailing address at the end of each.

RFP N01-CP-15811-72

Title: *Data bank on environmental agents*

Deadline: *Dec. 8*

The Office of Environmental Cancer of NCI is interested in receiving two year proposals to develop information resource(s) to handle large volumes of data and information encompassing several scientific disciplines, i.e., carcinogenesis, mutagenesis and toxicological research to the effect of multiple stresses such as water contaminants and their interactions in environmental cancer assessments.

There are presently four organizations awarded basic ordering agreements, which are scheduled to expire March 28, 1982. Two tasks were awarded under these BOAs: (1) N01-CP-05633-01, "Carcinogenicity of drugs and medical procedures," and (2) N01-CP-05633-02, "Carcinogenicity of cosmetic ingredients."

The Office of Environmental Cancer is interested in recompeting this effort. Proposals responding to this RFP shall include searching the proper sources to supply the data and information required, i.e., (1) supplying bibliographies with or without a screen for relevance (format to be specified), and (2) supplying critical analyses of defined areas of toxicology, carcinogenesis and mutagenesis. Involvement will range from scanning data and information and supplying reports on information prepared by established guidelines to actual involvement in manuscript preparation (i.e., analyses, writing, editing) and possibly printing and distribution.

Other examples of objectives of interest shall include state of the art reports on the classification of water and air pollutants as carcinogens, cocarcinogens and/or mutagens. Such reports include documentation regarding the presence of these agents in air and/or water as well as a survey of their biological activity as reported in the open literature.

The chemical and biological data being surveyed for these compounds are to be organized into monographs based on the International Agency for Research on Cancer format for their series: "Evaluation of the Carcinogenic Risk of Chemicals to Humans."

Although the actual specific task requirements are not presently known, it is intended that basic ordering agreement(s) will be awarded to those proposers who are capable of performing the tasks envisaged in the request for proposals. As the specific requirements develop, the tasks will be competed only among those who are awarded a basic ordering agreement.

Contract Specialist: Jackie Matthews
RCB, Blair Bldg. Rm. 2A07
301-427-8771

NCI CONTRACT AWARDS

Title: Mammalian cell transformation.

Contractors: Microbiological Associates, Task I, \$647,643; Arthur D. Little, Task I, \$848,254; Microbiological Associates, Task II, \$794,119; Northrop Services, Task II, \$719,247; Litton Bionetics, Task III, \$1,184,033; Northrop Services, Task III, \$761,663; Biotech Research Labs, Task III, \$386,247.

Title: Two alteration/renovation/maintenance/upgrading projects at Frederick Cancer Research Center, modification

Contractor: Litton Bionetics, \$122,098.

Title: Production and isolation of Type II (Immune) human interferon, master agreements:

Contractors: Meloy Laboratories, Flow Laboratories; Immuno Modulator Laboratories Ltd., and Associated Biomedic Systems.

Title: Production and isolation of Type II (immune) human interferon, Task I

Contractor: Meloy Laboratories, \$269,973.

Title: Relationship between thyroid diseases and breast cancer, continuation

Contractor: Massachusetts General Hospital, \$210,143.

Title: Benign and noninvasive breast lesions in populations at different risks for breast cancer, continuation

Contractor: Univ. of New Mexico Medical School, \$30,000.

Title: NCI sera bank facility for Breast Cancer Task Force, continuation

Contractor: Mayo Foundation, \$77,800.

Title: Development and validation of a multiple endpoint mutation system in cultured mammalian cells

Contractors: Allied Corp., Morristown, Penn., \$797,817; and Bioassay Systems Corp., Woburn, Mass., \$562,295.

Title: Therapy of patients with large bowel carcinoma, continuation

Contractor: New York State Dept. of Health/Health Research Inc., \$6,667.

Title: Data management and analysis center for breast cancer detection demonstration project followup

Contractor: University City Science Center, Philadelphia, \$815,867.

Title: Children's Cancer Study Group—cancer control program for clinical cooperative groups, six-month renewal

Contractor: Univ. of Southern California, \$381,618.

Title: Lipid levels and cholesterol metabolism in relation to human breast cancer risk, continuation

Contractor: Mount Sinai School of Medicine, New York, \$79,778.

The Cancer Letter — Editor Jerry D. Boyd

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