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FDA, CLINICAL INVESTIGATORS HEAD FOR SHOWDOWN OVER DEMAND TO SEE INDIVIDUAL PATIENT RECORDS

The Food & Drug Administration and clinical cancer investigators appear headed for another confrontation, this time over the demand by FDA field staff to inspect individual patient records—including, in some cases, patient names. (Continued to page 2)

In Brief

TWO NEW SECTION CHIEFS NAMED IN NCI RESEARCH CONTRACTS BRANCH; S. 988 MARKUP SET FOR APRIL 24

NCI RESEARCH CONTRACTS Branch has two new section chiefs. Hugh Mahanes, who headed the Control & Rehabilitation Section before he became administrative officer of the Div. of Cancer Control & Rehabilitation, returns to the branch as chief of the revamped Biology & Diagnosis Section. With most of the biology related contracts being phased out in favor of grants, that part of the name is being dropped from the section. The late Philip Webb was chief of that branch. Gary Kelly, who is chief of the Contract Management Section in the National Institute of Dental Research, will become chief of the Control & Rehabilitation Section. David Keefer, former chief of that section, is now deputy to Branch Chief James Graalman. . . . **SUBCOMMITTEE MARKUP** of S. 988, Sen. Edward Kennedy's bill renewing the National Cancer Act and other biomedical research authorities, now is tentatively scheduled for April 24. Only major change being contemplated from previous drafts of the bill relating to the Cancer Program would increase from three to five years the length of cancer center core grants. The subcommittee is not inclined to go along with the Assn. of American Cancer Institutes' request for a line item for centers. . . . **MEANWHILE, HOUSE** Health Subcommittee has not yet scheduled markup on H.R. 6522, Chairman Henry Waxman's version of the same legislation. NIH is developing some compromise proposals to offer Waxman, to soften or eliminate aspects NIH considers unworkable. Two provisions NCI particularly does not like are the requirement for National Cancer Advisory Board approval of contract proposals and for study section type review of intramural research. Board review of contracts would add a year to 18 months to the process and also would run afoul of present federal procurement regulations. Intramural research now undergoes peer review by boards of scientific counselors; study section type review would be inappropriate and unnecessary, NIH executives feel. . . . **TWO EUROPEAN** cancer centers have been added by Bristol-Myers to its $2.5 million program of unrestricted grants for cancer research—the Institute for Cancer Research at the Royal Marsden Hospital in London and Istituto Nazionale per lo Studio e la Cura dei Tumori in Milan. Ken Harrap, who heads the Dept. of Biochemical Pharmacology at Marsden, and Gianni Bonadonna, head of the Milan center's Medical Oncology Div., will administer the grants.

FDA HAS AUTHORITY TO SEE PATIENTS' NAMES WHEN PHONY DATA IS SUSPECTED

(Continued from page 1)

FDA has been conducting audits at institutions using clinical research protocols involving investigational drugs. Staff members and investigators at the institutions consider the audits annoying but for the most part cooperate with FDA staff. In some instances, that cooperation has ended when the auditors ask to see patient hospital charts.

Sydney Salmon, director of the Univ. of Arizona Cancer Center, brought the issue to the attention of the Div. of Cancer Treatment Board of Scientific Counselors.

"The problem relates to the current program of FDA audits of clinical research protocols involving new drugs, biological response modifiers, etc.," Salmon said. "A number of clinical investigators around the country have had their programs audited by FDA staff members with detailed review of specific clinical trials. We, in fact, are undergoing such an audit at the Univ. of Arizona at the present time, and have willingly provided the auditor with copies of the patients' flow sheets, signed consent forms, and other related study data.

"The auditor has also demanded that he be given direct access to the patients' hospital charts so that he may review those also. Dr. Stephen E. Jones, who is director of clinical cancer research for the Cancer Center, has denied this FDA request. I concur in his decision as do our chief of medical staff, chairman of the Human Subjects Committee, dean of the College of Medicine and the attorney who has represented the college on all legal matters. We all believe that this request constitutes a direct invasion of patient privacy and confidentiality of the medical record.

"Various FDA staff members locally, in the western region, and from Washington have been interacting with Dr. Jones claiming that such records are to be provided. Obviously, we disagree with this opinion as have other clinical investigators who are fully cognizant of the guarantees of patient confidentiality of information that are implicit in the physician's role.

"Other investigators, however, have apparently complied with the FDA request and have not considered this problem seriously, although they may be in jeopardy of future litigation from their patients who, in fact, did not give consent for their records to be examined by others than their primary physicians. In essence, this has the makings of a major issue in clinical research that needs to be discussed in the highest circles involved in clinical trials."

Salmon said that Charles Moertel, director of the Mayo Comprehensive Cancer Center, had also refused to permit FDA auditors to inspect patients' charts. He noted that the Assn. of American Cancer Institutes last year had unanimously approved a resolution objecting to the FDA policy.

"It does represent a very serious issue for clinical cancer research," Salmon concluded.

The DCT Board unanimously approved a resolution "strongly opposing" inspection of individual patient records by FDA.

Regulations governing investigational new drugs do give FDA the authority to see patient records. Investigators agree to do so when they sign FDA form 1573. Normally, however, patients' names do not have to be revealed. Here is how the pertinent regulation reads:

"Subject's name need not be divulged unless records of particular individuals are required for more detailed study, or unless there is reason to believe records provided do not represent actual cases studied, or do not represent actual results obtained."

Marion Finkel, who heads the Office of Scientific Evaluation in FDA's Bureau of Drugs, told ***The Cancer Letter*** that it was "uncommon" for auditors to demand to see patients' names. "That happens only when there is reason to suspect that the patients don't exist," Finkel said.

What? Do clinical investigators really make up phony data on phantom patients?

"It is rare, but it has happened," Finkel said. "We also may ask for names if we suspect that informed consent was not obtained."

That was not the case at the Univ. of Arizona or Mayo, she hastened to add. In those instances, the requests for individual hospital charts were strictly routine, and the investigators or their staff could remove patients' names if they so desired. "But they consider that a lot of trouble."

Part of the problem, Finkel said, is that some institutions feel FDA should have no access to records at all. "For 90 percent, there really is no problem," she added.

FDA agrees that some clarification is needed and is in the process of writing guidelines to spell it out. Finkel said the new guidelines are in draft form and could be ready for publication in a few months.

FDA's recourse, in the event an investigator absolutely refuses to comply with an auditor's request, is to refuse to accept any data from that study in the evaluation of the drug being tested. That would eliminate the study from the NDA, a heavy club and one FDA intends to use if necessary.

HEW REVIEW OF NTP COULD LEAD TO SOME CHANGES IN ADMINISTRATIVE STRUCTURE

HEW's Office of Planning Analysis is in the process of reviewing the National Toxicology Program, as directed by HEW Secretary Joseph Califano when he established it neary two years ago.

Califano recognized then that a hybrid program involving cooperative efforts of five HEW agencies and including the advisory involvement of indepen-

dent regulatory agencies could turn out to be an administrative nightmare. He ordered that NTP be looked at after a year with the understanding that its structure could be changed or even the entire program dismantled, if the review so warranted.

Califano did not last out the year, but the White House decided to proceed with the review anyway and ordered HEW to carry it out. The review is being conducted by planning office staff members Richard Shirasacua and Ginger Smith, who attended last week's meeting of the NTP Board of Scientific Counselors.

Shirasacua told ***The Cancer Letter*** that "everyone seems to like the concept of NTP, but as for the administrative structure, not so." He said the report his office would submit to Secretary Patricia Harris would include various options for her consideration. Those undoubtedly would include suggestions for revising the administrative structure, Shirasacua said.

The draft of the report to the secretary should be completed by late May or early June, Shirasacua said.

Other items brought up at the Board meeting included:

* NTP is using short term tests in conjunction with the long term animal tests of compounds. NTP Director David Rall said results of the short term tests will be released as they are available, with the announcement that the product is in long term test.

* After Dorothy Britton, contracting officer with the NCI Research Contracts Branch Carcinogenesis Section, explained how concept review of proposed contract programs works, the ensuing discussion indicated concept review means different things to different people.

NCI concept review is performed in open meetings by the division Boards of Scientific Counselors, or other advisory groups made up entirely of nongovernment members.

Rall, although acknowledging that NTP concept review could be handled by the Board, suggested it could also be done by the NTP Executive Committee. That body is made up of the heads of NTP's contributing agencies.

Board member Margaret Hitchcock noted that contract proposals must be reviewed by a peer group consisting of at least 75 percent nongovernment people.

"That excludes the Executive Committee," Board Chairman Norton Nelson said.

"That's different," Rall said. "Concept review doesn't have to be done by that kind of peer review group."

Explaining further the rationale for concept review, Rall said the primary question to ask is, "Is it a good idea? One of the problems with NIH contracts has been that there was no coherent overall look." Concept review was established to fill that need, he said.

"Did that come from Congress?" Nelson asked.

"From Uncle Joe," Rall replied.

"Joe's shadow is still with us," Nelson said.

Britton noted that concept review by the Board should be in general terms, without details that might be included in an RFP. Access to details before an RFP has been formally announced and made available to everyone might jeopardize Board members' right to participate in the competition, she said.

NTP Associate Director Richard Griesemer said, "My guess is that concept review by the Executive Committee would be fine, but we might like to come to the Board for individual pieces."

Nelson suggested that discussion of a scientific issue by the Board could constitute concept review, and that a Board consensus on the issue would be approval of the scientific approaches in a proposed contract program.

* James Huff, NTP senior toxicologist, said that the program would like to publish the bioassay reports, after they have been peer reviewed, in a scientific journal. "The reports otherwise are not archival," he said.

Nelson agreed, but said, "The trick will be in doing it, attracting the attention of editors."

Huff said plans were to develop a list of toxicology journals and submit the reports on a rotating basis.

* Griesemer said that NTP is trying to find a way to dispose of 10,000 pounds of old chemicals. "They have to be destroyed, but we have no place to do it."

"That's a problem a lot of people will have to face," Rall said. HEW has a committee working on it, he noted.

GIO GORI ACCEPTS FRANKLIN INSTITUTE JOB, SAYS "NCI HAS BEEN GOOD TO ME"

Gio Gori, one of the most colorful and controversial NCI scientist-executives over the past decade, will leave May 3 to join the Franklin Institute as vice president and director of a new Policy Analysis Center.

Gori thus ends 12 years at NCI during which time he played major roles in several highly visible programs and managed to draw down on himself—largely because of his outspoken nature—torrents of criticism.

Gori has retained to the last the title of deputy director of the Div. of Cancer Cause & Prevention although he has not been functioning in that position for two years. At one time, in addition to the deputy job, Gori headed the Smoking & Health Program, the Diet, Nutrition & Cancer Program, and the Carcinogenesis Program.

After Arthur Upton became NCI director, he relieved Gori of those positions one by one; although Gori's civil service status protected his DCCP title and the commensurate rank and pay, he has had few duties assigned to him for the past year.

Gori insisted he is not bitter. "The Cancer Institute has been good to me," he told ***The Cancer Letter.*** "It has given me the opportunity to do some very in-

teresting things. Some of my finest hours have been here."

That may be, but there is little question that Gori feels he is the victim of an establishment which cannot tolerate someone with the courage to be controversial. "I was crushed by an insensitive bureaucratic system," he said.

It was as director of the Smoking & Health Program that Gori made what may be his most importtant contribution, and which got him involved in the most controversy.

Gori took over the program in 1973 and became a staunch defender of the program's emphasis on development of a less hazardous cigarette. Critics of the tobacco industry, along with some NCI scientists and executives, contended that it was inappropriate for NCI to support product development for an industry that could well afford to do its own.

At that time, cigarette manufacturers had already made major reductions in average tar and nicotine content but appeared to have hit bottom. The lowest tar brands were not being accepted by smokers because they supposedly lacked taste, and the industry seemed incapable or unwilling to do anything more.

The Smoking & Health Program, with industry representatives included on its advisory committee, contracted for studies aimed at further reducing tar content while retaining flavor. Gori argued that smoking cessation efforts did not seem to be working, "and you have to accept the real world. If you want to reduce morbidity and mortality from cigarette related disease, you have to make less toxic cigarettes."

The effort seemed to be paying off in the mid 1970s when a plethora of new brands started coming onto the market with tar contents ranging down to 1 mg and with at least a certain amount of flavor retained. They caught on, to the point where brands classified as low tar now command 50 percent of the market, compared with about one percent in 1974.

Despite that evidence of the program's success (tobacco industry spokesmen were willing to give NCI credit for stimulating low tar R & D), Gori's critics never went away. Then he picked up a new and powerful corps of detractors when he wrote an article for *JAMA* in 1978, pointing out that an entire pack of the new low tar brands contained the same amount of tar and nicotine as two pre-1960 cigarettes. Although careful to state that not smoking at all was safer, Gori concluded that smoking no more than one pack a day of the low tar brands was not hazardous to health, on a population-wide basis.

That bombshell hit in the midst of HEW Secretary Joe Califano's antismoking campaign. Califano felt it undercut his new education initiatives, and Gori was in hot water at every level of HEW. Upton charged that Gori's article would encourage those who had quit to resume smoking. The Naderites demanded that Gori be fired. He wasn't, but Upton took the Smoking & Health Program away from him.

Gori had been appointed DCCP deputy by James Peters, who was director of the division in 1973. After Upton forced Peters out, new DCCP Director Gregory O'Conor wanted to name his own deputy.

Congress decreed when the National Cancer Act was renewed in 1974 that diet and nutrition studies should be stepped up. Gori was asked to get the new program organized and head it up. He put together an advisory committee of nongovernment scientists and lay persons, organized workshops, and developed contract RFPs and grant RFAs. Then when he presented the bill to management, NCI (under pressure of the Ford Administration's last unreasonably low budget) cut it in half.

Gori's advisory committee reacted by firing off a letter to the President, members of Congress and others bitterly complaining about the short shrift in the budget for diet and nutrition studies. The latter made the serious mistake of badmouthing certain other NCI programs. This brought down the considerable wrath of Benno Schmidt, who was chairman of the President's Cancer Panel. It also deeply offended Gori's NCI superiors. Going public with an intramural fight over the budget is a no-no in the federal government. Although the letter came from the committee, Gori does not deny having had something to do with it.

He did the best he could with the money they gave him, but it wasn't enough to stave off severe congressional criticism over NCI's failure to respond to the mandate with more enthusiasm. Upton's reaction, after being raked over the coals by Sen. George McGovern, was to take the program away from Gori and give it to Guy Newell, then Upton's deputy.

Gori had taken over the Carcinogenesis Program after the infamous backlog of bioassay reports had become an issue. Although he helped put the machinery into place which eventually took care of the backlog, he was unfairly associated with that mess. He was happy to turn that program over to Richard Griesemer in 1977.

Gori, 49, was born in Tarcento, Italy. He received a doctor of biological sciences degree in microbiology and botany from the Univ. of Camerino, and came to the U.S. in 1960 to work at the Wistar Institute. He became a U.S. citizen in 1964, and joined NCI in 1968.

The Franklin Institute, headquartered in Philadelphia, is the oldest scientific organization in the U.S. Gori will establish the new center at the institute's Washington D.C. facility.

An article written by Gori which will appear in this week's issue of *Science* probably will add to his reputation as an outspoken maverick. He questions the attempt to control carcinogens by the ideal of absolute safety at all costs. Bias is inherent in the prescribed bioassays, he writes; test findings cannot be translated into quantitative assessment of human risk.

Such data are improperly used in resolving regulatory questions case by case, Gori charges. He suggests that a system of relative standards be formulated, which paired to standards of tolerable risk or safety, would define a range of use restrictions.

ACS STUDY SHOWS LOW T/N PRODUCING FEWER DEATHS, AIDS THOSE QUITTING

An American Cancer Society study supports the contention by Gio Gori and others that the concept of less hazardous cigarettes is valid and is leading to a reduction in cancer related deaths.

Lawrence Garfinkel, ACS vice president for epidemiology and statistics, reported at the society's annual science writers seminar that:

* An epidemiologic study showed that those who smoked low tar and nicotine cigarettes had small but significantly lower mortality than those who smoked high T/N cigarettes.

* An autopsy study showed far fewer histologic cellular changes in the tracheo-brochial tree in people who died in the 1970s than in those who died 15 years previously.

* A study showed that people who switch to low T/N cigarettes are able to quit at a higher rate than smokers of moderate or high T/N cigarettes.

Most of the ACS findings were collected from data no later than 1971. Low tar and nicotine was defined as 17.7 mg and 1 mg, respectively. That is probably the average content now, with the lowest at 1 mg tar and .01 nicotine. The benefits of the massive movement to less hazardous brands may be just beginning.

"There is not a cigarette on the market today with as high T/N as the lowest 25 years ago," Garfinkel said. The lung cancer death rate in males started dropping in 1976, he commented. "There has been a remarkable increase in life expectancy since 1970, about the same as with the advent of antibiotics."

Garfinkel's report:

Cigarette smoking plays an important role in the overall cancer trends. But, because of changes in smoking patterns, death rates in various age cohorts have differing trends. In England and Wales, the death rates from lung cancer in men, ages 45-54 and 55-64, have been decreasing in the last 10-15 years, although the rates continue to rise in older men. In 1977, the overall age-standardized rate for lung cancer in men dropped for the first time. In the U.S., the lung cancer rate for men continues to increase, although there is a tendency for the rate in younger men to level off.

In women, the mortality rates in both England and Wales, and in the United States, continue to increase and they are increasing at a more rapid rate in younger than in older women.

In the United States, an estimated 30 million people have quite smoking and there is a strong trend toward use of lower tar/nicotine cigarettes. Is there any evidence of the impact of these changes in smoking habits on present or future mortality of lung cancer and other diseases?

Despite the fact that lung cancer in the United States has not decreased, the evidence from several recent American Cancer Society studies that changing smoking patterns is having an effect is compelling. We reported many years ago that those who quit smoking have lower lung cancer rates than those who continue to smoke. A few years ago, we published data from our epidemiologic study showing that smokers of low tar/nicotine cigarettes had lower mortality rates from total deaths, coronary heart disease and lung cancer than those who smoked high T/N cigarettes. Smokers of moderate T/N cigarettes had intermediate rates. This analysis included the deaths in a 12-year period from 1960-1971, and was a study of cigarette smoking groups matched on sex, age, number of cigarettes smoked per day, age when began smoking, and a number of other factors. Decreases in mortality comparing low to high T/N cigarettes for two periods of time (1960-65 and 1966-71) in both sexes averaged 16 percent for total deaths, 14 percent for coronary heart disease and 26 percent for lung cancer.

The study also showed that death rates from all causes for nonsmokers were between 57 percent and 76 percent of those of low T/N smokers. Lung cancer rates among nonsmokers were only 9 percent that of low T/N smokers; in females, the rates in nonsmokers were 22 percent to 43 percent of the low T/N smokers.

The number of cigarettes smoked per day was more important than the T/N content. Smokers of less than 20 "high" T/N cigarettes had **lower** rates than those who smoked 1-2 packs of "low" T/N cigarettes.

Another aspect of the evidence concerning low T/N smoking comes from our studies with Dr. Oscar Auerbach of the Veterans Administration Hospital in East Orange, N.J., concerning changes in bronchial epithelium. The changes in the tracheobronchial epithelium in 211 men who died in 1955-60 (group A) were compared to the epithelial changes in 234 men (group B) who died between 1970-1977. All of the men in the latter group had to have smoked cigarettes lower in T/N during the last 10-15 years of their lives than all of the men who died in the late 1950s. A total of 20,424 slides were read blind and the following epithelial changes were recorded and transferred to computer for analysis: increase in cell rows (hyperplasia); lesions with cilia absent; percent of cells with atypical nuclei. The results showed that with respect to all of these changes, the men in group B had far fewer changes than men in group A wtihin each number of cigarettes smoked category. The most advanced change (carcinoma-in-situ) was found in neither group A nor group B. In smokers in group A, 2.6 percent of the slides in those who smoked less than one pack a day had this finding: 13.2 percent of the slides in 1-2 packs a day smokers and 22.5 percent in the 2+ packs a day group. In group B, the percentages were 0.1 percent, 0.8 percent, and 2.2 percent, respectively.

It has been sometimes alleged that those who smoke cigarettes with low T/N increase the number of cigarettes they smoke. Our latest ACS studies show that in 1972, 60 percent of men and 52 percent of women smoked cigarettes with decreased T/N compared to brands they were smoking in 1959. If the hypothesis were true for all smokers, we should have seen a remarkable growth in number of cigarettes consumed in this country.

In comparing the changes among those in our study who smoked in 1959 and 1972, 29 percent of the men who increased the T/N level in the cigarettes they smoked increased the number of cigarettes they smoked per day. Among those who smoked cigarettes with decreased T/N levels, 31.5 percent increased the number they smoked per day. Among females, the comparable percentages were 36.7 percent and 41.3 percent. Thus, if there is an increase in number smoked when a smoker changes brands, it is very small indeed.

Perhaps the most important effect of switching to low T/N cigarettes is that it appears to make it easier for smokers to quit. By 1972, 41 percent of the men smoking low T/N cigarettes in 1965 had quit; only 35 percent of the high T/N smokers had quit. Among females, 27 percent of the low T/N and 20 percent of the high T/N smokers quit smoking. Those who smoked cigarettes with medium T/N quit at rates in between

low and high T/N smokers. The same pattern of quitting was observed when the smokers were divided into categories by the amount they smoked in 1959. The rate of quitting smoking was inversely related to number of cigarettes smoked, but within each of four groups classified by number smoked per day, the percent quit was highest in those who smoked low T/N cigarettes; next highest in moderate T/N smokers; and lowest in high T/N smokers. This was found both in men and women in both time periods.

We believe that all of these factors mentioned: a decrease in mortality attributable to massive numbers of people quitting smoking, or smoking cigarettes with lower T/N; and the implications of less damage to the lungs as shown in autopsy studies will result in a leveling off and a drop in lung cancer rates in men in the near future. In women, it seems doubtful if the upward trend will be halted for some time to come.

The changes that affect lung cancer mortality are occurring at a time when another important public health phenomenon is taking place. Death rates from cardiovascular diseases have dropped considerably in the last 15-20 years. The coronary heart disease death rates in the U.S. have shown a 20 percent drop in men and 24 percent drop in women between 1969-76, the largest drop observed among a number of countries. Australia, Canada, New Zealand, and Israel have also shown decreases but not as great. There has been virtually no change in coronary rates in the United Kingdom, and several European countries (Sweden, France, Germany) have shown continued increases in males, but no change or small decreases in females.

The decreases in the United States have occurred in all diseases except for cancer, chronic pulmonary disease, and homicide and suicide.

This has resulted in a remarkable three-year gain in life expectancy in both men and women since 1970. And while the percent of heart disease as a cause of all deaths has been decreasing in the last 10 years, the percent that cancer is as a cause of all deaths has been increasing from about 19 percent in females in the 1960s to 24 percent in 1977. In males, the percent has increased from about 16 percent to 20 percent.

Commenting on the ACS report, Gori said he agreed that perhaps the most important benefit from the move to low T/N cigarettes is the easier transition to quitting. "In another 20 or 30 years, no one will smoke. Lung cancer deaths in this country will drop from 100,000 to no more than 10,000. I like to think that our program is helping to make that happen."

TOBACCO COUNCIL AWARDS 12 NEW GRANTS, TOTAL $6 MILLION IN 1979

Twelve new smoking and health projects and more than 45 renewals, totaling more than $6 million, were funded last year by the Council for Tobacco Research-USA Inc., the organization announced. The new grants went to:

David Busbee, North Texas State Univ.; Robert Echt, Michigan State Univ.; V. Gene Erwin, Univ. of Colorado; Morton Galdston, New York Univ.; Hira Gurtoo, Roswell Park Memorial Institute; Aaron Janoff, SUNY (Stony Brook); James Lee, St. Louis Univ.; Hans Meier, Jackson Laboratory; J. Wister Meigs, Connecticut Cancer Epidemiology Unit; Beverly Paigen, Roswell Park; Dennis Petersen, Univ. of Colorado; and Eileen Remold-O'Donnell, Boston Center for Blood Research.

The grants were awarded on recommendation of an eight member scientific advisory board.

DEVITA PLANS RESHUFFLING OF NCI OFFICES TO CONSOLIDATE STAFF

As NIH and particularly NCI have grown over the last 10 years, they have exceeded the capacity of space available on the Bethesda campus. The result has been that administrative offices are scattered around in three leased buildings in Bethesda and another in Silver Spring, Md. Additional laboratory space is used in contractor owned facilities.

While some attempts have been made to keep programs and branches together (i.e., Div. of Cancer Control & Rehabilitation offices are all in the Blair Building in Silver Spring), most of the off campus operations are separated by several miles from key elements of their programs.

Vincent DeVita has said that he thinks people working in the same programs should be located on the same floor in adjacent offices. The acting NCI director has taken steps to correct what he perceives as bothersome inefficiencies.

DeVita explained his plans for consolidating NCI offices in a memo to his staff:

Several events of major importance to NCI and NIH are under way that offer us a rare opportunity to better consolidate our staff or risk losing those options for 10 years. These events are:

1. A major NCI reorganization that has been under way for almost two years and for which approval by the Secretary, HEW, is expected momentarily.
2. An eight-year program by NIH to renovate its older laboratory buildings. These renovations will begin with Bldg. 8 and necessitate vacating this building by the fall of 1981.
3. The return to the NIH campus or to the Frederick Cancer Research Center of NCI laboratory operations now conducted in contractor-owned facilities.
4. Reduced amounts of funds available for the intramural programs in FY '80 and FY '81 budget.

NIH has a long range plan to vacate the four buildings it currently leases (Westwood, Blair, Landow, and Federal) and consolidate these office activities into a single leased facility within walking distance of a Metro subway station on the Rockville Metro line north of the Bethesda campus. This project is in the planning stage and does not affect our current situation.

After much deliberation and with the concurrence of the division directors, I have decided on the following series of space shifts in order to achieve the maximum organizational consolidation feasible at this time:

Administrative/Extramural Space Assignments

1. The Literature Research Section, the Publications Section, and the Computer Analysis Office within the Div. of Cancer Treatment will move from the Blair to the Landow building. Also, there will be some consolidation within DCT's Developmental Therapeutics Program space in the Blair building.
2. The International Cancer Research Data Bank and the Journal of the National Cancer Institute will move from the Blair to the Westwood building. Dr. Upton and I have personally made two concerted attempts to get space for those programs within the National Library of Medicine complex but were unsuccessful.
3. Using primarily the space created by the steps described above, plus some vacant reserve space, the following changes will be made:

—Units of the Research Contracts Branch now located in Landow building and Bldg 31 will move to the Blair building,

thus consolidating the entire branch in one location.

–The Centers, Training and Education, Construction, and Organ Sites programs will move from the Westwood to the Blair building, where Cancer Control activities are now, and that will put all components of the new Div. of Resources, Centers & Community Activities in one location.

4. The portion of DCT's Cancer Therapy Evaluation Program now located in Bldg 37 will move to the fourth floor, Landow building. The CTEP staff already located there will move from the eighth to the fourth floor, where the entire program will be consolidated in contiguous space.

5. In order to facilitate the CTEP consolidation, the Breast Cancer Coordinating Branch, Div. of Cancer Biology & Diagnosis, will move from the fourth to the eighth floor of the Landow building.

6. NCI's Carcinogenesis Testing Program component of the National Toxicology Program will vacate its space on the second floor of the Landow building for use by DCT staff.

A number of organizations involved in this process–Cancer Control, Research Contracts Branch, Breast Cancer Coordinating Branch, and the Centers Program–will end up with less space than they have currently; but overall their space allocation will remain within the normal range.

Intramural Space Assignments

1. The entire Laboratory of Viral Carcinogenesis, DCCP, will move from Meloy Labs in Springfield, Va., and from Bldgs 37 and 41 to Bldg 560 at the Frederick Cancer Research Center. The laboratory chief, Dr. George Todaro, will retain office space in Bethesda.

2. The Cellular Transformation Section will be moved from Bldg 37 to Bldg 41, thus consolidating the Laboratory of Tumor Virus Genetics, DCCP, under the leadership of Dr. Edward Scolnick.

3. Dr. Stuart Aaronson's Laboratory of Cellular & Molecular Biology, DCCP, will be brought together in Bldg 37, except for the Viral Genetics Section (acting chief, Dr. John R. Stephenson), the Bio-Molecular Oncology Section (chief, Dr. Arnold Fowler), and the Viral Immunology Section (chief, Dr. Robert Huebner) which will remain at FCRC.

4. The Laboratory of Tumor Cell Biology, DCT, headed by Dr. Robert C. Gallo will be consolidated in Bldg 37.

5. In an effort to provide adequate and clean animal facilities, DCT will dedicate the 6E and a small portion of 6D corridors to consolidate laboratory animal facilities.

6. The following intramural organizations now in Bldg 8 will be relocated in buildings 36 and 37: The Laboratory of Cell Biology, DCBD, chief, Dr. Lloyd Law, and the Macromolecular Biology Section, Immunology Branch, DCBD, chief, Dr. Peter T. Mora.

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. Some listings will show the phone number of the Contract Specialist, who will respond to questions. Listings identify the respective sections of the Research Contracts Branch which are issuing the RFPs. Address requests to the contract officer or specialist named, NCI Research Contracts Branch, the appropriate section, as follows:
Biology & Diagnosis Section and Biological Carcinogenesis & Field Studies Section–Landow Building, Bethesda, Md. 20205; Control & Rehabilitation Section, Chemical & Physical Carcinogenesis Section, Treatment Section, Office of the Director Section–Blair Building, Silver Spring, Md. 20910. Deadline date shown for each listing is the final day for receipt of the completed proposal unless otherwise indicated.

RFP N01-CP-05671-50

Title: *Prechronic studies for the bioassay of 8-methoxypsoralen and related psoralen derivatives*
Deadline: *June 25*

The objective of this project is to perform prechronic experiments of the mouse portion of the 8-methoxypsoralen bioassay. The prechronic mouse psoralen toxicology studies are divided into "light" and "dark" experiments. A standard bioassay using 8-mop without ultraviolet is now being conducted.

The RFP will describe a subchronic study and provide other relevant data. The rat bioassay is strictly a "dark" study. For administrative reasons these experiments are being implemented independently. The objective of these studies is twofold. They should provide experimental support for the irradiance level and two chemical dose levels to be used for each type of UV light in the chronic studies. They should also provide experimental data on a number of chemical and/or light dependent parameters which should be studied in the HRA/Skh mouse because of their relevance to chronic toxicity study interpretation.

It is anticipated that multiple awards will be made as a result of this RFP; therefore offerors must be willing to coordinate their efforts with other participating offerors.

Contract Specialist: Dave Monk
Carcinogenesis
301-427-8764

RFP NCI-CM-07334

Title: *Qualitative and quantitative analysis of proteinaceous substances*
Deadline: *Approximately May 27*

The Pharmaceutical Resources Branch of NCI's Div. of Cancer Treatment is seeking interested organizations to respond to a request for proposal to provide services to qualitatively and quantitatively characterize peptides, proteins, glycoproteins and/or polynucleotides. Substances to be studied have exhibited a modification of tumor growth in experimental systems.

Approximately two or three substances will require evaluation annually. These agents will be supplied either in bulk or as pharmaceutical dosage forms. Organizations must submit evidence of in-house competence and experience with the following: a) molecular weight determinations; b) electrophoreses; c) amino acid composition; d) carbohydrate determination; e) production and purification of antibody to drug substance or modified drug substances; f) preparation of tagged antigen or antibody (preferably but not necessarily radiolabeled); and g) development of quantitative assays (radio-immune, other immune assays, fluorescence, cytotoxic and/or enzymatic) to detect the drug substance in bulk and pharmaceutical dosage forms.

It is anticipated that an incrementally funded contract will be awarded for a period of three years at a

level budget. The technical staff years of effort will be 2.5 staff years for the first year with 10 percent reductions per year for the two succeeding years.

Contract Specialist: Maria Decker
Cancer Treatment
301-427-8737

RFP N01-CP-05672-56

Title: *Chemical services support for carcinogenesis bioassay testing*

Deadline: *June 12*

Chemical procurement, analysis, storage, repackaging, and distribution services for approximately 25 chemicals per year in support of the activities of the Carcinogenesis Bioassay Testing Program. A four-year cost-reimbursement contract is anticipated for effective pursuit of this project.

Contract Specialist: Ann Peale
Carcinogenesis
301-427-8764

RFP CI 80-0386

Title: *Chemical analytical support for carcinogen field study*

Deadline: *See RFP*

Approximately 1,400 determinations from air, soil, water, sediment, vegetation, mollusc, and fish samples are to be analyzed for As, Cd, Cr, B(a)P, and benzene. In addition, approximately 10 samples are to be analyzed for 54 priority pollutants. Analytical instrumentation required includes atomic absorption gas chromatography GE-mass spectrometry and high pressure liquid chromatography. Alternate techniques such as inductively coupled plasma emission and sparks source emission spectrometry may be acceptable. May elect to classify this procurement as a Small Business Setaside.

Negotiated Contracts Branch
Contracts Management Division
Environmental Protection Agency
Cincinnati Ohio 45268

SOURCES SOUGHT

Title: *Handbooks on radiation protection*

Deadline: *May 23 (for submission of qualification statement)*

NCI proposes to contract for the development of two handbooks—one on basic radiation protection criteria and the other on radiation protection in mammography. Organizations or groups having capabilities to develop the materials required are requested to submit the information described below.

NCI seeks to develop handbooks treating the following topics: (1) radiobiological aspects of basic radiation-protection criteria and (2) mammography. The contractor will be required to develop two documents—one on mammography and the other on basic radiation criteria. The mammography document has as its goal a report providing guidance to those who perform mammography or who calibrate and monitor mammographic equipment. The mammography document should include information on the physics of mammographic systems, x-ray equipment, film mammography, xeroradiography, radiation dosimetry, absorbed dose calculations, image quality, other breast imaging methods, image optimization and dose reductions, typical technique factors, measurements and calculations, methods for improving image quality and quality assurance progress.

The document should serve as a reference for physicians, physicists, and technicians involved in x-ray mammography.

Another document developing basic radiation criteria for public health strategies must be developed. It should discuss such factors as aspects of low dose carcinogenesis, risks from low dose radiation, and measures for reducing dose to the public from various sources of ionizing radiation. The handbook should cover the radiobiology of carcinogenesis, both theoretical considerations relevant to specifications of dose response curve and experimental evidence describing the relationship between radiation exposure and carcinogenesis. Organizations desiring to be considered must meet the following criteria:

1) They must be recognized in the field of radiation-protection and must demonstrate access to and support of the radiological and health communities.

2) They must have access to recognized experts in the fields of radiation biology, radiology, health and medical physics, and epidemiology, who will work on the proposed contract.

3) They must have a demonstrated record in the development of radiation-protection documents and submit examples of such.

Interested organizations and groups should provide information on the above, a brief description of their organization, curriculum vitae, and a list of similar projects.

Contracting Officer: Sanford Kantor
Control & Rehabilitation Contracts Section
301-427-8745

The Cancer Letter _Editor Jerry D. Boyd

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