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UNITED STATES GENERAL ACCOUNTING OFFICE

WASHINGTON, D.C. 20548

RELEASED

HUMAN RESOURCES DIVISION

MARCH 30, 1979

B-164031(2)

The Honorable Henry A. Waxman
House of Representatives

Dear Mr. Waxman:

In your May 2, 1977, letter you asked us to review certain aspects of the National Cancer Institute's (NCI's) carcinogenesis program. In our July 26, 1978, report to you (HRD-78-143) we provided information on

--the roles and responsibilities of advisory groups to the carcinogenesis program and factual data on the relationships among advisory group members and organizations that could be affected by NCI activities,

--the extent that advisory groups encouraged or discouraged NCI efforts to conduct and sponsor research in cancer prevention and identification of environmental carcinogens, and

--the effect of the Clearinghouse on Environmental Carcinogens on the program.

At that time we said that we would provide information to you on the remaining questions you had asked on program operations. This report addresses your concerns about

--funding and staff allotments,

--the extent and causes of the backlog in the review and completion of bioassay reports,

--the efficiency of and need for improvements in contract management activities and the adequacy of quality controls over bioassay work,

--the structure of the program and the emphasis on environmental carcinogens, and

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(10387)

--the effect of personnel movements and organization realignments within the program.

As instructed by your office, we did not review the procedures NCI used to award or modify the prime contract for the management of bioassay activities, nor did we review how the contractor accounted for costs. Our review of contract management activities focused on the prime contractor's role and NCI's efforts to monitor the prime contractor's work.

NCI reorganized the carcinogenesis program in July 1977 by dividing it into two separate activities--a carcinogenesis testing program and a carcinogenesis research program. We reviewed personnel activities and reorganizations since that time. We found no problems attributable to the July 1977 reorganization, and since that time there have been no major changes in the organization of the carcinogenesis testing and research programs. However, the carcinogenesis testing program had significant personnel problems which are discussed in enclosure I.

Your question about the emphasis placed on environmental carcinogens was dealt with extensively in our first report. However, information in this report on the funds obligated and staff assigned to carcinogenesis activities should provide additional insight into the matter.

We primarily focused on the carcinogenesis testing program, since the questions you raised mostly concerned that program. However, we also reviewed matters pertaining to the research program when it was appropriate. Our work included reviewing NCI and contractor records and guidelines, interviewing NCI, Office of Personnel Management (formerly Civil Service Commission (CSC)), and contractor officials, and inspecting subcontractor facilities where bioassays were done.

Our findings and recommendations are summarized in this letter, and more detailed information is contained in enclosures I, II, and III. As instructed by your office, we asked NCI, the prime contractor (Tracor-Jitco, Inc.), and the subcontractor laboratories we inspected to comment on the matters included in this report within 10 days. Their comments, where appropriate, were considered in its preparation.

NCI'S RESOURCES DIRECTED TO CARCINOGENESIS ACTIVITIES

The National Cancer Program (established by the National Cancer Act of 1971 (42 U.S.C. 282)) emphasizes the importance of carcinogenesis activities and, in particular, the identification of carcinogenic hazards. NCI's appropriations and staff have increased significantly since the time the legislation was enacted. While NCI has devoted more resources to carcinogenesis activities, the proportion of its resources allocated for carcinogenesis in 1978 remained about the same as in 1972.

NCI HAS HAD DIFFICULTY WITH RECRUITING SCIENTISTS FOR THE TESTING PROGRAM

While staffing has not been a problem for the carcinogenesis research program, it has been a major problem for the testing program. Twenty (41 percent) of the 49 positions authorized for the testing program were vacant at the time of our field work--13 of these 20 vacancies were for scientific personnel. Recruiting certain types of scientists--toxicologists and veterinary pathologists--has been especially difficult; 7 of the 13 scientific vacancies were for these two specialties.

NCI stated that it was difficult to fill its scientific positions because the scientists lacked an opportunity to perform research, the testing program's future was uncertain, there was a shortage of toxicologists and veterinary pathologists and inadequate pay for Federal veterinary pathologists, and CSC lacked a job classification for toxicologists.

The vacant scientific positions primarily involved administrative duties dealing with extramural activities such as planning test projects, reviewing project proposals, and monitoring contracts. NIH's policy precludes scientists responsible for extramural activities from conducting intramural research. The associate director, Carcinogenesis Testing Program, stated that the lack of research opportunities for scientists has hindered recruiting efforts for the testing program. He added that scientists need to perform research to maintain and enhance their scientific skills.

An additional recruiting problem occurred because the Secretary of HEW was considering alternatives to how the Government should be organized to meet the Nation's chemical

testing needs; the future of the NCI testing program could have been affected by some alternatives. For example, the program could have been transferred to a new agency or transferred to an existing Federal organization but moved to another State. This created a period of uncertainty during which NCI could not assure prospective employees about their job location or whether they would be working for NCI or another agency. The Secretary of HEW decided to create a National Toxicology Program in September 1978. The program will consist of the relevant activities of several Federal agencies, but these activities will remain within their respective agencies. While the testing program remains virtually unaffected by creating the National Toxicology Program, the Secretary's decision has not eliminated the uncertainty of its future. The HEW Secretary will again review Federal testing efforts after a 2-year trial period and reach a final decision on how the Nation's chemical testing efforts should be organized. According to the Carcinogenesis Testing Program's associate director, the HEW Secretary could decide to move NCI's testing activities to another Federal organization in another State. Thus, the associate director stated, the Secretary's decision on testing activities has only continued the uncertainty and has not eliminated the burden on recruiting efforts.

Recruiting toxicologists and veterinary pathologists has been hindered because the demand for these specialists is high but the supply is limited. Toxicologists are in great demand both within and outside the Government, primarily because a substantial amount of environmental health legislation has been enacted that requires this specialty. Hiring veterinary pathologists has been further hindered because there are large salary differences between the Government and private industry.

NCI and others also claimed that recruiting toxicologists has been hindered because CSC has no toxicology job classification. CSC officials stated that other factors were more significant than this. CSC officials said the demand for toxicologists has increased because some legislation requires this specialty while the supply of toxicologists has been limited. CSC officials also said that NCI often failed to adequately justify why NCI's prospective employees should be considered above candidates CSC already had on its register. CSC officials also stated that other agencies have established training programs to fulfill its

need for scientists. NCI recognized its need to establish training programs for toxicologists and veterinary pathologists in testimony before the Senate Appropriations Committee in 1977; NCI also testified that it had the legislative authority to initiate these programs. However, except for institutional support grants and fellowships--which do not require recipients to work for the Government--NCI has not established any such training programs. Commenting on a draft of this report, NCI stated that a shortage of staff available to develop such programs, a subsequent determination that its legislative authority was questionable, and a shortage of funds prevented it from establishing training programs.

NCI'S DIFFICULTIES IN ELIMINATING THE BIOASSAY BACKLOG

NCI attempts to identify the carcinogenicity of chemicals through bioassays; until 1974, NCI contracted directly with laboratories to perform them. However, staffing shortages caused NCI to contract with Tracor-Jitco, Inc. in March 1974 to manage NCI's bioassay activities. (See p. 24, enclosure III.) Pursuant to this arrangement, NCI no longer contracted directly with laboratories but contracted with Tracor-Jitco, which subcontracted with laboratories to perform bioassays.

When NCI originally contracted with laboratories to conduct the bioassays, NCI did not contractually require them to prepare bioassay reports. NCI decided detailed bioassay reports were needed in 1975, and it began the technical report series, which is the current method of publishing reports.

NCI experienced significant delays between the time bioassays were completed and the time technical reports were published. The delay in publishing technical reports became a major concern to NCI. In 1976, NCI directed Tracor-Jitco to develop a plan to produce draft reports on all completed bioassays in which the test animals were killed before July 15, 1976--207 bioassays were included in this category. NCI's goal was to publish technical reports on all 207 of these bioassays; in testimony before the Congress in early 1978, NCI said it would do this by the end of September 1978.

While the Tracor-Jitco plan succeeded with providing NCI draft bioassay reports, NCI did not eliminate its backlog. NCI had published only 99 reports as of October 1978, and it had reduced its goal of publishing reports on all 207 bioassays to reporting only on 156 (NCI found the remaining 51 bioassays to be so deficient that it decided not to publish final reports on on the results). As of March 1979, NCI had published 139 technical reports.

NCI stated that, while it did not complete its work on the backlog by September 1978 as it intended, the backlog was eliminated by December 1978. NCI's rationale for this was that it had provided preliminary results of the backlogged bioassays to the regulatory agencies by that time. However, the regulatory agencies are reluctant to act on data until it is finalized. Thus, we believe NCI's action to eliminate the backlog should not be considered complete until technical reports are published on the backlogged bioassays.

MANY FACTORS CAUSED THE BACKLOG

The bioassay backlog was caused by many factors; NCI could control some of them and could not control others. The National Cancer Act of 1971 provided the impetus and finances to increase efforts to identify chemical carcinogens. Since the legislation did not specify who was responsible for testing suspected carcinogenic chemicals, NCI assumed the burden for such efforts.

As a result of the increased emphasis to identify environmental carcinogens, NCI began a large number of bioassays through contracts with private laboratories between 1971 and 1973. The results of these bioassays became available to NCI between 1973 and 1976. However, when contracts were awarded to the laboratories, NCI failed to require them to report on the bioassay results. This requirement was not included in bioassay contracts until 1976. The NCI unit that was to administer the bioassays was severely understaffed, and it could not properly monitor the bioassays while they were underway or deal with the results as they became available. These factors caused the bioassay backlog.

NCI'S DELAY IN ELIMINATING THE BACKLOG WAS DUE TO FACTORS BOTH WITHIN AND BEYOND ITS CONTROL

Several causes contributed to NCI's delay in eliminating the backlog, according to a report by the Clearinghouse on Environmental Carcinogens. The Tracor-Jitco plan was premised on having no problems at any point, but many problems developed. The plan did not allow time for teams at the laboratories that performed the bioassays to be assembled and trained to write draft reports; ultimately, this approach did not work, and Tracor-Jitco was assigned the responsibility of preparing draft technical reports.

Since NCI had not required laboratories to prepare bioassay reports, Tracor-Jitco experienced significant difficulty when it attempted to do this. In many instances, considerable time had passed since the laboratories completed the bioassays, records had been placed in storage, and personnel changes had occurred. Thus, efforts to gather test data to prepare reports were difficult. Other delays in preparing reports occurred because scientists attempted to analyze and interpret the data from early tests by using more advanced techniques which could not always be easily applied to the data from these earlier tests.

NCI staff for reviewing bioassay results was also limited. One person was responsible for reviewing most of the draft bioassays--the head of the Data Evaluation Group. Further delays with eliminating the backlog occurred because of the time needed for review by the Clearinghouse on Environmental Carcinogens and because of the few staff assigned by NCI's Office of Cancer Communications to process draft reports.

NCI HAS NOT INCLUDED ALL BIOASSAYS IN THE BACKLOG

We found that other existing completed bioassays fit the definition NCI used with identifying bioassays included in the backlog. These bioassays have not been reported to the Congress. We identified 223 such bioassays that were performed by the Frederick Cancer Research Center, the Eppley Institute for Research in Cancer, and NCI's inhouse Carcinogenesis Research Program. However, we are not certain that these are the only bioassays. NCI officials stated that these tests were not included in the backlog because NCI included only those for which Tracor-Jitco was responsible.

NCI HAS NOT ADEQUATELY MONITORED TRACOR-JITCO'S BIOASSAY RESPONSIBILITIES

NCI awarded a competitive prime contract to Tracor-Jitco, Inc. in March 1974 to manage its bioassay activities. NCI subsequently extended the contract without competition from May 1975 to May 1979. The contract is a cost-plus-award-fee type which allows Tracor-Jitco to recover its costs of performing the agreed-upon work ($39.7 million) plus a fixed fee of about $198,000. In addition, Tracor-Jitco can earn an award fee of about $3.2 million if NCI determines that its performance is satisfactory. NCI

plans to extend the contract for a short period beyond May 1979 to allow Tracor-Jitco time to complete certain agreed-upon work; NCI will then assume the responsibilities previously assigned to Tracor-Jitco for all future bioassays.

NCI has relied primarily on Tracor-Jitco to provide information on the bioassays by the subcontractor laboratories. However, Tracor-Jitco has not informed NCI of all the deficiencies it found during inspections of subcontractors' activities, nor has it required the subcontractors to correct the deficiencies. NCI was not aware of this situation because it had not adequately monitored Tracor-Jitco's efforts in reviewing subcontractor activities, nor had NCI done its own verification of the adequacy of Tracor-Jitco's reports.

To determine conditions at the laboratories that subcontract with Tracor-Jitco, we developed a method for inspecting laboratory conditions. This method was based on NIH, NCI, and FDA guidelines and procedures developed by Tracor-Jitco; we tested the methodology and had it approved by NCI, FDA, and industry officials. We hired experts who were recognized as qualified by both NCI and Tracor-Jitco to assist with our inspections.

Even though NCI required Tracor-Jitco to increase both the quantity and quality of its laboratory inspections, numerous deficiencies still existed at the laboratories that could affect the quality of bioassays. (See pp. 33 and 34, enclosure III.) One of these deficiencies--the testing of more than one chemical in a room--was our most serious concern. In some cases, our inspection revealed laboratory deficiencies which Tracor-Jitco did not detect. (See p. 34, enclosure III.)

CONCLUSIONS

While NCI has significantly increased funding and staff for carcinogenesis activities, the proportion of its resources directed for this purpose has remained virtually constant. NCI has had great difficulty in recruiting scientists for its carcinogenesis testing program because of the shortage of qualified individuals, unattractive employment conditions, and because NCI has taken little initiative to develop the specialists it needs.

The bioassay backlog occurred and has continued primarily because NCI did not require the preparation of bioassay reports until 1976 and limited staff has been devoted to the project. NCI reduced the number of bioassays for which it intended to publish reports, but it still failed to publish reports on the remaining bioassays by its intended goal of September 30, 1978, and as of March 1979 NCI had still not completed its work on the backlog.

Further, there are more bioassays which qualified for inclusion in the backlog than were reported to the Congress by NCI. We identified 223 unreported bioassays, but we are not certain these are all that exist. Thus, NCI has not disclosed to the Congress the full extent of the bioassay backlog.

Finally, NCI has not adequately monitored Tracor-Jitco's performance in managing bioassay testing activities. As a result, NCI was not aware of the subcontractor laboratories' conditions and did not have important information to use in determining the amount of the award fee to be paid to Tracor-Jitco.

RECOMMENDATIONS TO THE SECRETARY OF HEW

We recommend that the Secretary of HEW require the Director of NCI to determine the total number of bioassays completed before July 15, 1976, for which results have not been reported by NCI and to submit a plan for bringing a timely end to this situation and preventing a recurrence.

We also recommend that the Secretary of HEW require the Director of NCI: (1) to more closely monitor the performance of Tracor-Jitco, Inc. by making more frequent site vists to the subcontractors' laboratories and by verifying that Tracor-Jitco has required the laboratories to correct deficiencies found during inspections and (2) to use the information from NCI's site visits and inspections of the laboratories as part of the basis for determining the amount of the award fee.

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As you know, section 236 of the Legislative Reorganization Act of 1970 requires the head of a Federal agency to submit a written statement on actions taken on our recommendations to the Senate Committee on Governmental Affairs and the House Committee on Government Operations not later than 60 days after the date of the report and to the House and Senate Committees on Appropriations with the agency's first request for appropriations made more than 60 days after the date of the report.

We encourage the early release of this report so that the requirements of section 236 can be set in motion. However, as agreed with your office, we will not release this report for 30 days to the Department of Health, Education, and Welfare and to other interested parties unless you have approved its release or made its contents public.

Sincerely yours,

Philip A. Bernstein for

Gregory J. Ahart
Director

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NCI'S RESOURCES DIRECTED TO CARCINOGENESIS ACTIVITIES

In December 1971 the National Cancer Act was enacted to enlarge the authorities of NCI and NIH in order to advance the national effort against cancer. The act established a National Cancer Program and required the Director of NCI to plan and develop an expanded, intensified, and coordinated cancer research program. To carry out the program, NCI adopted a national cancer program plan based on the advice of 250 scientists who attended 42 planning sessions. The plan was divided into strategic and operational segments, both of which emphasized, among other things, the importance of carcinogenesis activities and, in particular, the identification of carcinogenic hazards.

NCI's appropriations and staff have increased significantly since the act was passed. NCI has devoted more resources to carcinogenesis activities; however, the proportion of its resources allocated for this purpose in 1978 remained about the same as in 1972.

NCI has experienced significant difficulty with recruiting scientists for the carcinogenesis testing program. When we made our review, the testing program was operating at only 59 percent of its authorized strength because of the difficulty with recruiting qualified staff. NCI has had a particularly difficult time with staffing two critical specialties--toxicologists and veterinary pathologists; 7 of the 13 scientific vacancies that existed in the testing program were for these specialties. The difficulty with hiring scientists, according to NCI, was caused by a lack of research opportunities in NCI, the uncertainty about the testing program's future, the general shortage of toxicologists and veterinary pathologists, inadequate pay for veterinary pathologists, and the lack of an Office of Personnel Management (formerly the Civil Service Commission (CSC)) classification for toxicologists.

CSC offered a partial solution to NCI's recruiting problems--it said that other agencies experiencing problems like NCI's had established their own training programs to fill scientific needs. NCI recognized the need to establish such training programs in testimony given to the Senate Appropriations Committee in 1977--it stated that it had the legislative authority to initiate programs but a shortage of funds prevented it from doing so. The Congress increased NCI's appropriation by about $52 million for the

following fiscal year. However, the Congress did not specify that NCI's funds were to be used for training programs that would help alleviate its shortages of scientific personnel, and NCI did not establish any such programs.

PROGRAM STRUCTURE

Research indicates that external chemical and physical substances called carcinogens cause the vast majority of cancers. The carcinogenesis program was established in 1968 in response to this fact.

The carcinogenesis program was one activity within the Division of Cancer Cause and Prevention (DCCP) before July 1977. NCI later reorganized the program into two activities--the Carcinogenesis Research Program and the Carcinogenesis Testing Program--which were still within DCCP. An associate director operates each program, and each program consists of several components. Both associate directors report to the DCCP Director.

In addition to the staff within the two programs, additional NCI staff involved in other carcinogenesis activities are located within the Office of the Director of DCCP and the Division of Cancer Research, Resources and Centers. Therefore, future references to the term "carcinogenesis activities" will include the positions and functions of the Carcinogenesis Research Program, the Carcinogenesis Testing Program, a portion of the Office of the Director of DCCP and a portion of the Division of Cancer Research, Resources and Centers.

NCI had 223 staff authorized for carcinogenesis activities for fiscal year 1978, most of which were in the carcinogenesis research and testing programs. NCI authorized 123 full-time permanent positions for the research program, but DCCP allocated only 112 positions to the program. The remaining 11 positions were retained for the Office of the Director of DCCP. NCI authorized the carcinogenesis testing program 49 positions. NCI also had 51 additional staff assigned to other components involved in carcinogenesis activities in the Division of Cancer Research, Resources and Centers and the Office of the Director of DCCP.

NCI FUNDS AND STAFF ALLOCATED FOR CARCINOGENESIS ACTIVITIES

NCI stated that it places great emphasis on carcinogenesis activities and, in particular, on the identification

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of carcinogenic hazards. The table below shows the NCI obligations for fiscal years 1972 to 1978 in both actual dollars and constant dollars (using 1970 as the base year), and the amounts obligated for carcinogenesis activities and bioassay testing of environmental carcinogens. The amounts in this table include salaries and wages, equipment purchases, travel, grant and contract costs, and miscellaneous expenses.

NCI Funds Obligated For Carcinogenesis Activities

Fiscal year	NCI obligations		Amount obligated for carcinogensis activities		Amount obligated for bioassays	
	Actual dollars	Constant dollars (note a)	Actual dollars	Constant dollars (note a)	Actual dollars	Constant dollars (note a)
	(000 omitted)					
1972	$ 372,517	$ 336,383	$ 53,755	$ 48,541	$ 8,047	$ 7,266
1973	425,234	368,253	65,748	56,938	6,105	5,287
1974	580,809	473,940	73,413	59,905	13,465	10,987
1975	699,000	522,852	85,642	64,060	13,931	10,420
1976	761,450	520,070	92,819	63,395	13,758	9,397
1977	814,957	508,533	b/94,024	58,671	17,867	11,149
1978	872,369	484,165	b/93,008	51,619	18,026	10,004
Total	$4,526,336	$3,214,196	$558,409	$403,129	$91,199	$64,510

a/Base year is 1970.

b/Between fiscal years 1976 and 1977, NCI decided that certain grants made by the Division of Cancer Research, Resources and Centers, previously identified as carcinogenesis grants and included in the above totals for fiscal years 1972 through 1976, should be reclassified. These grants, which amounted to $10,415,000 in fiscal year 1977 and an estimated $11,144,000 in fiscal year 1978, are not included in the totals.

Based on the figures from the table, we computed that from fiscal year 1972 through 1978

--NCI's obligations increased 134 percent in actual dollars and 44 percent in constant dollars,

--NCI's funds obligated for carcinogenesis activities increased 73 percent in actual dollars and 6 percent in constant dollars,

--NCI's funds obligated for bioassay testing increased 124 percent in actual dollars and 38 percent in constant dollars,

--the proportion of NCI's obligations for carcinogenesis activities decreased in both actual and constant dollars from about 14 percent to 11 percent of total obligations,

--the proportion of NCI's obligations for bioassay testing decreased in both actual and constant dollars from about 2.2 percent to 2.1 percent of total obligations, and

--the proportion of NCI's obligations for bioassay testing increased in both actual and constant dollars from about 15 percent to 19 percent of the amount obligated for carcinogenesis activities.

In terms of staffing, we found that from fiscal year 1972 to 1978

--NCI's staff increased from 1,665 to 2,042 (23 percent),

--staff assigned to carcinogenesis activities increased from 166 to 223 (34 percent), and

--the proportion of total staff assigned to carcinogenesis activities rose from 10 percent to 11 percent.

NCI HAS HAD DIFFICULTY IN RECRUITING SCIENTISTS FOR THE TESTING PROGRAM

NCI stated that the carcinogenesis program needed more staff for its effective operation during fiscal year 1977 House Appropriations Committee hearings. The Congress authorized DCCP 77 additional positions for fiscal year 1977.

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According to the House Appropriations Committee Report, 60 positions were for the carcinogenesis programs and 17 positions were for DCCP's Environmental Epidemiology Branch. Of the 60 positions for the carcinogenesis programs, NCI allocated 30 positions for the carcinogenesis testing program, 20 for the carcinogenesis research program, and 10 for the Office of the Director of DCCP.

We found that the carcinogenesis testing program has had problems with filling these additional positions--16 of the 30 additional authorized positions remained vacant as of August 1978. The testing program also had four vacancies from its prior position authorization, resulting in 20 vacancies in a program authorized 49 full-time permanent positions. Thirteen of these 20 vacancies were for scientific personnel; the remaining 7 vacancies were for technical and support personnel. According to the associate director for the carcinogenesis testing program, NCI had had difficulty with filling the scientific positions because

--scientists lacked an opportunity to perform research,

--the testing program's future was uncertain,

--toxicologists and veterinary pathologists are generally in short supply,

--Federal veterinary pathologists receive inadequate pay, and

--CSC lacks a position classification for toxicologists.

Scientists lack an opportunity to conduct research

Scientists working in the carcinogenesis testing program perform full-time administrative (i.e., contract administration), rather than scientific duties and do not have the opportunity to conduct research. This is because of NIH's policy which precludes scientists responsible for extramural activities from conducting intramural research. The associate director stated that the inability to conduct research has further hindered NCI's recruitment efforts for the program because scientists are reluctant to devote all their efforts to administrative duties. He added that scientists need this research opportunity in order to maintain and enhance their scientific skills. Commenting on our draft report, NCI stated that, while it would be advantageous for scientists who are

responsible for extramural contract operations to do intramural research, NCI intends to continue to comply with the general NIH policy of separating intramural from extramural activities.

The testing program's future is uncertain

According to NCI officials, since December 1977 the Secretary of HEW has held discussions with the National Institutes of Health, the Food and Drug Administration, and other Federal agencies on how the Government should be organized to meet the Nation's chemical testing needs. Some of the options considered were:

--Creation of a new Government agency that would be responsible for the toxicological evaluation of chemicals. Under this proposal the facilities of the Food and Drug Administration's National Center for Toxicological Research (NCTR) would be transferred to the new agency. The testing programs of NCI and the National Institute of Environmental Health Sciences (NIEHS), located in North Carolina, would also be transferred.

--Creation of a national toxicology program within a new organization which the National Institutes of Health proposed as an expanded NIEHS. Under this proposal all resources from NCTR would be transferred to the new organization, along with all of NCI's bioassay resources.

--Keeping the existing components intact, but coordinating their efforts by a committee.

--No change.

The Secretary of HEW decided to create a National Toxicology Program in September 1978. The program will be comprised of the relevant activities of the Food and Drug Administration, NCI, the National Institute for Occupational Safety and Health, and NIEHS, but these activities will remain physically and administratively within their agencies. The new program will be administratively a part of the Assistant Secretary for Health's office, and it will have an executive committee consisting of the heads of the Food and Drug Administration, the National Institutes of Health, NCI, NIEHS, the National Institute for Occupational Safety and Health, the Environmental Protection Agency (EPA), and the Consumer Product Safety Commission; the Assistant Secretary for Occupational Safety and Health, Department of Labor; and the Assistant Secretary for Health and Surgeon General. The

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NIEHS Director will also serve as the Toxicology Program Director.

The future of the testing program was uncertain while discussions were underway on the different proposals. This uncertainty contributed to the difficulty in recruiting program staff, according to the associate director. He stated, for example, that he was unable to give prospective employees any assurance about job location or whether they would be working for NCI or some other agency. According to the associate director for the carcinogenesis testing program, the Secretary of HEW's decision on the organization of Federal testing efforts has not eliminated the uncertainty about the testing program's future. After a 2-year trial period, the Secretary will again review Federal testing efforts and make a final decision on how the Nation's chemical testing efforts should be organized. At that time, according to the associate director, the Secretary could move NCI's testing activities to another Federal organization in another State. Thus, the HEW Secretary's decision has only continued the period of uncertainty and has not eliminated the burden on recruiting efforts, according to the associate director.

Toxicologists and veterinary pathologists are scarce

According to the associate director for the carcinogenesis testing program, the recruitment of two particular scientific specialties has been extremely difficult. In order to conduct the work assigned to the carcinogenesis testing program, DCCP needs experts in toxicology 1/ and veterinary pathology. 2/ However, the demand for these

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1/Toxicology is the scientific study of poisons. However, according to NCI and others, toxicology is concerned with the adverse effects of chemicals and other substances on living organisms and the assessment of the likelihood that such adverse effects will occur under specified conditions of use or exposure.

2/Veterinary pathology is the branch of medicine that treats the essential nature of disease in animals, especially of the structural and functional changes in tissues and organs of the body which cause or are caused by disease.

two specialties is great but the supply is limited, according to the associate director and as stated by NCI in testimony in 1977. Of the 13 scientific vacancies in the testing program, 3 are for toxicologists and 4 are for pathologists.

The demand for toxicologists both within and outside the Government has increased because a substantial amount of environmental health legislation has been enacted that requires this expertise, according to several Government studies. The studies found that 15 statutes relate directly to the regulation of chemicals and other hazardous substances, and an additional 15 statutes relate directly to other aspects (such as assessing risk to health and the environment). Sixteen Federal agencies, as well as the White House, have administrative and regulatory authority from these statutes. The shortage of toxicologists is also caused by the newness of the field of toxicology--there is no consensus about the characteristics of a training program in this field. Often, according to the testing program's associate director, persons working in the toxicology field have developed their expertise through experience rather than by formal training, and they are not qualified in the areas needed by the program. For example, in attempting to fill toxicologist positions NCI staff interviewed 16 people working as toxicologists; 8 of the 16 were not qualified in the areas of expertise needed.

Federal veterinary pathologists receive inadequate pay

The carcinogenesis testing program has had difficulty with recruiting veterinary pathologists because there are vast differences in Government and private industry salaries. A 1976 study by the American College of Veterinary Pathologists showed that the mean salary for a veterinary pathologist working for the Government was about $29,000 a year (not including fringe benefits and secondary income); the comparable salary for a veterinary pathologist in industry was about $40,000 a year. When fringe benefits and secondary income are included, the mean income for a Federal veterinary pathologist increased to about $37,500 a year; for industry the salary increased to $53,000 a year.

In attempting to hire veterinary pathologists who are certified by the American College of Veterinary Pathologists or by the American College of Pathologists (commonly referred

to as "board certified" 1/), the program's associate director stated that none were willing to be interviewed, primarily because of the salary disparity. NCI personnel also reported that veterinary pathologists usually decline potential employment because of insufficent salary.

CSC lacks a job classification for toxicologists

We found that CSC does not have a job classification for toxicology; NCI stated that the lack of a toxicology classification has also hindered recruitment efforts.

According to NCI and CSC officials, since no job standards for toxicology exist, toxicologists are rated against pharmacology 2/ standards. As a result, toxicologists that NCI wanted to employ for the testing program were found by CSC to be less qualified than job candidates on the CSC register that have some toxicology background. However, the testing program's associate director stated that the problem with the CSC candidates is that they have often developed their toxicology background through job experience rather than formal education, and they are not qualified to work in the areas needed by the testing program.

According to NCI, CSC should establish a job classification for toxicologists because toxicology and pharmacology are different specialties. Pharmacology deals basically with the effect of drugs that are intended for human consumption; however, toxicology deals with the adverse effects of chemicals and other substances not intended for human consumption.

In 1977 NIEHS, EPA, and other private groups involved in chemicals sponsored a workshop on toxicology training issues at which representatives of NCI (including the testing program's associate director); EPA, the Food and Drug Administration (FDA), NIEHS and other Government and industry representatives attended. A 1978 report on the workshop stressed the need for a job classification for toxicologists:

1/According to the associate director for the carcinogenesis testing program, NCI decided that bioassay reports must be reviewed and approved by board-certified pathologists in order for the report to be used by the regulatory agencies and to withstand challenges in court.

2/The study of drugs.

"The absence of a federal civil service job category entitled 'toxicologist' is a severe impediment to effective recruitment of outstanding toxicologists into the regulatory agencies, since the entire existing federal apparatus for advertising and hiring, as well as for career advancement, is based on the existence of a carefully defined civil service professional ladder. Lacking a civil service category of 'toxicologist,' if a federal agency wishes to hire a toxicologist, it must fill a job category called 'biologist' or 'pharmacologist/toxicologist'; the specific qualifications most central to toxicology cannot be taken into account and rewarded adequately."

CSC officials don't believe that NCI's main recruiting problem is the lack of a job classification for toxicologists. CSC officials stated that NCI's problems are due to the demand for toxicologists because of legislation (particularly the Toxic Substances Control Act) requiring this specialty--but the supply of toxicologists is limited.

CSC officials also stated that NCI has had difficulty hiring the toxicologists it wanted because NCI often fails to justify to CSC why these individuals should be considered above candidates CSC already has on its register. In November 1978 EPA, FDA, the Consumer Product Safety Commmission, and the Occupational Safety and Health Administration formally requested that CSC adopt a classification for toxicology. CSC still had the matter under consideration at the time of our review. CSC officials stated that NCI could possibly alleviate the shortages in these fields if it establishes training programs in toxicology and veterinary pathology. We believe that training programs will not offer immediate relief in these specialties because they require considerable time, nor will they prevent individuals from leaving the Federal service for more lucrative positions. However, according to CSC other Federal agencies have used these types of programs to fulfill the need for scientists. Two of these training options are discussed below.

Government Employees Training Act (5 U.S.C. 41)

Under this act agencies can train employees by paying for tuition and other related training expenses. Agencies

can also use this act to conduct their own training programs to develop skills not available. According to CSC officials, several agencies have developed their own training programs for scientists:

--Naval Research Laboratory.

--Naval Surface Weapons Center.

--Naval Ship Research and Development Center.

--National Bureau of Standards.

--National Oceanic and Atmospheric Administration.

Cooperative Education Program

Agencies can train college students in job-related courses under this program, which is authorized under the Government Employees Training Act. According to CSC the trainee is actually a Federal employee while in school. If tuition assistance has been provided, the trainee is required to work for the Government after completing training.

NCI has no training programs for toxicologists or veterinary pathologists, except for institutional support grants and fellowships, according to NCI officials. However, these programs do not require Government-supported individuals to work for the Government as a condition of receiving support. In testimony before the Senate Appropriations Committee in 1977, NCI recognized the need to establish training programs for veterinary pathologists and toxicologists, but it added that it would need additional funds to accomplish this. NCI also told the Appropriations Committee that it had the legislative authority to initiate these programs. While the Congress increased NCI's appropriation for fiscal year 1978 by about $52 million, it did not specify that NCI was to use any of its funds to establish training programs for toxicologists and veterinary pathologists. NCI did not use any of its funds to establish such programs.

NCI stated that it never intended to establish intramural training programs for toxicologists and veterinary pathologists for carcinogenesis testing because these scientists were so scarce that it could not direct the ones it employed to establish training programs. Further, NCI does not consider scientists who work in the carcinogenesis testing program to be involved in research, and believed

that it could only use its training authority to support research personnel. With the amendment of the cancer act in November 1978, NCI believes it can now support training of nonresearch personnel in carcinogenesis testing, and it is now beginning to develop such programs.

Finally, NCI stated that it did not establish these training programs because its fiscal year 1978 appropriation represented little more than it needed to maintain ongoing activities in light of inflation, and that the appropriation was made well after the start of the fiscal year.

CONCLUSIONS

NCI has significantly increased the funds obligated and staff assigned for carcinogenesis activities from the enactment of the National Cancer Act of 1971. However, the proportion of NCI's total obligations and authorized staff assigned to carcinogenesis activities has remained virtually constant.

NCI has had great difficulty with recruiting scientists for its carcinogenesis testing program. Part of the staffing problem has been a shortage of qualified personnel--particularly toxicologists and veterinary pathologists to work in the carcinogenesis testing program. The shortage of toxicologists occurred because it is a relatively new specialty and a substantial amount of legislation has been enacted that requires the expertise of this specialty. The shortage of veterinary pathologists occurred primarily because of the vast salary differences between industry and the Federal sector.

NCI's staffing problems for the carcinogenesis testing program were further complicated because under NIH's policy scientists do not have the opportunity to perform research and few scientists are willing to make that sacrifice. The uncertainty surrounding the carcinogenesis testing program's future has also hindered NCI's staffing efforts.

NCI also claimed that its staffing problems were due to the absence of a CSC job classification for toxicologists. However, qualified toxicologists are in short supply, and NCI has taken little initiative until recently to develop the specialists it needs, apparently because NCI believed other factors precluded it from doing this, including the lack of legislative authority. However, NCI believes that the recent amendments to the National Cancer Act have expanded and clarified its training authority and removed

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the obstacles to establishing training programs for nonresearch personnel. We recognize that the establishment of training programs will not solve all of NCI's staffing problems because training for scientists takes a considerable amount of time, and scientists could still leave the Government for more lucrative positions. However, we do believe that NCI's efforts to establish such programs could help to relieve its shortages of certain scientific personnel.

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NCI HAS PROBLEMS ELIMINATING THE BIOASSAY BACKLOG

The carcinogenesis testing program attempts to identify the carcinogenicity of chemicals through the conduct of bioassays. The results of NCI's bioassays are frequently used by agencies such as FDA or EPA as the basis for regulating chemicals. However, NCI has experienced lengthy delays between the time bioassays are completed and technical reports on the results are published. NCI included 207 chemical tests in a category defined as the "bioassay backlog." Although NCI testified before the House Appropriations Committee in early 1978 that it would eliminate the backlog by the end of September 1978, it failed to meet this goal. NCI also revised its goal of publishing reports for all 207 bioassays. NCI decided not to report on about 25 percent of the bioassays because they were found deficient in either the design or execution phase of the test. Thus, NCI's goal is to now publish technical reports on only 156 of the 207 backlogged bioassays.

Many factors contributed to the backlog and NCI's delay in eliminating it; some of these factors were within NCI's control and others were not. However, of all the factors that contributed to the backlog, we believe NCI's lack of commitment to reporting on bioassays until 1976 was the most important.

NCI also has more than 200 additional bioassays that meet the criteria it used for defining the original backlog. NCI has not reported these bioassays to the Congress.

NCI HAS FAILED TO ELIMINATE THE BACKLOG

When NCI originally contracted with laboratories to conduct the bioassays, NCI did not contractually require them to prepare bioassay reports. NCI decided detailed bioassay reports were needed in 1975, and it began the technical report series, 1/ which is the current method of publishing the results of bioassays. However, NCI found that it took about

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1/Technical reports detail the results of NCI bioassays, are approved by the NIH Director, and are used by the various regulatory agencies (such as EPA and FDA) to decide if chemicals and other substances should be allowed to remain on the market or be banned. The technical reports describe the chemical tested, the methods used in the bioassay, the test results, and NCI's conclusions on carcinogenicity.

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1 year to prepare these reports; efforts to speed up the process were unsuccessful. The lack of reports on completed bioassays became a major concern to NCI.

Under a 1975 contract modification, Tracor-Jitco of Rockville, Maryland, was made responsible for developing a system to report bioassay results. NCI directed Tracor-Jitco to develop this system in August 1976. NCI took two actions to produce reports on completed bioassays in 1976. First, NCI required Tracor-Jitco to assure that all ongoing and future contracts with its subcontractor laboratories contained a provision for reporting on bioassays. Second, under terms of the Tracor-Jitco contract, NCI directed Tracor-Jitco to develop a plan to produce draft technical reports on all completed but unreported studies within 1 year. NCI approved the plan in November 1976. According to NCI, the plan was to include all completed bioassays in which the animals were killed before July 15, 1976. In most cases, these bioassays were initiated prior to Tracor-Jitco's designation as the prime contractor. A total of 207 bioassays were included in this category; they were the bioassay backlog which NCI reported to the Congress. NCI stated that it would publish final technical reports for all 207 bioassays. NCI stated it would complete work on the backlog and report the results to the regulatory agencies by September 30, 1978, in testimony before the Congress in early 1978.

We found that the Tracor-Jitco plan succeeded in providing NCI with draft bioassay reports; however, NCI failed to eliminate the backlog by September 30, 1978, since it had published only 99 technical reports as of October 1978. As of March 1979 NCI has published 139 reports.

NCI revised its goal of publishing reports for all 207 bioassays; NCI found that 51 of them were deficient in either design or execution, and it decided not to publish final reports on these bioassays. NCI did, however, publish technical journal articles on 32 of these 51 bioassays. Commenting on our draft report, NCI stated that the chemicals included in 50 of the 51 bioassays have been or are being examined by DCCP's Chemical Selection Working Group to determine whether new bioassays should be done on them; NCI decided to retest the remaining chemical without going through the Chemical Selection Working Group. Also, the testing program's Associate Director stated that, because of these 51 deficient bioassays, NCI's goal is to now publish technical reports on only 156 of the 207 backlogged

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bioassays, 1/ and the Tracor-Jitco plan produced draft reports on all these bioassays.

Commenting on our draft report, NCI stated that it eliminated the backlog by December 1978 since it had provided the results on the tests to the regulatory agencies prior to formally publishing technical reports. We contacted EPA and FDA to determine whether regulatory action is taken on this preliminary data. FDA stated that, while it would begin to develop a regulatory position, it would not take a final regulatory action based on NCI's preliminary data because of possible legal actions that could result from acting on data that are still unofficial. EPA stated that it also preferred to act only on published technical reports; however, it had acted on preliminary data in special cases (such as chemicals found to be in wide usage). EPA further stated that the only reason it decided to act on NCI's preliminary data in such cases was because EPA and NCI had an arrangement whereby EPA has access to "raw" data from the NCI tests (particularly pathology results) and could analyze the information NCI used to reach its conclusions. Because of the importance the regulatory agencies place on NCI's published technical reports, we believe NCI's conclusion that it had eliminated the backlog in December 1978 is incorrect. We believe NCI's action to eliminate the bioassay backlog should not be considered completed until NCI has published technical reports on the 156 chemicals NCI determined worthy of reporting. As of March 1979 NCI had not accomplished this.

We also believe that NCI had the obligation to report to the Congress the fact that it was not preparing technical reports on 51 deficient bioassays, because these bioassays account for a significant percentage of the reported backlog.

THE REPORTED BACKLOG WAS CAUSED BY FACTORS THAT NCI COULD AND COULD NOT CONTROL

The Clearinghouse on Environmental Carcinogens (an NCI advisory group established to advise the NCI and DCCP Directors on the identification of environmental carcinogens) stated in a May 1978 report to the NCI Director that a number of factors contributed to the backlog. Two of the factors discussed in the report were beyond NCI's control--the

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1/NCI plans to combine the results of more than one bioassay in a technical report. Thus, the overall goal is to publish 150 reports on the 156 bioassays.

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passage of the 1971 National Cancer Act (which emphasized identifying environmental carcinogens), and the fact that the legislation did not assign responsibility for testing suspected carcinogens (which led NCI to assume this responsibility).

Given the above circumstances, NCI established a Bioassay Segment to evaluate carcinogenic hazards and to initiate a number of contracts for conducting bioassays. As a result NCI started a large number of bioassays--392 in total--from 1971 to 1973. The number of bioassays started during this period is substantially higher than the 69 bioassays begun during the following 3 years--1974 to 1976. As previously stated, NCI did not require the laboratories conducting them to prepare reports on the bioassay results when these contracts were awarded. The failure to require the laboratories to prepare reports contributed to the backlog.

The Bioassay Segment was handicapped by a severe shortage of staff; this was another factor that caused the backlog, according to the Clearinghouse report. It was initially directed by only one intramural scientist who was also responsible for an inhouse research program. The only full-time professional staff was a segment manager who was responsible for administering the bioassay contracts. Project officers, veterinarians, pathologists, statisticians, and others who collaborated in monitoring, evaluating, and analyzing bioassays participated on an ad hoc basis and came from various program areas--in some cases from outside DCCP. Because of this inadequate staffing and the informal structure of the operation, the segment could not properly monitor the bioassays while they were under way, nor could it deal with the results as they became available.

These factors created a workload that far exceeded the capacity of the limited NCI staff assigned to handle it and a large number of completed bioassays for which no reports were published.

THE DELAY IN ELIMINATING THE BACKLOG RESULTED FROM SOME FACTORS NCI COULD AND COULD NOT CONTROL

The plan developed by Tracor-Jitco to eliminate the backlog succeeded in providing NCI with draft bioassay reports, although some problems were experienced. As of October 1978 Tracor-Jitco had provided NCI with draft reports

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on the 156 bioassays in the backlog for which NCI decided to publish reports. However, NCI had published only 99 final reports on the bioassays. NCI failed to eliminate the backlog because of problems not anticipated in the Tracor-Jitco plan.

Report preparation problems slowed publication of test results

The Clearinghouse report stated that the Tracor-Jitco plan was overly optimistic about the time needed for completing bioassay reports. The plan was based on having no problems at any step, and many problems developed.

The plan called for teams to be established at the laboratories that performed the bioassays to write the draft bioassay reports. However, the plan did not allow time to recruit and train staff and, as a result, the writing teams were not fully functioning until early 1977. According to the Clearinghouse report, Tracor-Jitco's performance in developing the laboratories' teams was poor--this further complicated the development of the writing teams. In December 1976 NCI notified Tracor-Jitco that, if its performance did not improve, NCI would withdraw its function of preparing bioassay reports. Commenting on our draft report, Tracor-Jitco stated that the main problem with the writing teams was inconsistency in style and detail of the reports prepared by the laboratories. Due to the difficulty in having the laboratories' teams prepare bioassay reports, Tracor-Jitco ultimately was assigned this responsibility.

Tracor-Jitco experienced difficulty when it attempted to prepare reports on the laboratories' bioassays. In many instances considerable time had elapsed since the bioassays were completed. Records of the tests had been placed in storage or were kept in a format that made it difficult for Tracor-Jitco staff to gather for use in preparing reports. Also, in some instances personnel changes at the laboratories had occurred; thus further hindering efforts to gather test data.

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Advances in testing caused disagreements on test results

Other problems with the Tracor-Jitco plan occurred because, at the time the tests were started, the method for conducting these tests was very new. No standard methodology existed for conducting the long-term phases of the bioassays, for performing the pathology analyses, or for reporting results. NCI has now developed and adopted standard methodologies.

The pathological examination of tissues is, to a degree, a subjective art and, in several cases, disagreements occurred among pathologists on the results. The problems encountered in the pathology performed on the older bioassays were so severe that NCI initially rejected about 60 percent of the written pathology narratives that were submitted from the laboratories that conducted the bioassays and, in several instances, NCI had to have the pathology work redone.

Another problem resulted because many of the older bioassays used very small numbers of animals in their control groups. 1/ Some tests used as few as 10 control animals; this method required that control groups from two or more tests be pooled into control groups to make statistical analyses. Pathologists responsible for the tests did not always agree on the interpretation of tissues from the pooled controls; serious problems occurred in the statistical analysis of the test data as a result.

NCI staff limitations slowed processing of bioassay reports

Another delay occurred because one person--the head of DCCP's Data Evaluation Group (DEG)--was responsible for reviewing most of the draft bioassays. According to the Clearinghouse report, this responsibility required the commitment of more than one person because of the volume of

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1/Control animals are a group of untreated animals that serve as a standard of comparison in experimental studies.

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draft reports ready for review. However, the associate director of the Carcinogenesis Testing Program stated that the DEG leader is unique because he had developed such expertise and experience. The associate director further stated that it would not be worthwhile to train additional personnel to support the DEG leader because of the time required to train them and the amount of the backlog remaining. While neither we nor the Clearinghouse could substantiate or disprove the associate director's claim, we believe his contention is reasonable.

After NCI staff have reviewed a draft bioassay report, the report is forwarded to the Clearinghouse on Environmental Carcinogens for review. NCI stated that the Clearinghouse review of each report adds about 2 months to the process; this causes another delay in publishing the backlog. While the Clearinghouse stated that it could not ascertain the accuracy of its part in the delay, the chief of the Office of Cancer Communications stated that the Clearinghouse review did sometimes cause significant delays.

A further problem has been the length of time that elapsed between the date when a printable copy was sent to NCI's Office of Cancer Communications (OCC) and the date of the report's publication. OCC is responsible for preparing abstracts of the bioassay results for publication in the Federal Register, clearing the abstract through various NCI and NIH offices, preparing press releases, having reports printed, and scheduling the simultaneous publication of reports, abstracts, and press releases.

We found that a primary cause of delay was due to the few OCC staff assigned to process the bioassay reports. Until April 1978 OCC staff assigned with processing bioassays consisted of the Chief of the Research and Program Reports Section, a science writer, and a secretary.

In January 1977 the Chief of the Research and Program Reports Section established a goal of having one bioassay report per day printed in the Federal Register. However, OCC has not been able to meet this goal. We compared the number of reports scheduled for printing in the Federal Register with the number of reports available to OCC from June to August 1978. OCC had 40 draft reports on hand as of June 1, 1978. OCC received 26 more draft reports from DCCP from June to August, resulting in OCC having 66 draft reports for processing. However, OCC only had 16 reports scheduled to appear in the Federal Register during this period. The Chief of the Research and Program Reports Section

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stated that three factors affected OCC's failure to meet its goal:

(1) Between January and April 1978, OCC received a number of very urgent reports to process, some of which were not backlogged bioassays. Because of the few staff assigned to OCC, the processing of less urgent backlogged bioassay reports was delayed from 8 to 12 weeks.

(2) The only secretary assigned to type the documents necessary for processing reports resigned in April 1978, and it took OCC about 6 weeks to hire a replacement. This factor accounted for a delay of about 8 weeks.

(3) DCCP sometimes changed reports after the printable draft was prepared. These changes caused delays of about 2 months in a few cases, and in one case the delay was 6 months (however, for the majority of cases the delays seldom exceeded 1 week).

NCI HAS NOT INCLUDED ALL BIOASSAYS IN THE BACKLOG

Although NCI reported to the Congress that the backlog consisted of 207 bioassays, we found that NCI had other completed bioassays in which test animals were sacrificed before July 15, 1976 (the criteria NCI established for bioassays to be included in the backlog).

NCI officials stated that NCI included in the backlog only those bioassays for which Tracor-Jitco was responsible. We identified other bioassays that meet the criteria of having test animals sacrificed before July 15, 1976, that were not included in the backlog reported to the Congress and for which no technical reports had been published. Although we identified 223 such bioassays, we are not certain that we have identified all bioassays that fall into this category. Some of the substances included in these 223 bioassays were saccharin, cyclamates, hair sprays, and dandruff control shampoos.

We found 19 unreported bioassays that were performed at the Frederick Cancer Research Center. NCI plans to publish these bioassays as technical reports by using the same procedures developed for preparing reports on the 207 backlogged bioassays. Commenting on our draft report, NCI stated that it had provided the results of these tests to the

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regulatory agencies in December 1978. However, as of March 1979 only five of the tests had been published as technical reports.

We also found that the Carcinogenesis Research Program performed 37 small-scale bioassays with animal sacrifice dates between 1970 and 1972 which were not included in the reported backlog. These tests are to be published as scientific papers. Papers have been published on 21 bioassays as of March 1979, and papers on the remaining 16 are in preparation.

In 1968, NCI awarded a contract to the University of Nebraska's Eppley Institute for Research in Cancer to perform carcinogenesis research and testing. As of March 1979, the total amount awarded to Eppley was about $25 million. The Eppley Institute was responsible for 378 bioassays on 134 chemicals. We found that 334 of these 378 bioassays had animal sacrifice dates before July 15, 1976 (the backlog cutoff date). A total of 167 of Eppley's tests consisted of carcinogenesis bioassays, according to an NCI official responsible for administering the Eppley contract. The NCI official, however, stated that this listing was also incomplete.

We were advised that NCI has not published any of the Eppley results as technical reports, although the results have been published in scientific literature. Commenting on our draft report, NCI stated that it has supported many experiments on the development of bioassay methods and on the mechanisms of chemical carcinogensis in which hundreds of chemicals have been used. NCI stated that the results of these studies were never considered in the backlog, nor were the results of some experiments that were nonstandard bioassays. With regard to the chemicals tested at the Frederick Cancer Research Center, the bioassays were conducted by standard procedures. NCI advised us that Tracor-Jitco is preparing draft technical reports on these bioassays.

While the bioassays conducted by the Eppley Institute and NCI's inhouse staff were not done using standard procedures, we were advised by NCI's Eppley project officer and by the acting Associate Director, Carcinogenesis Research Program that one of the purposes of the bioassays was to determine the carcinogenicity of the chemicals being tested.

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CONCLUSIONS

A number of factors have contributed to the backlog and NCI's delay in eliminating it. These factors include the large number of bioassays started and completed while NCI had a shortage of qualified staff to review, analyze, and process technical reports, the failure to require laboratories to prepare written reports on the bioassays done through 1975, the delay in getting assistance in preparing reports, and the problems with working in an area where the methodology was rapidly changing. We believe the single most important factor that contributed to the backlog was the lack of commitment by NCI to preparing bioassay reports until 1976. Even though NCI directed Tracor-Jitco over 2 years ago to develop a plan to eliminate the backlog and NCI significantly revised its original goal to publish reports on all 207 bioassays, the backlog has not been completely eliminated. NCI now plans to publish only 150 reports on 156 chemicals because 51 bioassays were deficient. We believe NCI's efforts in publishing reports on the backlogged bioassays, even at this reduced level, have been sluggish; only 99 reports had been published as of October 1978 and, as of March 1979, NCI had published reports on 139 chemicals.

We have also found additional unreported bioassays that meet the criteria NCI used in defining the original backlog to the Congress. We found 223 such bioassays, but we are not certain these are all. Thus, NCI has not fully disclosed to the Congress the extent of bioassays that were completed before July 15, 1976, that lack published technical reports.

RECOMMENDATION TO THE SECRETARY OF HEW

We recommend that the Secretary of HEW require the Director of NCI to determine the total number of bioassays completed before July 15, 1976, for which results have not been reported by NCI, and to submit a plan for bringing a timely end to this situation and preventing a recurrence.

ENCLOSURE III

NCI HAS NOT ADEQUATELY MONITORED TRACOR-JITCO'S BIOASSAY RESPONSIBILITIES

NCI contracted with Tracor-Jitco to develop a plan to eliminate its bioassay backlog and to manage its bioassay testing activities. Under the terms of the contract, Tracor-Jitco had an opportunity to earn an award fee of up to $3.2 million if NCI determines that contractual requirements have been satisfactorily performed. While NCI's monitoring of Tracor-Jitco's performance with the bioassay backlog has been good, its monitoring of Tracor-Jitco's management of bioassay testing activities has not been adequate.

NCI has relied primarily on reports from Tracor-Jitco to assess bioassay testing activities, and NCI has done little independent verification to check the accuracy and adequacy of these reports. We found that Tracor-Jitco

--did not inform NCI of certain laboratory deficiencies that occurred in the past,

--did not assure that deficiencies were corrected, and

--did not detect certain deficiencies which we found during our laboratory inspections that could affect the quality of bioassays.

Since NCI was not aware of these matters, it did not have important information which should have been used to determine the amount of the award fee to be paid to Tracor-Jitco.

Although NCI has paid only about 52 percent of the maximum award fee available to Tracor-Jitco through September 1978, it might have paid even less had it been fully aware of problems with the bioassay testing activities. When an award-fee type contract is awarded, it is not prudent management to rely on the contractor to report problems which could affect the amount of profit the contractor can earn.

NCI MADE TRACOR-JITCO RESPONSIBLE FOR MANAGING BIOASSAYS

NCI awarded a competitive prime contract worth about $6.6 million to Tracor-Jitco in March 1974 to manage the bioassay program because NCI did not have adequate staff for the task. NCI modified the contract several times on a noncompetitive basis since that time, and it extended the completion date from May 1975 to May 1979. The most

significant increase in the Tracor-Jitco contract occurred in June 1975--when NCI increased the contract's total amount from about $6.6 million to $41.3 million. NCI awarded this increase noncompetitively.

The justification for this noncompetitive procurement stated that the project was to develop a contractor capable of providing technical and managerial support for all aspects of NCI bioassay activities. The proposed work was considered a logical extension of past and ongoing work. NCI considered it infeasible to seek competition from other sources because doing so would relinquish Tracor-Jitco efforts of the past year and would require termination of long-term studies before their completion; there would be a long delay before such studies could be resumed by another contractor. The justification also noted that the principal investigator of ongoing work had experience which provided special knowledge for performing the proposed work. Commenting on our draft report, Tracor-Jitco stated that NCI's original request for proposal which was issued competitively was for a 5-year program. Tracor-Jitco added that NCI chose to issue a 1-year contract as a prudent management practice. It also stated that the contract was modified to a 5-year effort following an outside peer review by NCI in March 1975.

Under the contract, Tracor-Jitco is paid for its costs of performing the agreed-upon work ($39.7 million), a fixed fee of about $198,000, and, as previously mentioned, an award fee of about $3.2 million (depending upon NCI's satisfaction with the contractor's performance). NCI's contract with Tracor-Jitco specifies that the contractor can earn only a certain amount of the award fee every 4 months. Tracor-Jitco had the opportunity to earn about $2.9 million of the $3.2 million award fee as of September 1978. NCI has paid about $1.5 million of the $2.9 million to Tracor-Jitco; thus, NCI has paid Tracor-Jitco about 52 percent of the maximum available award fee.

NCI plans to extend the contract slightly past May 1979 to allow Tracor-Jitco to complete certain agreed-upon work. NCI will then assume the responsibilities previously assigned to to Tracor-Jitco for all future boiassays.

Tracor-Jitco's responsibilities with managing subcontracts with the laboratories performing bioassays include

--providing the laboratories with test chemicals and animals,

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--inspecting the laboratories to make sure they comply with NCI's and its own controls,

--informing NCI of the status of bioassays and any significant problems that occur,

--providing support personnel for specific tasks (such as pathology and statistical analysis),

--reviewing and approving the laboratories' bioassay results,

--reviewing all raw data and laboratory reports and resolving questions and discrepancies, and

--furnishing NCI with a draft report of bioassay results from summaries submitted to it by the subcontractor laboratories.

Subcontractor laboratory responsibilities

The subcontractor laboratories are responsible for performing bioassays. The bioassays are to be performed strictly according to the experimental design developed by NCI and to the statement of work in the subcontract. These documents provide a detailed description of the numerous procedures to be followed during the bioassay.

The laboratories must submit a monthly bioassay status report to Tracor-Jitco which is to include

--the status of each chemical being tested;

--chemical purity and dosage preparation analyses;

--a discussion of problems (such as unexpected animal deaths, dosages out of tolerance, or equipment failures);

--a histopathology progress report; and

--an updated bioassay schedule for completing various test phases.

At the conclusion of the bioassays the laboratories are also required to submit a pathology narrative that describes diagnoses of slides reviewed, all individual animal data records, and other animal tissues and slides.

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NCI responsibilities

In terms of quality control of bioassays, NCI is primarily responsible for (1) establishing requirements for conducting quality bioassays, (2) monitoring prime contractor quality control efforts, (3) reviewing subcontractor laboratory operations, and (4) reviewing laboratory pathology diagnoses and overall results.

NCI HAS NOT INDEPENDENTLY VERIFIED TRACOR-JITCO'S PERFORMANCE IN MANAGING BIOASSAYS

NCI has relied primarily on Tracor-Jitco for information on the quality and status of bioassays performed by the laboratories; it has done very little of its own verification to determine Tracor-Jitco's performance. Because NCI relies on Tracor-Jitco, NCI has not been adequately informed about the overall laboratory conditions that could affect the quality of the bioassays. NCI, therefore, is not in a favorable position to determine the amount of award fee that should be paid to Tracor-Jitco.

NCI only recently required Tracor-Jitco to make thorough laboratory inspections

We found that NCI did not require Tracor-Jitco to make thorough inspections of its subcontractor laboratories for the first 2-1/2 years of its contract. However, the current system for monitoring laboratory performance appears to be quite thorough.

One of Tracor-Jitco's contractual responsibilities is to inspect the laboratories to assure that the bioassays are conducted properly. To fulfill this requirement, Tracor-Jitco uses two types of onsite inspections--site visits and program reviews. However, until October 1976 NCI required Tracor-Jitco to only inspect the laboratories semiannually, and these inspections covered only Tracor-Jitco's responsibilities for animal control and management.

NCI began to require Tracor-Jitco to inspect each bioassay laboratory at least four times a year in October 1976; one inspection was to be unannounced. NCI also required Tracor-Jitco to make a separate inspection of specific areas such as animal care, chemistry, pathology, toxicology, and safety.

Tracor-Jitco also started conducting program reviews at the subcontractor laboratories in October 1976. The program review is performed as required (approximately once a year) and is an intensive, multidisciplinary inspection of all aspects of the laboratories' bioassay procedures. During the program review, a team of Tracor-Jitco scientists from different disciplines (toxicology, pathology, safety, animal care, and chemistry) inspects the laboratory and reviews its operation. NCI scientists usually observe the inspections. Tracor-Jitco officials prepare a list of deficiencies and laboratory officials are briefed by Tracor-Jitco representatives. According to an NCI official, the Tracor-Jitco program reviews are an effective tool for monitoring and assessing the quality of the work performed.

Tracor-Jitco has given NCI incomplete and inaccurate inspection reports

NCI did not contractually require Tracor-Jitco to prepare and submit a complete report on the results of its laboratory inspections before our visits to laboratories. Previously, Tracor-Jitco prepared summaries of its laboratory inspections for NCI. We found that these summaries did not include all test condition deficiencies that were mentioned in Tracor-Jitco's original reports. Tracor-Jitco said that it did not include certain deficiencies in the summaries sent to NCI because the summaries are publicly available under the Freedom of Information Act. Thus, according to Tracor-Jitco, it could be subject to a libel suit, particularly when observations are made by unqualified observers (i.e., a laboratory animal medicine specialist commenting on chemistry). Tracor-Jitco stated it was concerned because, under its contract with NCI, it is not protected from possible damages resulting from such an action.

We compared the original inspection reports prepared by Tracor-Jitco with the summarized versions forwarded to NCI, and presented the differences to the NCI program director responsible for the Tracor-Jitco contract for comment. He stated that several unreported items were significant and should have been brought to his attention. In the case of the Falls Church, Virginia, facility of Litton Bionetics, Inc., (which he had recently visited) the program director stated that the reports prepared by Tracor-Jitco did not give "an accurate representation of conditions at the lab." After a visit to Litton in December 1977, NCI directed Tracor-Jitco to not start any new chronic bioassays there until standards were improved.

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As a result of our advising NCI about the summaries' shortcomings, in February 1978 NCI began to require Tracor-Jitco to submit complete reports on its laboratory inspections.

NCI has done little verification of Tracor-Jitco's laboratory inspections

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We inspected three of six laboratories--Litton, Hazleton Laboratories of America, and Gulf South Research Institute--that perform bioassays for NCI as Tracor-Jitco subcontractors, to determine the laboratory conditions. While overall test conditions at the laboratories varied, we rated one laboratory as acceptable and the other two good. Although NCI required Tracor-Jitco to increase both the number and thoroughness of its laboratory inspections, we found that numerous deficiencies still existed at the laboratories that could affect the bioassays' quality. One of these deficiencies--the testing of more than one chemical in a room--was our major concern.

We found that NCI has made very few visits to the three laboratories we inspected to verify the accuracy and thoroughness of inspections made by Tracor-Jitco. According to NCI records, during a 4-year period ended in May 1978 NCI averaged one visit a year to these laboratories. Two of these laboratories (Litton and Hazleton) are within 30 miles of the NCI offices in Bethesda. NCI officials stated that critical staff shortages prevented more visits to these laboratories during this period.

THE NATURE OF BIOASSAY TESTING

Before discussing the audit approach we used for evaluating the conditions of the subcontractor laboratories conducting bioassays for NCI and the results of our audit, it is necessary to understand the nature of a bioassay and some of the methods for administering chemicals to animals.

Quarantine period

Upon their arrival at the subcontractor's laboratory, animals to go on chronic (long-term) bioassays are required to be placed in a sanitized room and observed for 2 weeks. This is to assure that the animals are healthy before starting the bioassay. If the animals are diseased, they might die from nondose-related chemical effects before completing the chronic bioassay. Thus, a 2-week quarantine period is considered necessary for reducing the chance of ending a bioassay because of diseased animals.

Maximum tolerated dose

To determine whether or not a chemical causes cancer, the laboratory attempts to administer the maximum tolerated dose (MTD) of the chemical to the test animals (usually rats and mice). The MTD is the highest dose level that the animals can tolerate and still live out their normal lives with few toxic effects other than carcinogenicity.

Predicting what the MTD should be is often difficult; as a result the laboratory administers a lower dose level to a separate group of animals. This lower dose is a fraction of the MTD and serves two purposes: (1) it provides additional information on whether the tumors developed in the animals are dose related (more tumors are produced by higher doses) and (2) the laboratory uses the lower dose level as insurance in case the high-dose animals die from noncancer-related causes. This second group assures that the bioassay can provide some meaningful results even if the entire high-dose group dies before the experiment ends.

Chronic toxicity test

After the MTD has been established, the laboratory administers a chemical to the test animals for 2 years in the chronic bioassay to determine whether the test chemical is carcinogenic. NCI, FDA, and Tracor-Jitco have established firm protocols on test conditions to assure bioassay validity. For example, only one chemcial is to be tested in an animal room at a time; insecticides, some of which may be carcinogenic, are to be used only after approval by NCI and Tracor-Jitco; temperature and humidity of animal rooms are to be constant; certain test equipment is to be washed at high temperatures to avoid contamination by microorganisms; and the laboratories are to be kept clean and in good repair.

Continued chemical analysis is also to be used throughout the chronic portion of a bioassay to provide information on the actual composition of the material being administered to the test animals. If, for example, the tested chemical is contaminated at the beginning of an experiment or breaks down during the administration period, the bioassay cannot be fairly represented as a test of that specific chemical for which the bioassay was desired. Therefore, good chemical analysis is very important to a bioassay program.

The animals receive the chemical for 103 weeks, are observed for 1 week, and are then killed. The test animals

are usually given the chemical in one of three ways--orally, by application to the skin, or by inhalation.

The animals are to be observed twice daily while under test, and specified tissues are to be taken during necropsy 1/ and made into slides. The laboratory pathologists are to study these slides, diagnose tissues, count tumors, prepare a pathology narrative summarizing their findings, and send the narrative to Tracor-Jitco. After its review, Tracor-Jitco forwards the narrative to NCI's Pathology Working Group for review. NCI's final report indicates whether, under the test conditions, the chemical did or did not cause cancer in the test animals. Testing a chemical from the time a chemical is approved for bioassay by NCI to publication of a report on the bioassay results averages a little more than 5 years.

OUR AUDIT APPROACH USED TO ASSESS TEST QUALITY

NCI officials stated that, while bioassay procedures have improved considerably in recent years, the methods for conducting bioassays are changing so rapidly that the results of experiments done 5 years ago are barely adequate now and those performed currently will probably be barely adequate in 5 years. To assess the conditions at the laboratories for conducting the highly technical bioassays, we first inspected the laboratories to gather raw data on the conditions and procedures they followed. Two of our expert bioassay scientists then reviewed the raw data and inspected the laboratories. After their inspection, our experts prepared a report on the overall test conditions at each laboratory.

We developed a checklist of over 300 individual bioassay procedures to gather the raw data at the laboratories. According to the NCI project officer, these procedures, if carefully followed, should assure a high-quality bioassay. Most of our checklist came from Tracor-Jitco's "Basic Ordering Agreement" that was developed in October 1977 for use by laboratories that wished to bid on bioassay contracts. The Agreement was approved by NCI. An NCI official said that the Agreement reflected the current method of bioassays and addressed every major aspect of bioassay procedures. We also

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1/The post-mortem examination of test animals.

incorporated into our checklist additional bioassay procedures contained in the NCI "Guidelines for Carcinogen Bioassay in Small Rodents," the NIH "Guide for Care and Use of Laboratory Animals," and the Food and Drug Administration's "Proposed Good Laboratory Practices."

To assure that the checklist was accurate and comprehensive, we tested it at the Battelle Memorial Institute laboratories in Columbus, Ohio (a Tracor-Jitco subcontractor), and we had bioassay scientists from NCI, the Food and Drug Administration, and industry review it. They all agreed that the checklist was satisfactory.

We included on our checklist some procedures not contractually required of the laboratories. Most of the subcontracts for the laboratories reviewed were awarded in 1974 and 1975. Since we based our checklist primarily on the Basic Ordering Agreement (which was not a contractual requirement at the time of our review), laboratories not complying with the checklist did not necessarily violate their contracts. We realized this before inspecting the laboratories, but believed it was more important to assess the quality of the tests based on the current methodology.

Our experts made all scientific judgments on the conditions at the laboratories and their effects on the quality of the tests. NCI and Tracor-Jitco recognized our experts as being qualified to make these judgments.

When our study began, only six Tracor-Jitco subcontractor laboratories were doing bioassays. We selected three of the six laboratories for detailed review; each of these laboratories has conducted NCI bioassays for over 5 years. Taken together, these laboratories have been assigned about 41 percent of the NCI bioassays conducted under Tracor-Jitco's jurisdiction.

Each laboratory inspection had three stages. In the first, we reviewed all pertinent correspondence on the laboratories' operations. This included Tracor-Jitco inspection reports, laboratory monthly progress reports, the bioassay subcontract, and NCI and Tracor-Jitco correspondence files. From these documents we prepared a preliminary briefing package for our experts.

For the second stage, we visited the laboratories, interviewed officials, reviewed records, and completed the checklist. We also selected at least one bioassay at

ENCLOSURE III

each laboratory and traced its paperwork from chemical and animal receipt to its termination.

The final stage of the inspection involved the experts. We briefed them on present and past conditions at the laboratory and reviewed our completed checklist. The experts then inspected the laboratory and interviewed key personnel. At the conculsion of their inspection, we held a briefing with officials of the three laboratories, informing them of our findings and providing them with a chance to comment.

We rated various aspects of laboratory operations by using the superior, good, acceptable, marginal, and unacceptable ratings. Several items not rated for the laboratories were either unremarkable or not studied in enough detail to justify a rating. Based on their inspection and the raw data we provided, the experts reported on the conditions at the laboratories and procedures followed in conducting bioassay tests.

DEFICIENCIES EXIST AT LABORATORIES THAT COULD AFFECT TESTS RESULTS

Although we found that overall test conditions at Hazleton and Gulf South were good and the conditions at Litton acceptable, deficiencies exist at the laboratories that could affect the quality of the bioassay tests. These deficiencies exist despite the fact that in 1977 Tracor-Jitco made 31 inspections of the three laboratories we inspected. Some of the deficiencies we found had also been detected by Tracor-Jitco in its inspections, but they were not reported to NCI.

Examples of these unreported deficiencies include

--multiple chemicals being tested in a single room (Litton),

--spot application of unapproved insecticides in the animal testing room (Hazleton),

--pathologists not having all necessary data on the animal conditions while reviewing slides (which we considered to be a serious oversight) (Litton and Gulf South),

--a bioassay test being moved to a different room during the course of the test (Hazleton), and

--animals killed by improper gavage 1/ techniques being designated as "natural deaths" (Gulf South).

We also found other deficiencies that, according to our review of Tracor-Jitco's records, were apparently undetected in its inspections. These deficiencies include

--temperature or humidity alarms not functioning properly (Gulf South);

--animals on quarantine being placed in a room with animals already on test (Litton);

--drinking bottle stoppers that animals chewed which could be a source of microorganisms (Hazleton);

--failure to analyze the amount of test chemical in drinking water before administering it to animals (Hazleton); and

--general housekeeping problems--painting, cleanliness, structural faults, etc. (Litton).

The overall ratings of test conditions at the laboratories appear as enclosure V. Commenting on our draft report, Gulf South stated that it had made changes in both its operations and facilities to correct the deficiencies we found.

Regarding the practice of testing more than one chemical in a room, Litton stated that this is a questionable practice and it had called this to the attention of both NCI and Tracor-Jitco. Further, Litton stated that its policy has always been to limit studies to one compound per room, with the exception of the NCI bioassay program. Under the terms of its contract, Litton stated it is required to test more than one compound in a room. In addition, Litton stated that the bioassays we found being conducted with other chemicals in a room were begun prior to NCI's requirement prohibiting this practice; Tracor-Jitco directed Litton not to relocate bioassays that were already in process.

Concerning the practice of pathologists not having all data on animal conditions, Litton stated that some pathologists prefer to read slides as a blind study. However,

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1/Administration of nourishment or chemical dose directly to the gastrointestinal tract through a tube.

Litton said it had modified its procedures so that pathologists are provided with clinical histories of the animals while reviewing slides. In addition, Litton adopted procedures to assure that any lesions or tissue masses found during bioassays will be reviewed and commented on by its pathologists.

In responding to our point on housekeeping deficiencies, Litton stated that, since it was awarded its contract, it had invested about $500,000 for facility improvement and equipment at its Falls Church, Virginia, facility. Litton stated that the facility was also reviewed and accredited by the American Association for Accreditation of Laboratory Animal Care and has passed inspections from the Department of Agriculture. Litton also stated that the overall survival rate of the test animals was good.

During our review at Litton, we found several structural and maintenance deficiencies (i.e., holes and cracks in ceilings, floors, and walls and inadequate air exchanges and lighting in the animal rooms) at Litton's Falls Church facility. We considered these deficiencies to be serious, since they could alter the results of the bioassays, and we believe they should be corrected.

Regarding the application of insecticides, movement of bioassays, and chemical analysis, Hazleton stated that its current operating procedures prevent the use of insecticides and the relocation of bioassays unless exceptional circumstances occur which would affect the validity of the study. Hazleton also stated that, while it was not a contractural obligation to analyze test chemicals prior to administering them to animals, it now does this concurrently with the animal phases of its laboratory studies.

TRACOR-JITCO HAS NOT ASSURED
THAT DEFICIENCIES ARE CORRECTED

We found that, at Litton, Tracor-Jitco had found some of the same deficiencies found in our inspections, but the laboratory had not taken corrective actions. These deficiencies include

--the temperature in the cage and rack washer did not reach the required 180 degrees Fahreheit and

--unsatisfactory chemical storage conditions.

We also found some deficiencies that had gone uncorrected for a considerable period of time--as long as 2 years. The continuing nature of these problems indicates that Tracor-Jitco has not required the laboratory to correct deficiencies. One possible explanation for this is the fact that Tracor-Jitco did not send copies of its inspection reports to Litton. Thus, the laboratory may not have been fully aware of its deficiencies.

Commenting on our draft report, NCI stated that it had initiated two additional methods to monitor Tractor-Jitco. These include the appointment of deputy project officers for each subcontractor laboratory and a chemical manager for each chemical assigned to bioassay. NCI also stated that, by adding new staff and assigning additional staff, NCI expects to more directly manage the chemicals placed on test.

CONCLUSIONS

NCI awarded a contract to Tracor-Jitco to manage its bioassay testing activities due to a lack of adequate staff. While NCI's monitoring of Tracor-Jitco's performance in dealing with the bioassay backlog has been good, its monitoring of Tracor-Jitco's management of bioassay testing activities has not been adequate.

NCI relied primarily on Tracor-Jitco reports to assess the contractor's performance in managing bioassay testing activities, and NCI did little independent verification to check these reports' accuracy and adequacy. Since NCI was not aware of conditions at the subcontractor laboratories, it did not have important information which should have been used to determine the amount of the award fee to be paid to Tracor-Jitco. Although NCI has paid only about 52 percent of the maximum possible award fee to Tracor-Jitco, NCI might have paid even less had it been fully aware of problems at the subcontractor laboratories. NCI did not follow prudent management practices by relying on the contractor to report problems that could affect the amount of profit the contractor can earn.

We also believe that the quality of Tracor-Jitco's inspections needs improvement, because we found numerous deficiencies at the laboratories which Tracor-Jitco had not detected at its inspections. The deficiency that was our major concern was the laboratories' testing of more than one chemical in a room.

ENCLOSURE III

Finally, we believe that NCI needs to verify that Tracor-Jitco has required the laboratories to correct deficiencies Tracor-Jitco has found during its laboratory inspections.

RECOMMENDATION TO THE SECRETARY OF HEW

We recommend that the Secretary of HEW require the Director of NCI to more closely monitor the performance of Tracor-Jitco by making more frequent site visits to the subcontractor laboratories and by verifying that Tracor-Jitco has required the laboratories to correct deficiencies found during inspections. We further recommend that the Secretary require the Director of NCI to use the information from NCI's site visits and inspections of the laboratories as part of the basis for determining the amount of the award fee.

ENCLOSURE IV

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May 2, 1977

Honorable Elmer B. Staats
Comptroller General
General Accounting Office
441 G Street
Washington, D.C. 20548

Dear Mr. Staats:

There is growing recognition among scientific bodies of the link between the incidence of human cancer and exposure to environmental carcinogens. As the nation's principal cancer biomedical research arm, the National Cancer Institutue (NCI) plays a pivotal role in the direction of federal government efforts to prevent, detect and treat cancer.

In recent years, questions have been raised about the lack of emphasis given preventive cancer research within the Institute. With annual cancer treatment costs soaring into the billions, there is strong support from the scientific and government community for greater attention to the causes of this virulent disease. With estimates that as much as 90% of cancers are environmentally induced, greater efforts at cancer prevention, through the identification of environmental carcinogens, would go far to reduce cancer's annual toll in human lives and rising medical costs.

Recent personnel turnovers within the Carcinogenesis Program of the NCI's Division of Cancer Cause and Prevention have called attention to programatic inefficiencies and low staff morale. I have become increasingly concerned that the Directorate of the Institute tends to downplay the importance of research in carcinogenesis and other areas of cancer prevention to the possible detriment of potentially fruitful areas of biomedical research.

In an effort to review the efficiency and adequacy of the NCI's Carcinogenesis Program I am interested in obtaining answers to the following inquiries:

1. Please review the relationship between advisory groups and the Institute's Carcinogenesis Program with special attention to:
   a) the role and responsibilities of advisory groups.
   b) factual data on relationships between advisory group members and outside agencies.

ENCLOSURE IV

Honorable Elmer B. Staats
Comptroller General
General Accounting Office
May 2, 1977
Page two

c) the extent to which advisory groups encourage or discourage NCI efforts to conduct and sponsor research in cancer prevention and identification of environmental carcinogens.

2. Please review the operations of the Carcinogenesis Program with respect to:

a) factual data on funding and staff allotments in relation to other NCI departments.
b) extent and cause of backlog in review and completion of bioassay reports.
c) examine efficiency of and need for contract management activities of the Carcinogenesis program.
i. assess management of contracts in the Carcinogenesis program.
ii. determine the adequacy of quality control in bioassay work.
d) How is the program structured? Are environmental carcinogens emphasized in cancer research efforts? How does the definition of environmental carcinogen at NCI differ from the definition used by the Environmental Protection Agency?
e) review and assess the effect of personnel movement and organization realignment within the Carcinogenesis program.

3) How do the efforts of the National Clearinghouse on Environmental Carcinogens impact on the Carcinogenesis Program?
4) Recommendation to improve efficiency and effectiveness of the Carcinogenesis Program.

With appreciation for your attention to this matter, I am,

Sincerely,

Henry A. Waxman

HENRY A. WAXMAN
Member of Congress

HAW:rfk

ENCLOSURE V

EXPERTS' RATINGS OF BIOASSAY LABORATORY CONDITIONS

Category	Hazleton	Gulf South	Litton
Personnel	Good	Senior staff--marginal Technical staff--good	Acceptable
Facilities	Acceptable to good	Acceptable to good	Falls Church--unacceptable Kensington--good
Quarantine procedures	Acceptable	Good	Marginal
Diet preparation	Acceptable	Acceptable	Marginal
Detecting moribund animals	Marginal to acceptable	Good	Acceptable
Sacrifice	Good	Good	Not rated
Necropsy	Good	Good	Good
Histology	Good	Good	Good
Histopathology	Good	Good	Good
Histology reporting	Good	Acceptable	Not rated
Technician training	Not rated	Good	Not rated
Chemical analysis	Unacceptable	Acceptable	Not rated
Lab safety	Good	Not rated	Not rated
Water analysis	Acceptable	Marginal	Not rated

Animal feed	Acceptable	Not rated	Not rated
Bottle stoppers	Unacceptable	Not rated	Not rated
Vermin control	Good	Acceptable	Marginal
Pathology data reporting	Marginal	Acceptable	Not rated
Cage washing	Acceptable	Acceptable	Marginal to acceptable
Emergency power	Not rated	Acceptable	Not rated
Waste disposal	Not rated	Good	Marginal
Animal transportation	Not rated	Marginal	Not rated
Clinical lab	Not rated	Acceptable	Not rated
Gavage technique	Not rated	Good	Not rated
Clinical observations	Not rated	Acceptable to good	Acceptable
OVERALL CONDITIONS FOR TESTING	Good	Good	Acceptable