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Released 8/24/78

UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

HUMAN RESOURCES DIVISION

B-164031(2) JULY 26, 1978

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) carcinogenesis program. Through discussions with your office, we agreed to respond to your concerns in two separate replies. In this first reply we are providing information on

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

--the extent to which advisory groups encourage or discourage 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.

You also asked several questions regarding program operations. We are continuing our fieldwork on these matters and anticipate sending a response to you by August 1978.

In July 1977 NCI reorganized the carcinogenesis program by dividing it into two separate activities--a carcinogenesis testing program and a carcinogenesis research program. These programs are in NCI's Division of Cancer Cause and Prevention (DCCP). The information contained in this report is applicable to both of these programs. Our work included reviewing NCI records, minutes of advisory group meetings, and discussions with officials of NCI, the White House, the President's Cancer Panel, the National Cancer Advisory Board, the Clearinghouse on Environmental Carcinogens, and the Carcinogenesis Program Scientific Review Committee. We

also reviewed the financial disclosure statements for 10 advisory group members.

Our findings and recommendations are summarized below, but more detailed information is contained in enclosures I and II. As instructed by your office, we did not obtain written comments from NCI. However, the matters included in this report were discussed with an NCI official who is familiar with advisory group matters, and his comments, where appropriate, were considered in its preparation.

ROLES AND RESPONSIBILITIES OF ADVISORY GROUPS

NCI uses public advisory groups composed of experts to assist it in achieving its goal of preventing or curing cancer. As of January 1978, NCI had 32 advisory groups, 5 of which can provide advice on the carcinogenesis programs. These five groups are: the President's Cancer Panel, the National Cancer Advisory Board, the Clearinghouse on Environmental Carcinogens, the Carcinogenesis Program Scientific Review Committee, and the Board of Scientific Counselors. The President's Cancer Panel and the National Cancer Advisory Board were established by the National Cancer Act of 1971 (42 U.S.C. 282) to provide advice to the President and the Director, NCI, respectively, on the National Cancer Program. Thus, both the Panel and the Board may influence the carcinogenesis programs which are a part of the National Cancer Program. All 3 members of the Panel and 18 of the 23 Board members are appointed by the President. The remaining five Board members are specified by the Act.

The Clearinghouse on Environmental Carcinogens was established in 1976 by the Director, NCI, to provide advice specifically to the carcinogenesis programs. But, according to its charter, the Clearinghouse is to provide advice on substances requiring carcinogenicity testing, experimental design of test protocols, carcinogenicity of substances tested, and the substances' potential human risk. However, the Clearinghouse was established to also provide advice on the programs' structure, direction, or priorities.

Like the Clearinghouse, the Carcinogenesis Program Scientific Review Committee provides advice specifically to the carcinogenesis programs. However, its role is to provide advice to the Director, NCI, on the scientific merit of carcinogenesis programs' contract proposals.

The Board of Scientific Counselors was established in January 1978 and is not expected to be operational until July 1978. It is to provide scientific advice to the Director, NCI, and the Director, DCCP, on the progress and policies of the programs of the Division of Cancer Cause and Prevention which includes the carcinogenesis programs.

ATTENTION GIVEN TO CANCER PREVENTION AND CARCINOGENESIS RESEARCH

For various reasons, four of the five advisory groups that can influence the carcinogenesis programs have given little attention to cancer prevention and carcinogenesis research.

Since the first meeting of the President's Cancer Panel in 1972, there has been minimal discussion of cancer prevention and carcinogenesis research at its meetings.

The Board, however, has shown a greater interest in this type of research. It established a Subcommittee on Environmental Carcinogenesis in 1974 to specifically address these issues and recommended the role NCI should play in the area. NCI responded to some of these recommendations by creating the Clearinghouse on Environmental Carcinogens.

The Subcommittee presented seven recommendations to the Board in 1975 in the areas of cancer prevention and environmental carcinogenesis. Action was taken on three of the recommendations, but little has been done on the others. In addition, problems still exist in implementing one of the three recommendations NCI acted on. The Subcommittee further concluded that the carcinogenesis programs are underfunded in comparison to NCI's program for determining the role of viruses in cancer, commonly called viral oncology research.

The Clearinghouse has done little to emphasize environmental carcinogenesis even though it is supposed to provide advice on these programs. This was apparently due to the fact that the role of the Clearinghouse is not clear.

In December 1977, the executive secretary of the Clearinghouse stated that it had failed to meet its objectives of nominating chemicals to test, improving test design, and assessing human risk, and suggested that it be dissolved. He further suggested that, instead of the Clearinghouse, an advisory committee to the carcinogenesis testing program should be established to provide advice on program matters such as direction and scope. The creation of the Board of Scientific Counselors should fulfill this need. However, neither the Director, DCCP, nor the Clearinghouse Chairman agree that the Clearinghouse should be abolished.

The Carcinogenesis Program Scientific Review Committee has done little to emphasize environmental carcinogenesis research because it deals solely with the technical review of contract proposals.

Since the Board of Scientific Counselors will not be staffed or operational until July 1978, it has not had a chance to affect the programs.

CONTRACTS HELD BY ADVISORS AND THEIR EMPLOYERS

As of January 1978, NCI employed 57 advisors who represented 47 different organizations. Ten of the 57 advisors had been designated as principal investigators on individual DCCP contracts. From July 1973 through February 1978, the 10 contracts totaled about $19.5 million. Seven of these 10 members were serving as principal investigators on contracts involving the carcinogenesis programs.

We reviewed the files of the contracts involving 4 of the 10 members and found that each contract underwent peer review either before the member's appointment as an advisor or by a committee other than that to which the member was appointed. The awards did not appear to be influenced by a principal investigator's

committee membership. In addition, for two of the four contracts, requests for proposals were solicited on a competitive basis. While two of these contracts received funding increases of $100,000 or more within 2 years of their award, the funding increases appeared to be reasonable and justified.

Twenty-one of the 47 organizations represented by advisory group members had a total of 49 active contracts from the carcinogenesis programs. An additional five organizations had a total of six contracts from other programs within DCCP. Generally the number or value of the contracts varied the same as the contracts awarded to other institutions, and had no direct relationship to an individual's membership on an NCI advisory group.

REVIEW OF FINANCIAL DISCLOSURE STATEMENTS

Our review of financial disclosure statements for the 10 advisory group members who served as principal investigators on DCCP contracts showed that 5 had some form of interest in an organization which could possibly be involved with NCI. In two of the five cases, the members owned stock in an organization that had DCCP contracts. In the other three cases, the member was employed as a consultant to either a pharmaceutical or manufacturing company or to an organization that had DCCP contracts. NCI has adopted procedures to preclude conflicts of interest, and for the five cases cited has determined that a conflict is not apparent.

ADVISORS APPOINTED BEFORE FINANCIAL DISCLOSURE REVIEW

NCI advisory group members are appointed before the review of their financial disclosure statements. Part of the problem is due to members of the Panel and the Board being appointed by the President. For these appointments, NCI stated it has little or no input or advance notification, and learns of them most often through the media. A White House official told us that a conflict of interest investigation is not required before making these appointments. After the appointment is made NCI then requests a financial disclosure statement to be filed, but an NCI official reported it really has no recourse to a mechanism to

withdraw the appointment if a conflict of interest is determined to exist. A similar situation exists with other NCI advisory groups whose members are appointed by the Director, NCI. Letters of invitation are sent out to potential advisors and acceptances are received before NCI requests financial disclosure statements. An NCI official expressed reservations about what action could be taken if NCI determines that an apparent conflict of interest exists after the individual has either been appointed or accepted an invitation to serve as an advisor. However, NCI is considering a number of proposals dealing with this issue including the requirement that financial disclosure statements for all advisory group members be reviewed before approval of the individual.

CONCLUSIONS AND RECOMMENDATIONS TO THE SECRETARY OF HEW

The Clearinghouse has done little to emphasize environmental carcinogenesis research apparently because its role needs to be clarified. As a result, it has failed to meet most of its objectives. Because of this and the creation of an advisory group to provide advice to the carcinogenesis programs, the continued need for the Clearinghouse as it now exists is questionable.

The procedure for appointing advisory group members needs to be changed in order to avoid potential conflict of interest situations. Financial disclosure statements should be obtained and reviewed before making appointments.

We recommend that the Secretary of HEW take the following actions:

--Require the Director, NCI, to determine if there is a need for the Clearinghouse on Environmental Carcinogens, and if so, to decide the exact responsibilities it should have.

--Through discussions with White House officials, develop administrative procedures to ensure that conflict of interest determinations are made based on a completed financial disclosure statement before appointing individuals to the President's Cancer Panel and the National Cancer Advisory Board. Such procedures should also be

used for appointments made by the Director, NCI, for other NCI advisory groups.

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 the 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 other interested parties unless you have approved its release or make its contents public.

Sincerely yours,

Gregory J. Ahart
Director

Enclosures

ENCLOSURE I ENCLOSURE I

CARCINOGENESIS PROGRAM ADVISORY GROUPS

INTRODUCTION

The goal of NCI is to prevent or cure cancer. To achieve this, NCI sponsors research on the causes of cancer and methods to prevent it. Research indicates that the vast majority of cancers affecting people throughout the world are environmentally caused by external chemical and physical substances, called carcinogens. Due to the rapidly growing awareness of this fact, a carcinogenesis program was established in 1968 to identify and define carcinogens and to explain the mechanisms by which these agents cause cancer. This program evolved from earlier NCI activities involving the causes of cancer that began in 1961.

In July 1977 NCI reorganized the carcinogenesis program by dividing it into a carcinogenesis testing program and a carcinogenesis research program. The purpose of this reorganization was to promote a clearer designation of authority and responsibility between carcinogenesis testing and research and a more effective development of priorities between the two programs. The testing program encompasses the identification of chemical and physical agents which induce cancer in man and the research program involves explaining the mechanisms by which these agents cause cancer. The two programs are administered by NCI's Division of Cancer Cause and Prevention (DCCP).

ADVISORY GROUPS

NCI is mandated to seek advice from public advisory groups to assist it in achieving its goal of preventing or curing cancer. These groups are composed of individuals with scientific or clinical expertise as well as leaders in such fields as education, law, social services, and public affairs.

As of January 1978, after a series of mergers and terminations, NCI had 32 advisory groups, 5 of which can provide advice on the carcinogenesis programs. The five groups are: the President's Cancer Panel, the National Cancer Advisory Board, the Clearinghouse on Environmental Carcinogens, the Carcinogenesis Program Scientific Review Committee, and the Board of Scientific Counselors.

Another group, the Carcinogenesis Scientific Advisory Committee was terminated after having met only once. This committee was supposed to provide advice on carcinogenesis program policy. According to NCI, this termination was made in response to the President's efforts to reduce the number of Federal advisory groups.

The President's Cancer Panel was established by the National Cancer Act of 1971 (42 U.S.C. 282) to provide advice to the President on the development and execution of the National Cancer Program. Panel members are presidentially appointed. By providing advice on the National Cancer Program, the Panel may influence the carcinogenesis programs, which are a part of the National Cancer Program. (See enc. III for a list of Panel members.)

The National Cancer Advisory Board was also established by the National Cancer Act of 1971 and is composed of 23 members, 18 of which are presidentially appointed and the remaining 5 are specified by the act. 1/ The Board's role is to provide advice to the Director, NCI, on the National Cancer Program and thus may influence the carcinogenesis programs. (See enc. IV for a list of Board members.)

The Clearinghouse on Environmental Carcinogens was established in May 1976 by the Director, NCI, to provide advice specifically to the carcinogenesis testing and research programs. However, the exact role of the Clearinghouse in providing advice is unclear. According to its charter, the Clearinghouse is to provide advice on substances requiring carcinogenicity testing, experimental design of test protocols, carcinogenicity of substances tested and the substances' potential human risk. However, the Clearinghouse was established to also provide advice on the carcinogenesis programs' structure, direction, or priorities. (See enc. V for a list of the Clearinghouse members.)

1/The members specified by the National Cancer Act of 1971 are the Secretary of Health, Education, and Welfare; Director, Office of Science and Technology; Director, National Institutes of Health; chief medical officer of the Veterans Administration, and a medical officer designated by the Secretary of Defense.

The Carcinogenesis Program Scientific Review Committee resulted from the October 1977 merger of two other scientific review committees that were established by the Director, NCI, in April 1974. This Committee is to provide advice on the scientific merit of carcinogenesis contract proposals. (See enc. VI for a list of Committee members.)

In January 1978, NCI chartered a Board of Scientific Counselors to provide scientific advice to the Director, NCI, and the Director, DCCP, on the progress and policies of the programs of the Division of Cancer Cause and Prevention which includes the carcinogenesis programs. According to an NCI official, the Board will be staffed and operating about July 1978.

ATTENTION GIVEN TO CANCER PREVENTION RESEARCH AND IDENTIFICATION OF ENVIRONMENTAL CARCINOGENS

President's Cancer Panel

A review of the minutes since the first meeting of the President's Cancer Panel in 1972 reveals that not much has been said about cancer prevention or environmental carcinogens. The scope of the discussions has been limited mostly to the budget and to the annual report of the Director, NCI. The Panel was given a presentation in January 1976 by DCCP officials concerning the activities of the carcinogenesis programs. Other than this, the Panel has not addressed the issue.

The Panel chairman told us that adequate emphasis was being placed on environmental carcinogenesis and that more money is actually being spent in this area than from just the carcinogenesis programs. He also stated that money spent in other areas of research often has a relationship or impact on environmental carcinogenesis. As an example, he cited the Ames test, a fairly effective short-term screening test for chemical carcinogenicity developed by Dr. Ames, a researcher at the University of California, while working in the area of cell biology.

Regarding the identification of environmental carcinogens, the Panel chairman stated that bioassay testing should be done by industry under Federal guidelines and monitoring. This would be similar to the method the Food and Drug Administration uses for drug testing and

is also consistent with requirements imposed by the Toxic Substances Control Act (Public Law 94-469). 1/

In summary, the Panel has not formally addressed the issue of what NCI's role should be in environmental carcinogenesis. The Panel has shown some interest, but has not taken any major initiatives in this area.

National Cancer Advisory Board

The Board has shown a greater interest in environmental carcinogenesis. In 1974 the Board established a Subcommittee on Environmental Carcinogenesis and also recommended the following as NCI's role in the environmental carcinogenesis area

--Identifying carcinogens.

--Setting priorities for carcinogen testing and assessing risk to man.

--Defining mechanisms of carcinogens.

--Delineating dose-response relationships.

--Providing information on a continuing and formal basis concerning environmental carcinogens to the public and governmental regulatory agencies.

NCI responded to some of the recommendations by creating the Clearinghouse on Environmental Carcinogens and chartering it to identify and evaluate chemicals which have been tested or should be tested.

In two 1975 meetings, the Board's subcommittee further defined NCI's role. The subcommittee said that NCI should "foster and coordinate research related to the problem of cancer causation by environmental factors and the eventual control and prevention of cancer in man."

1/Among other things, the Toxic Substances Control Act places the responsibility for developing data on the health effects of chemical substances on those who manufacture and process the substances. In developing this data, the act authorizes the Administrator of the Environmental Protection Agency to require testing of chemical substances.

In more specific terms, the subcommittee felt that NCI's role should be to identify potential carcinogens in the human environment but that NCI should not bear the major responsibility for routine testing of environmental carcinogens. The subcommittee emphasized that NCI should be more involved with the basic research aspects of the carcinogenesis problem. In this role, NCI would foster the development and validation of new and innovative analytic and bioassay techniques. Testing, the subcommittee emphasized, "...should be a joint responsibility of the private sector, certain government agencies and NCI. In this joint endeavor, the NCI and its advisors can provide expertise, and assistance in coordination and scientific leadership." While the Board has not specifically expressed an opinion on bioassay testing, its chairman stated that NCI should not stop testing chemicals until another organization assumes that responsibility. In addition, the subcommittee took the position that the NCI programs in environmental carcinogenesis are underfunded in comparison to NCI's program for determining the role of viruses in cancer, commonly called viral oncology research. The subcommittee felt it was unlikely that cancers of a viral cause would be found for humans. According to an NCI official, the viral oncology program is currently being deemphasized by NCI.

The Board's subcommittee also prepared a series of recommendations that it presented to the Board at a March 1975 meeting. These recommendations included

--using comprehensive cancer centers to compile information on all patients concerning their environmental exposure to carcinogens,

--establishing a study section in NIH to review grant applications in the area of environmental carcinogenesis,

--developing training programs for medical students and physicians in environmental carcinogenesis,

--establishing further cooperation with the National Institute of Occupational Safety and Health (NIOSH) in making epidemiological studies in industry,

--establishing specialized cancer centers for research in environmental carcinogenesis,

--conducting studies to develop and evaluate in-vitro (observable in a test tube) test systems, and

--defining the relationship of NCI to other governmental agencies, particularly to the regulatory agencies.

Overall, the recommendations encourage NCI to get more and more into the research area of carcinogenesis. Testing of chemicals is not mentioned and NCI officials told us they would like to do less chemical testing and more basic research in carcinogenesis.

In evaluating the implementation of these recommendations, we found that action has been taken on some, but not all of them and that problems exist in some areas. NCI has, and is continuing to evaluate in-vitro test systems. In this area, the Clearinghouse on Environmental Carcinogens has recently adopted a proposal to use in-vitro tests as an aid in selecting chemicals for the bioassay testing program. In addition, the recommended cooperation with NIOSH in making industry epidemiological studies has been obtained, according to the Director, DCCP.

The NIH Division of Research Grants established a special ad hoc study section to review carcinogenesis research proposals. However, the Board subcommittee expressed dissatisfaction with the makeup of the study section because some essential disciplines (i.e. epidemiology) were not represented. In March 1978, an NCI official told us that the Division of Research Grants, after consulting with NCI, is in the process of establishing a permanent study section to review environmental carcinogenesis grants. This study section will include the scientific disciplines necessary for an adequate review. The official also stated that the study section's proposed charter will be submitted to the Secretary of HEW for action which often takes 6 months to a year to complete. Also, since the administration is attempting to limit the number of Federal advisory committees, the proposed study section may not be approved.

For the other subcommittee recommendations it appears that little has been done. According to the minutes of a 1975 subcommittee meeting, the reason there are not enough specialized centers for environmental carcinogenesis is that environmental carcinogenesis is not and has not been popular with the Board.

No indications were found that NCI or the Board took any action on the recommendation to establish and support training programs in environmental carcinogenesis. However, the National Institute of Environmental Health Sciences, another NIH institute, will support training in toxicology, epidemiology, and environmental pathology in response to implementing the Toxic Substances Control Act.

Finally, NCI has made efforts to help define its relationships with the regulatory agencies, but has experienced problems in their implementation. To aid the regulatory agencies, NCI began routinely providing interim reports on the chemicals it had under test. Because of the unofficial status of these reports, the regulatory agencies were unable to use them to take action. However, the interim reports were publicized and certain adverse reactions resulted, such as declines in the market value of the stocks of certain companies. NCI then stopped publishing these interim reports and substituted "as needed" communications to the regulators. NCI also proposed the establishment of an interagency committee to coordinate work on the National Cancer Program to be composed of the heads of the concerned regulatory agencies and NCI. But due to poor attendance by the agency heads, NCI terminated the committee.

In summary, the Board and its Subcommittee on Environmental Carcinogenesis have encouraged NCI to emphasize identification of potential carcinogens in the human environment and to do basic carcinogenesis research. However, the Board chairman stated that while more needs to be done in the environmental carcinogenesis and cancer prevention areas, it should not be done at the expense of the rest of the cancer program.

Clearinghouse on Environmental Carcinogens

The Clearinghouse has done little to emphasize environmental carcinogenesis although it is one of two advisory groups that is supposed to provide - ice on these programs (the other being the Carcinogenesis Program Scientific Review Committee). The abolition of the Carcinogenesis Scientific Advisory Committee after only one meeting has further complicated the problem because it was the only group specifically chartered to provide policy advice on the carcinogenesis programs.

The lack of emphasis by the Clearinghouse has occurred because its exact role is somewhat unclear. According to its charter, the function of the Clearinghouse is to provide advice on substances requiring carcinogenicity testing, experimental design of test protocols, carcinogenicity of substances tested, and the substances' potential human risk. Advice on the carcinogenesis programs' structure, direction, or priorities is not cited as a function of the Clearinghouse. However, program advice of this type is cited as one of the purposes for establishing the Clearinghouse in the charter. The Chairman of the Clearinghouse also expressed uncertainty about its role when speaking at a recent meeting of the Board's Subcommittee on Environmental Carcinogenesis. He expressed the belief that it may not be appropriate for the Clearinghouse to consider policy questions. According to a former director of DCCP, the Clearinghouse has not provided advice to the carcinogenesis programs and probably will refrain from doing so until its role is clarified.

In December 1977, the executive secretary of the Clearinghouse suggested that it be dissolved. Except for reviewing tested chemicals for carcinogenicity, he indicated that the Clearinghouse has not achieved its objectives and even in this regard, the executive secretary questioned the quality of the reviews by the Clearinghouse. He stated that it has nominated only one chemical for testing, has made few, if any, concrete suggestions to improve test design, and has been unable to assess human risk due to a lack of necessary information.

The executive secretary further suggested that an advisory committee to the carcinogenesis testing program be established to provide advice on program matters such as its direction and scope. At least one Clearinghouse member agrees. He proposed that the Clearinghouse role be modified to that of an advisory group and reduced in size. Presumably, there would also be a reduction in operating costs. As of December 1977, the Clearinghouse had cost NCI about $90,000 not including NCI staff support which the executive secretary estimates would add about another $60,000. However, neither the Director, DCCP, nor the Clearinghouse Chairman agrees with these recommendations. They believe the Clearinghouse is useful and should continue.

Carcinogenesis Program Scientific Review Committee and Board of Scientific Counselors

The Carcinogenesis Program Scientific Review Committee has also done little to emphasize environmental carcinogenesis because it deals solely with the technical review of contracts.

Since the Board of Scientific Counselors will not be staffed or operational until about July 1978, it has not had a chance to affect the programs. However, it appears that the creation of the Board should satisfy the need for the advisory group as proposed by the executive secretary of the Clearinghouse.

CONCLUSIONS AND RECOMMENDATIONS TO THE SECRETARY OF HEW

The Clearinghouse on Environmental Carcinogens has done little to emphasize environmental carcinogenesis research because its exact role is unclear. As a result, the Clearinghouse has failed to meet most of its objectives. Because of the little emphasis given by the Clearinghouse to environmental carcinogenesis research and the creation of an advisory group to provide advice to the carcinogenesis programs, the continued need for the Clearinghouse as it now exists is questionable.

We recommend that the Secretary of HEW require the Director, NCI, to determine if there is a need for the Clearinghouse on Environmental Carcinogens, and if so, to decide on the exact responsibilities it should have.

STATUS OF ADVISORY GROUP MEMBERS

For advisory group members active as of January 1978, we determined the number and value of contracts and the organizations which they were associated with had received from the Division of Cancer Cause and Prevention and the carcinogenesis programs. This was done for each year of membership on advisory groups. We also reviewed the relationship of advisory group members to organizations affected by NCI's carcinogenesis programs.

EXTENT OF CONTRACTS HELD BY NCI ADVISORS AND THEIR EMPLOYERS

As shown in enclosures III-VI, we identified 57 advisory group members to the carcinogenesis programs. 1/ These members represented 47 organizations. Ten of the 57 advisors had been designated as principal investigators on individual DCCP contracts. From July 1973 through February 1978, the 10 contracts totaled about $19.5 million. Seven of these 10 members were serving as principal investigators on contracts involving the carcinogenesis programs.

We reviewed contract files for 4 of the 10 advisors to determine if their proposals received peer review before award, whether the award was made before or after the advisory group members' appointment, and whether funding increases resulted from increased scope of work.

Two of the four advisors serving as principal investigators on contracts are current or former members of the Carcinogenesis Program Scientific Review Committee which is responsible for reviewing contracts. The other two advisors are either a member of the Clearinghouse on Environmental Carcinogens or the National Cancer Advisory Board. Our work showed that the reviews of the proposals for these contracts were handled in a manner that precluded involvement of the individuals. The four contracts we examined were reviewed by peers either before the member was appointed as an advisor or by a committee other than that to which

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1/ The actual number of advisors totals 59. However, two advisors serve on two groups.

the member was appointed. The awards did not appear to be influenced by a principal investigator's committee membership. In addition, for two of the four contracts, requests for proposals were solicited on a competitive basis.

Two of the contracts we reviewed were increased by $100,000 or more within 2 years of award. One contract received an increase in funding with an increase in the scope of work to be done. The second contract had been funded at only 50 percent of the recommended level due to a shortage of funds. It subsequently received additional funding to raise it to the recommended funding level. In both cases, the funding increases appeared to be reasonable and justified.

Twenty-one of the 47 organizations represented by advisory group members had a total of 49 active contracts from the carcinogenesis programs. Five additional organizations had a total of six contracts from other programs within DCCP. Generally, the number or value of the contracts awarded to these organizations varied as did contracts awarded to other institutions, and had no direct relationship to an individual's membership on an NCI advisory group.

REVIEW OF FINANCIAL DISCLOSURE STATEMENTS

In October 1977, NIH adopted procedures to preclude conflicts of interest from occurring. In implementing these procedures, NCI requires that whenever an advisory group considers a product or other matter that might financially or otherwise affect an organization to which the member has a personal or professional relationship, the member is required to bring this to the attention of advisory group officials. The member is then required to abstain from deliberations concerning the matter. In addition, if a member is uncertain if a situation presents a conflict of interest, he is required by NCI procedures to bring the matter to the attention of advisory group officials who will determine if the member should abstain. The NCI procedures also recommend that when the advisory group considers a product or other matter in which the member has no conflict of interest at that time, the member should avoid future relationships with organizations which may have been affected by the advice rendered on that particular product or matter.

For our sample, we reviewed the financial disclosure statements for the 10 advisors serving as principal investigators to determine if there were any potential areas of conflicting interest.

Our review showed that 5 of the 10 members have some form of financial interest in organizations which could possibly be involved with NCI. In two of the five cases, the members were stockholders in an organization that had contracts with DCCP. In the other three cases, the member was employed as a consultant to either a pharmaceutical or manufacturing company or to an organization that had DCCP contracts. In the five cases cited, NCI has determined that a conflict of interest is not apparent. However, an NCI official expressed reservations about possible action they could have taken if a conflict of interest existed. In the case of Presidential appointments to the Panel and Board, he stated that NCI has little or no input or advanced notification of these appointments and learns of them most often through the media. A member of the White House Presidential appointments staff told us that investigations for conflicts of interest are not required before making appointments to the Panel and the Board. After the appointment is made, NCI then requests a financial disclosure statement to be filed, but NCI stated it really has no mechanism to withdraw the appointment if a conflict of interest is determined to exist.

A similar problem exists with other advisory group members appointed by the Director, NCI. Letters of invitation are sent to potential members and acceptances are received before NCI requests financial disclosure statements.

In effect, the current procedures seem to be the reverse of what might be expected. Instead of determining if a potential conflict of interest exists before appointing an advisory group member and thereby avoiding a problem, current procedures result in a member being appointed to a position and then checking for potential conflicts of interest.

NCI has recently reviewed its procedures and is considering a number of proposals dealing with this issue. The proposals include

--modifying procedures for appointing Panel and Board members to permit the Secretary of HEW to make the appointments, 1/

--requiring that financial disclosure statements for all NCI advisory group members, including the Panel and Board, be received and reviewed before formal approval,

--informing individuals that they are under consideration, but final action will depend on a review and evaluation of financial disclosure information, and

--establishing an internal NCI committee to review financial disclosure information before all final appointments.

CONCLUSIONS AND RECOMMENDATIONS TO THE SECRETARY OF HEW

We agree with NCI that the procedures need to be changed to prevent possible conflicts of interest for advisory group members from occurring. However, we do not believe that the Panel and Board members need to be appointed by the Secretary of HEW to accomplish this. The appointing official is not as important as the method in this case. Rather, we recommend that the Secretary of HEW, through discussions with White House officials, develop administrative procedures to ensure that conflict of interest determinations are made based on a completed financial disclosure statement before appointing individuals to the President's Cancer Panel and the National Cancer Advisory Board. We also recommend that such procedures should also be used for appointments made by the Director, NCI, for other NCI advisory groups.

1/ According to the NIH Legal Advisor, this action would either require an amendment to the National Cancer Act or a specific delegation of authority from the President to the Secretary of HEW to make these appointments.

ENCLOSURE III

ENCLOSURE III

PRESIDENT'S CANCER PANEL AS OF JANUARY 1978

Name and affiliation	Appointment date
Benno C. Schmidt -- Chairman J. H. Whitney & Company New York, New York	Jan. 1972
Dr. Paul A. Marks Columbia University New York, New York	Aug. 1976
Dr. Elizabeth C. Miller University of Wisconsin Madison, Wisconsin	Sept. 1977

ENCLOSURE IV

ENCLOSURE IV

NATIONAL CANCER ADVISORY BOARD AS OF JANUARY 1978

Name and affiliation	Appointment date
Dr. Jonathan E. Rhoads -- Chairman University of Pennsylvania Philadelphia, Pennsylvania	Mar. 1972
Dr. Bruce N. Ames University of California Berkeley, California	Aug. 1976
Dr. Harold Amos Harvard Medical School Boston, Massachusetts	Mar. 1972
Dr. William O. Baker 1/ President, Bell Telephone Laboratories, Inc. Murray Hill, New Jersey	Aug. 1974
Dr. Frank J. Dixon Scripps Clinic and Research Foundation La Jolla, California	Mar. 1972
Dr. G. Denman Hammond University of Southern California Los Angeles, California	Aug. 1974
Dr. David S. Hogness 1/ Stanford University Stanford, California	Jan. 1977
Mrs. Albert D. Lasker, President Albert and Mary Lasker Foundation New York, New York	Mar. 1972
Mrs. Vincent Lombardi Manalapan, Florida	Aug. 1976
Dr. Joseph H. Ogura Washington University St. Louis, Missouri	July 1972

ENCLOSURE IV

Name and affilation	Appointment date
Dr. Henry C. Pitot 1/ University of Wisconsin Madison, Wisconsin	Aug. 1976
Dr. William E. Powers 1/ Thomas Jefferson University Philadelphia, Pennsylvania	Aug. 1974
Mr. Laurance S. Rockefeller Chairman of the Board Memorial Sloan-Kettering Cancer Center New York, New York	Mar. 1972
Mr. Morris M. Schrier Vice President and Secretary MCA, Inc., New York, New York	Mar. 1976
Dr. Frederick Seitz Rockefeller University New York, New York	Mar. 1972 to Mar. 1974 (reappointed Aug. 1976)
Dr. William W. Shingleton Duke University Medical Center Durham, North Carolina	Jan. 1977
Dr. Philippe Shubik 1/ University of Nebraska Omaha, Nebraska	Mar. 1973
Dr. Gerald N. Wogan 1/ Massachusetts Institute of Technology Cambridge, Massachusetts	Oct. 1976

1/ Member--Subcommittee on Environmental Carcinogenesis.

ENCLOSURE V

ENCLOSURE V

CLEARINGHOUSE ON ENVIRONMENTAL

CARCINOGENS AS OF JANUARY 1978

Name and affiliation	Appointment date
Dr. Arnold L. Brown -- Chairman Mayo Clinic Rochester, Minnesota	Nov. 1976
Louis S. Belicsky, M.S.,M.P.H. United Rubber Workers International, AFL-CIO Akron, Ohio	Dec. 1976
Dr. David B. Clayson University of Nebraska Omaha, Nebraska	Sept. 1976
Jerome Cornfield George Washington University Washington, D.C.	Sept. 1976
Lawrence Garfinkel American Cancer Society New York, New York	Sept. 1976
Dr. E. Cuyler Hammond American Cancer Society New York, New York	Oct. 1976
Dr. Robert W. Harkins Grocery Manufacturers of America, Inc. Washington, D.C.	Sept. 1976
Dr. Joseph H. Highland Environmental Defense Fund Washington, D.C.	Sept. 1976
Dr. Charles J. Kensler Arthur D. Little, Inc., Cambridge, Massachusetts	Nov. 1977
Dr. Marvin Kuschner State University of New York Stony Brook, New York	Sept. 1976

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Name and affiliation	Appointment date
Dr. William Bijinsky Litton Bionetics, Inc. Frederick, Maryland	Sept. 1976
Dr. Peter N. Magee Temple University Philadelphia, Pennsylvania	Oct. 1976
Dr. Norton Nelson New York University Medical Center New York, New York	Oct. 1976
Dr. Paul Nettesheim Oak Ridge National Laboratories Oak Ridge, Tennessee	Sept. 1976
Dr. Henry C. Pitot University of Wisconsin Madison, Wisconsin	Sept. 1976
Dr. Verne A. Ray Pfizer Medical Research Laboratory Groton, Connecticut	Oct. 1976
Dr. George Roush, Jr. Monsanto Company St. Louis, Missouri	Sept. 1976
Dr. Verald K. Rowe Dow Chemical U.S.A. Midland, Michigan	Sept. 1976
Sheldon W. Samuels Industrial Union Dept., AFL-CIO Washington, D.C.	Oct. 1976
Dr. Michael B. Shimkin University of California San Diego, California	Oct. 1976
Dr. Louise Strong University of Texas Health Sciences Center Houston, Texas	Sept. 1976

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Name and affiliation	Appointment date
Dr. Paul O.P. Ts'o The Johns Hopkins University Baltimore, Maryland	Sept. 1976
Dr. I. Bernard Weinstein Columbia University New York, New York	Jan. 1977
Dr. John H. Weisburger American Health Foundation Valhalla, New York	Sept. 1976
Dr. Kenneth Wilcox Michigan State Health Department Lansing, Michigan	Apr. 1977
Dr. Gerald Wogan Massachusetts Institute of Technology Cambridge, Massachusetts	Sept. 1976
Dr. Sidney M. Wolfe Health Research Group Washington, D.C.	Nov. 1976

ENCLOSURE VI ENCLOSURE VI

CARCINOGENSIS PROGRAM SCIENTIFIC
REVIEW COMMITTEE AS OF JANUARY 1978

Name and affiliation	Appointment date
Dr. Robert E. Greenfield -- Chairman St. Vincent Hospital Worcester, Massachusetts	Mar. 1975
Dr. Gerald L. Bartlett Pennsylvania State University Hershey, Pennsylvania	Apr. 1975
Dr. Howard A. Bern University of California Berkeley, California	Mar. 1975
Dr. Louis M. Fink University of Colorado Medical Center Denver, Colorado	July 1976
Dr. Danuta Molijka-Giganti VA Hospital Minneapolis, Minnesota	Dec. 1974
Dr. Phillip Issenberg University of Nebraska Omaha, Nebraska	May 1977
Dr. M. Edward Kaighn Pasedena Foundation for Medical Research Pasadena, California	Oct. 1976
Dr. Louis S. Lombard Argonne National Laboratory, University of Chicago Chicago, Illinois	Oct. 1976
Dr. Prabkahar D. Lotlikar Temple University School of Medicine Philadelphia, Pennsylvania	Mar. 1975
Dr. Roy E. Ritts Mayo Clinic Rochester, Minnesota	Apr. 1975
Dr. Evelyn M. Rivera Michigan State University East Lansing, Michigan	Jan. 1977

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Washington, D.C. 20515
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8435 W. Beverly Boulevard
Los Angeles, California 90048
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Congress of the United States

House of Representatives

Washington, D.C. 20515

HENRY A. WAXMAN
24TH DISTRICT, CALIFORNIA

Committees
INTERSTATE AND FOREIGN COMMERCE
SCIENCE AND TECHNOLOGY

Burt Margolin
Administrative Assistant

Bruce Wolpe
Legislative Assistant

May 2, 1977

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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.

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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