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WASHINGTON, D.C. 20548

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APR 25 1979

B-164031(2)

The Honorable Edward M. Kennedy
Chairman, Subcommittee on Health
and Scientific Research
Committee on Labor and Human
Resources
United States Senate

SEN 07102

Dear Mr. Chairman:

As you requested by letter dated January 18, 1979, we are reviewing selected [research management activities of the National Institutes of Health] (NIH). Our review includes activities of four NIH components: the National Cancer Institute, the National Heart, Lung, and Blood Institute, DLG01452 the National Eye Institute; and the National Institute of Arthritis, Metabolism, and Digestive Diseases. DLG01453

On April 13, 1979, your office asked that we provide the current results of our work, for use in connection with planned hearings on NIH programs. As agreed with your office, we are providing information on

- how NIH evaluates its research programs and
- the roles, activities of, and appointments to selected advisory groups.

This information is contained in enclosures 1 and 2.

Because our review is not complete, the observations we are presenting must be considered as tentative. We have not fully explored all aspects of the matters discussed, nor have we formulated conclusions or recommendations pertaining to these matters. We plan no further distribution of this report.



120177

Sincerely yours,

James R. Atch

Comptroller General
of the United States

Enclosures - 2

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HRD-79-74
(103950)

OBSERVATIONS ON HOWNIH EVALUATES ITS PROGRAMSBACKGROUND

The National Institutes of Health (NIH) is the primary source of Federal financial support for biomedical research. NIH's basic goal is to discover the biological bases of health and disease and to develop safe and effective ways to prevent, detect, diagnose, and treat disease.

NIH's research efforts are carried out by developing various institute or multi-institute programs. Each institute has specific biomedical research responsibilities and programs. These programs are further subdivided into reasonably definable projects or objectives. However, many important research decisions or problems extend beyond the program interests of any single NIH institute, these call for special coordination among NIH institutes. The health areas that cut across NIH categorical lines are called Trans-NIH health issues.

NIH fosters research through grants, contracts, and intramural projects; most often, NIH research is done through grants awarded to individuals or institutions. Research funded by contract is more directed than that supported through grants. For example, developing and evaluating medical devices or vaccines would typically be funded through contracts. Intramural research supports NIH inhouse programs such as laboratory and clinical activities.

As noted, NIH research activities are organized according to programs and projects. For example, the National Eye Institute (NEI) has developed a priority program in cataract research. One project (or objective) of that program is to develop tissue culture procedures for the human lens and lens cells. However, the subject of diabetes--a Trans-NIH issue, for which the Director, NIH, has responsibility--requires joint effort by several institutes. Each is examining a particular aspect of diabetes as a part of an overall Diabetes Program and several projects (grants, contracts, or inhouse research) may be necessary to encompass all aspects of the program. During fiscal year 1978, for instance, one institute alone received 420 grant applications for research into aspects of diabetes. Of this group, 283 were approved and 97 funded at approximately \$4.5 million in total direct costs.

NIH EVALUATION ACTIVITIES

Internal management controls are a key element for assuring that activities are carried out efficiently, effectively, and economically. While there are several elements

to an adequate system of internal controls, we have concentrated our efforts to date on two elements--planning for research activities and evaluating what is being accomplished.

Regarding planning, management would be expected to devote its efforts to determining issue areas and establishing priorities for research funding. The four institutes we are reviewing appear to devote adequate staff and advisory council time to planning for biomedical research activities.

However, feedback from evaluations should ensure management that activities are going as planned or, if they are not, what corrective action is needed. As discussed later, we have several observations on how NIH carries out its evaluation activities.

NIH has increased the emphasis on institute evaluations during the past several years. For example, all institutes are required to develop detailed evaluation plans. These individual plans then become the NIH consolidated evaluation plan. The NIH plan that includes each evaluation project then has to be reviewed and approved by Public Health Service (PHS) and the Department of Health, Education and Welfare (HEW), respectively.

NIH evaluations are funded through two mechanisms--a legislatively authorized 1-percent set-aside and NIH research program funds.

The 1-percent set-aside evaluation activities stem from a special fund established in 1970 with passage of Public Law 91-296, amending the Public Health Service Act. This amendment established a tap of up to 1-percent of funds appropriated to any program authorized by the PHS act (42 U.S.C. 229 b). The legislation states that the 1-percent funds are to be used at the discretion of the Secretary of HEW, for evaluating health programs. Responsibility for releasing funds and coordinating evaluation planning was delegated by the Secretary of HEW to the Assistant Secretary for Planning and Evaluation (ASPE). ASPE and *DLG01757* the Assistant Secretary for Health (ASH), each may retain one-fourth of the 1-percent set-aside funds for projects to be conducted under their auspices. The remaining one-half of 1-percent is available to the respective PHS agencies such as NIH. Most 1-percent set-aside evaluations are retrospective in that they are concerned either with completed programs or certain elements of the completed programs.

Nearly all evaluation activities supported by the 1-percent set-aside funds are conducted by contract. For

fiscal year 1978 HEW allocated approximately \$8.0 million to NIH to perform program evaluation, of which only \$3.8 million was obligated for this purpose.

However, \$9.2 million of research funds were also used in fiscal year 1978 to perform some evaluations which NIH called "regular" evaluations. Regular evaluation activities are performed by both contract and institutes staffs working either alone or along with various advisory groups.

Evaluations are not program oriented

According to NIH, most programs are so broad that comprehensive analysis is not feasible; therefore, NIH studies only certain aspects of programs at any one time. The focus of NIH program evaluation is, therefore, to identify questions to which answers are needed on project activities within programs or on specific grants. Nevertheless, much staff and consultant time is annually devoted to developing the overall national programs at the various institutes. If the national programs and their associated objectives are not independently evaluated and compared to the plan periodically, scarce resources may not be fully utilized and may be spent on programs not making substantial progress or those requiring a change in direction.

Evaluation set-aside funds
are not used effectively

A maximum of one-half of the 1-percent set-aside funds can be made available to NIH each year for conducting evaluation studies. Release of these funds for specific NIH projects is contingent upon the approval of the NIH evaluation plan by ASH and ASPE. The NIH evaluation plan is a consolidated summary of all new and ongoing evaluation projects proposed by each institute. Therefore, before a contract can be awarded, three layers of review--NIH, ASH, and ASPE--must take place.

Although the 1-percent set-aside funds are specifically provided for evaluation, research funds are frequently used to perform some evaluations. We were informed the reason for this is not the lack of set-aside funds, but rather the considerable length of time required by ASH and ASPE to approve funding of set-aside evaluations. Therefore, NIH organizations find it easier to use funds that were originally earmarked for research to perform evaluations. According to one official in HEW's Office of the Secretary, the departmental approval time should be significantly reduced in the future

due to a recent administrative change in the process. The fiscal year 1980 evaluation guidelines will include a procedure for simultaneous review of PHS agencies' evaluation plans at ASH and ASPE levels.

In addition to the time-consuming review process, ASH and ASPE frequently disapprove NIH submissions. For example, the fiscal year 1978 NIH evaluation plan shows 68 projects approved by NIH and submitted to ASH. Of those, 25 (approximately 37 percent) were disapproved. One reason is that ASH will not approve certain types of evaluations (such as those related to staffing, the costs of illness, or state-of-the-art projects). In addition, although approved by NIH, 10 were not considered program evaluations by ASH.

Considerable confusion exists among ASPE, ASH, and NIH with respect to how 1-percent set-aside funds can be obligated. Other PHS agencies indicated a similar lack of understanding.

Some unanswered questions are:

- Can inhouse evaluations be funded by 1-percent set-aside funds (including personnel salaries, travel, supplies, etc.)?
- Can part-time employees be hired by 1-percent set-aside funds?
- Should inhouse evaluation costs be included in determining the 1-percent criteria?

These questions are complicated. Several officials we interviewed have different understandings of how these funds can be obligated. According to HEW legal counsel there is no legal basis for not funding inhouse evaluations (including travel costs, etc.) with 1-percent funds. Many NIH officials stated that some evaluations could have been performed cheaper and faster if 1-percent set-aside funds could have been used internally. Three PHS agencies we contacted have requested part-time employees to help with evaluations, but ASPE told them they could not. However, we learned that ASPE was using a portion of its 25-percent allotment to hire part-time employees for the same purpose.

PHS and NIH officials agreed with us that adequate guidelines need to be developed to provide criteria for the use of 1-percent set-aside funds.

According to NIH neither ASH nor ASPE have used their share of 1-percent money to perform evaluations which benefit

NIH activities. These departmental funds are usually spent on evaluating the delivery of health care provided by PHS agencies.

Limited staffing available
for evaluation activities

Evaluation activities at NIH have not appeared to attain the same internal priority as planning for research. One indication is comparing the number of staff in planning with their counterparts in evaluation. For example, within the four institutes we reviewed, 31 individuals are assigned to planning--only 5 are assigned to evaluation.

The largest of the institutes--NCI--does not view evaluations as a process distinct from program operation; therefore, there is no specific evaluation staff at NCI. The second-largest institute--National Heart, Lung, and Blood Institute--has only two full-time evaluators compared to 14 in planning.

At the Director of NIH level only two professionals are assigned to the evaluation staff. As a result, most of their efforts are administrative--coordinating NIH and departmental requirements--with minimal time to oversee the specifics of individual institutes' evaluation activities.

Evaluation activities are not conducted
independently from other functions

It appears that sufficient independence is not exercised in the selection of those activities which are to be evaluated. Typically, the individual institutes are responsible for selecting which of their projects are to be evaluated. They also prepare the requests for evaluation and select the contractor.

We also noted that some institute personnel are involved in both planning and evaluation. Since evaluation involves assessing the agencies' plans, this function should be performed by someone who is not directly involved in developing those plans.

ADVISORY GROUPS

DLG 01458

We are reviewing the functions of the National Advisory Councils for three National Institutes--Eye; Heart, Lung, and Blood (NHLBI); and Arthritis, Metabolism, and Digestive Diseases (NIAMDD)--the National Cancer Advisory Board; and the President's Cancer Panel (Panel). The Councils and Board review grants-in-aid related to research and research training relative to their institute's particular area of concern. They also give advice to the Institutes' Directors on program matters. The number and general background for members who serve on the Councils and Board are designated in their enabling legislation. The membership on the Councils and Board ranges from 12 to 29 members of three general types:

DLG 01456

- Scientists or physicians who are among the leading authorities in their respective Council's disease area.
- Laymembers who have an interest in the Council's disease area.
- Ex-officio members who represent Federal agencies whose operations affect the study of disease.

The Panel monitors the development and execution of the National Cancer Program and reports to the President on its efficiency. The Panel consists of three members, including a chairman, who by virtue of their training, experience, and background are qualified to appraise the National Cancer Program.

Our review to date has revealed problems in appointing members to these advisory groups and the extent that grant applications are modified by the Councils or Board.

The appointment of advisory group members

Advisory Council, Board, and Panel members are appointed for staggered terms of 4, 6, and 3 years, respectively. Council members are appointed by the Secretary of HEW, while the Board and Panel members are appointed by the President.

Nominations of individuals to replace Council and Board members, whose terms are expiring, are submitted by the respective institutes about 6 months prior to expiration. These nominees are then reviewed in progression by the

- (1) Director, NIH,
- (2) Committee Management Office, PHS,

- (3) Assistant Secretary of Health, PHS,
- (4) Department Committee Management Office, Office of the Secretary, HEW, and
- (5) Office of the Secretary, HEW.

Although different issues of nominee qualifications are considered by each review level, reviewers attempt to insure equitable distribution of members in regard to geographic origin, sex, race, and discipline (e.g., clinician versus researcher, disease area of expertise).

Institutes' officials cite the lengthy review process for candidates as a reason for delays in replacing members whose terms have expired. An NHLBI official indicated nominations cannot be made earlier because of the need to know the characteristics of all members on the council. His institute's council still has not received replacements for members whose terms expired in October 1978. Without knowing the replacements and their characteristics, the institute cannot select nominees that provide an equitable distribution on the council for terms expiring in October 1979. The Cancer Board also had members whose terms expired in September 1978, and had not been replaced by new appointments as of April 1979.

We analyzed the nomination forms for 13 laymembers serving on the three councils. Six of the 13 members were appointed from 2 to 7 months after the expiration of the term of the council member they were replacing. An HEW official stated that delays in appointing professional members were comparable and, in some cases, longer. Most council members remain until their replacement is appointed, but some have resigned resulting in vacancies that have existed up to 6 months.

The Panel has also experienced a delay in appointing a member which has resulted in a problem in completing its activities. The Panel is required to submit to the President an annual evaluation of the program's effectiveness and suggestions for improvements. The 1976 Annual Report transmitted to the President in draft in January 1977, however, was the last annual report prepared by the Panel. The chairman's term expired on February 20, 1978, which was when the 1977 Annual Report was to be prepared. This chairman, who is now acting until a replacement is appointed, indicated that the annual report is the responsibility of an appointed chairman. However, as of April 10, 1979, a chairman had not been appointed. An HEW official told us

that several HEW nominations for the chairperson either were declined informally by the nominees or rejected by the President's staff. The nomination process is currently at a standstill.

Dual review of grant applications

Requests for grants received by NIH must go through several stages of review. Grants pass through the Division of Research Grants and then to an Initial Review Group. Finally, the Advisory Councils and Board review these grant requests. *DLG 01/457*

All grant applications sent to NIH are received initially by the Division of Research Grants which examines them and determines which research area they pertain to. Based on this review, the application is then assigned to an Initial Review Group for the first level of peer review.

Initial Review Groups are organized according to scientific discipline and are comprised of members with recognized competence in their respective research field. The Initial Review Groups review grants for scientific merit. They then approve or disapprove grants as appropriate and assign priority ratings. The groups forward summary statements which include the priority rating and reviewer's opinions for approval or disapproval to the appropriate advisory groups for a second peer review.

The Advisory Councils and Board are chartered by NIH to review grant applications for program relevance and scientific merit and to recommend those which merit funding. The Councils and Board take one or more of the following actions on grant applications:

- Concur with the Initial Review Group.
- Defer to an Initial Review Group for additional review.
- Reverse the approval or disapproval recommendation by the Initial Review Group.
- Designate the application as having either high or low program relevance.
- Modify the budget, anticipated completion date, or other aspect of the application.

The following chart shows the number of applications each council received for review, the total number of actions, type of action taken, and percentage of applications modified during fiscal year 1978.

COUNCIL ACTIONS ON APPLICATIONS REVIEWED BY
INTERNAL REVIEW GROUPS IN FISCAL YEAR 1978

	<u>Advisory Councils (note a)</u>		
	<u>Arthritis, Metabolic, and Digestive Diseases</u>	<u>Eye</u>	<u>Heart, Lung, and Blood</u>
Number of grant applications	2,018	632	2,129
Total actions resulting in modifications	57	73	36
Percent of applications modified	2.8	11.6	1.7
Actions resulting in application modification by category			
Priority change	8	40	8
Budget/time	12	14	10
Deferred to IRG	35	13	18
Approval or disapproval reversed	2	6	0

a/Information has not been fully developed for the National Cancer Advisory Board at this time.

Many of the reviews done by the councils do not reach different results than the Initial Review Groups. For instance, the Eye Advisory Council modified 11.6 percent of reviewed applications, while the other councils modified less than 3 percent of the Initial Review Groups' recommendations. In addition, at least half of the actions taken by the Heart, Lung, and Blood and the Arthritis, Metabolism, and Digestive Disease Councils were deferrals to an Initial Review Group for further review.