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COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-197871 March 18, 1980

AGC 00145
AGC 00393
DLG 04140

The Honorable Harley O. Staggers
Chairman, Committee on Interstate
and Foreign Commerce
House of Representatives HSE 02300

Dear Mr. Chairman:

Subject: Comments on H.R. 6522 (HRO-BILL-10)

Your February 15, 1980, letter requested our comments on H.R. 6522, a bill to amend the Public Health Service Act, to revise and extend the authorities under that act relating to national research institutes, and for other purposes.

Our comments on the proposed sections of the Public Health Service Act contained in H.R. 6522 are as follows:

1. Section 401 specifies 11 institutes as agencies of the National Institutes of Health (NIH) and permits the Secretary of HEW to establish other institutes relating to particular diseases or groups of diseases or any other aspect of human health. Neither this section of the bill nor any other makes reference to the Division of Research Resources (DRR) which is an operating entity within NIH. In 1962 the Secretary of HEW established DRR as a division within NIH separate from any of the research institutes. Sections 301 and 472 of the Public Health Service Act are used as authorizing legislation for programs carried out by DRR which include support for clinical, biotechnology, and biomedical research. DRR is funded separately from the research institutes and has a budget larger than four of the institutes. Because of the importance of DRR both from a programmatic and budgetary standpoint, we believe that DRR should be acknowledged as an operating entity of NIH in authorizing legislation and its functions formally stated. DLG 04139

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2. Sections 407(b)(2)(B)(i) and (ii) discuss authority to approve grants and contracts when direct costs exceed $50,000, and when they do not. We suggest that the following language be substituted at the beginning of each subsection:

"(i) if the total cost of the grant or contract to be approved does not exceed $70,000 annually, such grant or contract * * *."

"(ii) if the total cost of the grant or contract to be approved exceeds $70,000 annually such grant or contract * * *."

There are two reasons for our suggested changes. First, total cost is a better basis to use than direct costs because direct costs can vary for a project according to the accounting system used, but total cost will not vary. Second, because advisory councils meet only a few times a year and therefore have limited time for reviewing project applications, the basis for determining the need for advisory council review should be an annual total cost of $70,000 which will require fewer reviews than using a total direct cost of $50,000 which would result in advisory council review of almost every grant or contract.

3. Section 408(a)(3)(A)(ii) should be revised as follows:

"in accordance with Section 407(b)(2)(B)(ii) review proposals for grants or contracts for research or training and recommend for approval by the Director of the institute those proposals which show promise of making valuable contributions to human knowledge with respect to the cause, prevention, or methods of diagnosis or treatment of diseases pertinent to the institute, and"

This language will clarify that each council will review only proposals having an annual total cost of $70,000, or more. Also, it defines more specifically the contributions to human knowledge.

4. Section 410 authorizes amounts to be appropriated for the national research institutes. As pointed out in our first comment, the Division of Research Resources has a budget larger than four of the institutes covered in this section. If authorized appropriation amounts are retained in the bill, we believe that DRR, which has a current appropriation of over $169 million, should also have authorized appropriation amounts designated.

5. Section 410(a)(1)(B) puts limits on the amounts that can be authorized for cancer control programs. Since we believe separate authorization for these programs is not needed (see comment 6), this section also would not be needed.

6. Section 413 contains language which authorizes support programs respecting cancer to be established and supported. We do not believe this section is needed. Under Section 407 of the bill, all research institute directors are required to do essentially the same things as specified in the first paragraph of Section 413.

We recently completed a review of the cancer control program which showed that the primary purpose for which the cancer control program was established (to transfer research findings into general practice) did not require the use of all the resources devoted to cancer control. A pending reorganization will merge cancer control activities with other activities, making it more difficult to identify how much effort is going into cancer control. If the National Cancer Institute does not consider it beneficial to keep cancer control separate from other activities, we question the need for separate legislative language authorizing cancer control programs.

Cancer control activities related to detection, diagnosis, treatment, prevention, etc., can be handled by existing divisions within the National Cancer Institute, such as the Division of Cancer Biology and Diagnosis, Division of Cancer Treatment and the Division of Cancer Cause and Prevention.

7. Section 301(a)(3) is amended, but we suggest some additional changes be made. The Division of Research Resources currently operates the general support programs which benefit all the research institutes at NIH and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA). If this arrangement is continued, we recommend that paragraph (3) be amended by striking everything after "recommended by the" and inserting in lieu thereof "advisory council to the national research institute supporting such projects, or in the case of mental health projects, by the National Advisory Mental Health Council; and make, upon recommendation of the National Advisory Research Resources Council grants-in-aid to public or private universities, hospitals and other nonprofit institutions for the general support of their research." DLG 04140

This suggested change eliminates outdated legislative language referring to transfer of appropriations. General support is now funded directly, thereby making all language in paragraph (3) beginning with "Provided, That such" through the end of the paragraph unnecessary. Also, our suggestion recognizes that since the Division of Research Resources operates the general support programs and all the funds come from DRR's budget, grants should be made upon the recommendation of its advisory council--National Advisory Research Resources Council. If ADAMHA should choose to initiate its own general support program, then the National Advisory Mental Health Council's recommendation would be needed to provide general support of research on mental health.

8. Section 4 of the bill provides that the Comptroller General shall evaluate the National Research Service Awards (NRSA) program to determine its effect on the number of physicians entering various medical specialties and report to the Congress on the results of this evaluation by January 1, 1982. We question the need for our making such an evaluation. Under Section 463 of the bill, the Secretary of HEW is to arrange for a continuing study of various matters pertinent to the NRSA program. This study is to be done by the National Academy of Sciences or, if it declines, by another appropriate nonprofit group or association.

A report on the study is to be furnished at least every two years to the appropriate House and Senate Committees. We believe that the evaluation requested of GAO could be made a part of the continuing study.

As we understand from Subcommittee staff, the study is being requested to determine whether relaxing the NRSA program's service payback requirement would result in more physicians entering research. The bill amends the current NRSA legislation by providing that there will be no payback requirement for training of one year or less. This is intended to remove reported disincentives to physicians to undertake research training. We suggest that the language be clarified to relate the requested study to the impact that the new payback provision included in the bill will have on the extent to which physicians engage in research upon completion of training.

We believe the reporting date of January 1, 1982, would be too early to assess the effects of the change in payback requirements included in the bill. There would need to be some track record of physicians receiving training under NRSA. We suggest that the reporting date be delayed to January 1, 1983.

We have discussed these matters with staff of the Subcommittee on Health and the Environment, and a copy of our comments has been sent directly to the Subcommittee Chairman, Congressman Henry A. Waxman.

Sincerely yours,

Elmer B. Staats

Comptroller General
of the United States