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December 16, 1965

William H. Stewart, M. D.
Surgeon General
Public Health Service
330 Independence Ave., S. W.
Washington, D. C.

Dear Doctor Stewart:

The following comments concerning the proposed regulations implementing Public Law 89-239, the Heart Disease, Cancer and Stroke Amendments of 1965, are submitted to you in response to the invitation extended to the participants at your meeting held on December 9, 1965.

As you know, the American Medical Association has a very deep interest in this new program. We are therefore very pleased to have the opportunity to comment upon the proposed regulations.

At the outset, we should like to make the general observation that the proposed regulations are apparently not intended as being complete regulations at this time. We can appreciate that from time to time, regulations must be amended and amplified. However, it would appear that these regulations, insofar as it is possible, should provide a complete implementation of the Act, so that potential participants and others may see this program in its full expectation.

We should also like to direct your attention to a matter we deem to be of significant importance. We note that part of the Act contained in Section 901(c) which provides that the funds appropriated shall not be available to pay the cost of hospital, medical, or other care of patients, except to the extent it is, as determined in accordance with regulations, incident to those research, training, or demonstration activities which are encompassed by the purposes of this title (the purposes herein referred to being those recited in Section 900). Under Section 900 the demonstrations of patient care must be related to research and training (including continuing education).

In our review of the proposed regulations, we do not find regulations as contemplated under Section 901(c). We believe that it is important that the intentions under this section should be spelled out. As the Report of the Committee on Interstate and Foreign Commerce states (p. 10): "As introduced, the bill prohibited the use of appropriated funds to pay for the care of patients except to the extent that such care was incident to research, training, or demonstration activities. A clarifying amendment has been adopted which requires that the research, training, and demonstration activities referred to be those encompassed by the reported bill." The Report contains the further statement (p. 11): "The committee wishes to emphasize that this legislation is intended to be administered in such a way as to make no change whatsoever in the traditional methods of furnishing medical care to patients in the United States, or to methods of financing such care."

We believe that the intent of Congress is clear that patient care is limited as being "incident" to research and training activities. We also believe that this intent should be clearly pronounced in regulations.

Our comments to the sections of the proposed regulations, in the order in which they appear, follow. Additions which we believe should be made are indicated by underscored matter.

- (1) Section 66.3 - Definitions. Subsection (d), defining "related diseases," should be amended by inserting the words and established after the word "direct," so that the phrase will read, "bear a direct and established relationship," etc. We believe that this additional term carries the requirement that the related disease have a medically recognized relation to the primary disease, and that this was the intent of Congress.
- (2) Section 66.3 - Definitions. In subsection (g), "practicing physician" is defined. Under the term "practicing physician," as defined in the regulations, all that is required is licensure by the applicable state. We believe that this sole criterion gives no effect to the word "practicing" and is therefore not in keeping with the Congressional intent. Accordingly, we recommend that the period after the word "laws" be

changed to a comma, and that the following phrase be added: and who is primarily engaged in the diagnosis and treatment of patients. It is our opinion that Congress intended active practitioners to be members of the advisory group and the National Advisory Council.

- (3) Section 66.3 - Definitions. We believe that the word "demonstrations" should be defined to emphasize the intentment of this legislation concerning such demonstrations. An additional definition under Section 66.3 should be added as follows: (j) "Demonstrations" means an activity the purpose of which is the education of physicians and other health personnel. The inclusion of this definition would reaffirm the intent of the Act as to the scope of the demonstrations, that is, that they must be related to research and training (including continuing education). The demonstration of patient care must be only that which is "incident" to research and training (including continuing education).
- (4) Section 66.3 - Definitions. We also suggest that the following definition be added to Section 66.3: (k) "Regional" shall relate to a minimal geographical area possessing all of the components necessary for carrying out the purposes of Title IX.
- (5) Section 66.4 - Eligibility. We believe that it would be helpful to the applicant to have "such other criteria" as the Surgeon General may establish, set out as fully as possible in these regulations, so that the organizations now planning programs under this law know as fully as possible the criteria which they must meet.
- (6) Section 66.5 - Application. Insert in subsection (c), in the second line after the word "shall," the numeral (1); change the period at the end of the sentence to a semicolon; and (2) with respect to an application for a grant under Section 904, show evidence that the proposed program has been approved by the advisory group provided for in Section 903(b)(4).

- (7) Section 66.6 - Terms, conditions, and assurances. Under subsection (a), changes may be made in the use of grant funds by a grantee "only in accordance with procedures established by the Surgeon General." The law provides that the Surgeon General may make a grant only upon recommendation of the National Advisory Council on Regional Medical Programs. We believe that to permit a change in the use of funds without requiring an approval of such change by the National Advisory Council would not fulfill the intent of the law requiring that the Council pass upon the intended use of these funds. Accordingly, we would recommend that the following sentence be included at the end of subsection (a): Notwithstanding anything contained in Section 66.6 to the contrary, such changes in the use of grant funds shall have the approval of the National Advisory Council on Regional Medical Programs.
- (8) Section 66.7 - Award. Insert, in subsection (a)(1), in the second line, before "regional" the word intra, so that the phrase reads: "through intra-regional cooperation"; and also delete the closing phrase "within a geographic area." The original sentence appears to contain either redundant or conflicting phrases, inasmuch as the relation between "regional" and "geographic" is not evident.
- (9) Section 66.8 - Establishment and operation of regional medical programs documentary evidence. Strike the word "and" after "Title IX"; insert a semicolon after Title IX; change the period at the end of the paragraph to a semicolon, and conclude with the following phrase: and (c) the agreement by members of the advisory group to the recommendation of said application. This suggestion is made to give effect to the language of the Report of the Committee on Interstate and Foreign Commerce as follows (p. 11): "The committee has amended the bill to provide that before any application

submitted for establishment and operation of a program in any area may be approved by the Surgeon General, the local advisory group must have considered the application and recommended its approval. "

- (10) Section 66.9 - Termination. This section authorizes the Surgeon General to revoke or terminate a grant award, in whole or in part, by a summary procedure, at any time whenever he finds that in his judgment the grantee has failed in a material respect to comply with requirements of Title IX and the regulations of this part. We believe that this provision for revocation or termination should provide for a sufficient notice to the grantee and should include a procedure by which the Advisory Council must concur in this decision. Accordingly, we suggest that Section 66.9 be amended by the addition of the following opening phrase: With the approval of the National Advisory Council and upon reasonable notice to the grantee, which notice shall contain the reasons for the revocation or termination, any grant award may be revoked, etc.

- (11) Section 66.10 - Expenditures by grantee. We would recommend the following change in subsection (d): Insert in the second line after "patients" and before "is" the following: to the extent provided in the stated purposes of Title IX. Again, this change is suggested so that patient care is limited to the extent intended by Congress, viz., demonstrations in patient care which are incidental to research and training (including continuing education) activities.

We wish to express our appreciation for this opportunity to review the proposed regulations. We hope that these comments will receive your careful consideration.

Sincerely,

F. J. L. Hasingame, M. D.

cc: Secretary John W. Gardner
Philip R. Lee, M. D.
James A. Shannon, M. D.
Stuart M. Essoms, M. D.