August 17 1971

The Honorable Senator Edward M. Kennedy United States Senate Old Senate Office Building, Room 431 Washington, D. C. 20515

Dear Senator Kennedy:

It was, as always, a pleasure being with you recently.

I would like to suggest that the time has come to consider a comprehensive review and analysis of the objectives, structure, organization, and function of the whole National Institutes of Health and health education and research enterprise insofar as the Federal government is concerned. The recent discussions and debates about National Health Insurance, Health Manpower Legislation, and the Cancer Conquest Program have emphasized the need for the development of a National Health Policy. As you have pointed out on many occasions, the objective of bringing not only good medical care but good health to the American people seems to become more difficult rather than easier to achieve as we learn more about man and his diseases.

Numerous studies have compared costs and growth and have identified some gaps in resources, information, and authorities. There seems to be little indication, however, of a cohesive plan to achieve new objectives in this large new system in a new social setting. It is difficult to assess the impact of separate measures on the total system, and it is particularly difficult to forecast, plan, and evaluate without access to a complete overview of the system.

The education of all health-related personnel, and the performance of medical research are indispensable to the success of any national health care plan. To examine only medical care delivery and training without looking at research is to miss the third part of an intimately interrelated triad. You have admirably demonstrated the need for reform in medical care financing and delivery as well as in manpower training, but I also believe there is now a compelling need to re-examine the organization and financing of biomedical research in this country. Piecemeal reorganization would be far less than ideal. Health insurance plans have had and will continue to have growing impact on medical center finances and functions; manpower subsidies will necessarily influence the distribution of efforts of physicians and scientists. Research programs are often carried out in this same environment, often by the same personnel. The interdependence of the various segments of the system is obvious.

Many advantages of the Federal health research support system have been aired during the debates on S.34. Some weaknesses were alleged, such as too many bureaucratic layers, prolonged reaction time, and lack of flexibility. I am not surprised that this growing system has developed some difficulty in being responsive to our rapidly evolving needs. It is not so much a lack of <u>quality</u> of work; the Woolridge Committee, in fact, praised the caliber of federally supported research in 1965. (Parenthetically, this was the last, and perhaps the only, investigation of the organization, structure, and activities of the N. I. H., and it was rather limited in its charge.) It is the <u>structure</u> of the total research support system, including the entire National Institutes of Health, that needs re-evaluation. Such an assessment need not threaten peer scientific review or the freedom of investigators. Nor need it portend the dissolution of the N. I. H. On the contrary, it might result in a stronger, earlier, and more effective impact of research and development on education and health care.

The recent well-intentioned interest in establishing a Cancer Authority separate from N. I. H. is symptomatic of a widespread basic discontent with N. I. H. because of its failure to adapt its purposes and structure to change, its failure to relate more satisfactorily to the biomedical and social realities and opportunities of our time, and its posturing as a National Institutes of Health Science rather than as the National Institutes of Health, as intended by the Congress in its enabling legislation. Moreover, there is an appalling lack of coordination and collaboration of the various agencies of N. I. H. and other agencies in H. E. W. that impinge upon research, health manpower, and health delivery.

There have been changes in science, technology, and health care in recent years that N. I. H. has not responded to, and its increasingly selective posturing around a pure science concept of mission has rendered it incapable of responding imaginatively, or even adequately, to the pressures of the Senator Edward M. Kennedy

present, let alone to the obviously expanding demands of the future.

The evaluation of N. I. H. which I recommend should focus on the following facets:

- 1. Responsiveness of N. I. H. programs to publicly-perceived needs: relative funding levels in comparison with net social value of programs, their predictability of success, and the relative costs of research; adequacy of the study section/Advisory Council mechanism for making relevancy determinations.
- 2. Responsiveness of N. I. H. programs to needs in the medical care delivery community at medical centers, as well as in community hospitals.
- 3. Usage of N. I. H. research results: specialty usage, community hospital usage. Barriers to usage. Adequacy of administrative mechanisms within N. I. H. to achieve wide usage.
- 4. Social impact of N. I. H. programs: the positive and negative direct and indirect effects in terms of lengthening life, but also increasing the aging population; the impact on medical care costs; other effects. Adequacy of administrative mechanisms within N. I. H. to discover and communicate prospective positive and negative results.
- 5. Administrative capacity within N. I. H. for carrying on "targeted research" programs to resolve specific health problems: presence or absence of administrative and scientific personnel, facilities; delegation procedures; financing mechanisms; procedures for planning, evaluation, review, accountability.
- 6. Impact of N. I. H. funding mechanisms on institutions that attempt not only to foster research, but also to respond to demands for training and community medical care. Does the individual grant system inhibit innovation? Do contracts distort institutional efforts?
- 7. Responsiveness of N. I. H. research training and fellowship mechanisms to evolving needs for training professional and technical personnel.

Senator Edward M. Kennedy -4 -

- 8, N. I. H./Institute interrelationships: effectiveness and use of inter-Institute relationships; effectiveness of current Institute structures; appropriateness of categories of decisions made at N. I. H. central office on personnel, financing, and programs, in contrast to those delegated to individual Institutes in light of needs for flexibility, responsiveness, and growth.
- 9. Appropriateness of N. I. H. staffing and funding patterns in relation to current demands for inclusion of expanded opportunities for minority groups (blacks, women, Spanish-speaking); less-advantaged institutions; and the use of social science disciplines (economics, psychology, sociology).

I believe that such a study will reveal the urgent need for expanding N. I. H.'s mission with respect to:

- 1. expediting the practical application of knowledge gained in biomedical research;
- 2. extending its responsibility for more organized and directed activity in categorical diseases, thereby allowing desirable mission-oriented activities to be more readily realized;
- 3. providing it with mechanisms for capitalizing on selected patientoriented technology that arises from its pool of basic and applied research;
- 4. proving a common home for basic and applied biomedical research and those tangential considerations of categorical disease mission and technology that are appropriate to a National Institutes of Health; and
- 5. providing a more concerted and integrated input of quality to our emerging arrangements for the provision of health care.

To this end, an independent N. I. H. Commission or Study Group, composed of distinguished biomedical scientists, clinicians, and well-informed laymen reporting both to Congress and the President should be assembled to carry out a comprehensive study of this entire enterprise and, on this basis, to draw up a revised and expanded Charter for the National Institutes of Health.

Such an action would constitute an important step toward an improved and more rational Federal Health Policy.

I understand the D. H. E. W. studied "health options" in some detail last year, but it was apparently largely an internal study. Since we have learned little about it, I presume it was not successful in forging a National Health Policy.

Someone needs to put the fragments of our present system in place so that we can proceed with the primary objective. Perhaps the Senate could exert leadership by systematically studying the enterprise.

Sincerely yours,

Michael E. DeBakey, M. D.

bc: Mr. Mike Gorman