MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

TO : Acting Director, NHLI

DATE: June 27, 1974

FROM : Special Assistant for Technology
OD, NHLI

SUBJECT: The Academic Surgical Community's Estimate of Policy Needs for the National Heart and Lung Institute

You requested late in February, 1974, that information on this subject be collected and coordinated into a report. After the making of appropriate arrangements, a portion of the joint meeting of the Allen O. Whipple Surgical Society and the Society of Surgical Chairmen on April 19, 1974, at Hamilton, Ontario, was utilized for an open discussion as a result of which the Presidents of the two societies, Dr. David C. Sabiston and Dr. G. Tom Shires, respectively, appointed a Special Committee to mobilize the information considered appropriate by the group. The Committee consisted of Dr. Henry T. Bahnson, University of Pittsburgh; Dr. Gilbert S. Campbell, University of Arkansas; Dr. Jerome DeCosse, Medical College of Wisconsin at Milwaukee; Dr. James D. Hardy, University of Mississippi; Dr. Worthington Schenk, University of Buffalo; and Dr. John Waldhausen, Pennsylvania State University. Dr. Sabiston and Dr. Shires also served on the Committee, and Dr. W. Gerald Austen of Harvard University served as Chairman. A preliminary report was sent to your office on April 23, 1974. (Attachment 1)

The Committee reconvened during the meeting of the American Surgical Association, on May 2, 1974, in Colorado Springs. A report on the cogitations of that meeting was sent to the Director's Office, NHLI, on May 8 and discussed in Executive Staff Meeting on May 20, 1974. (Attachment 2)

In view of the fact that the Executive Staff Meeting uncovered some vigorous differences of opinion and some errors in understanding on the part of the academic group, a memorandum was sent to the members of the Committee on May 20, 1974, with a copy to Dr. Winfred L. Sugg, Secretary-Treasurer of the Directors of Thoracic Surgical Training Programs. (Attachment 3)

Feedback has come from Dr. Austen and several members of the Special Committee, and some 2 dozen letters have been received. The full List of communicants is attached. (Attachment 4)

There appeared to be a general feeling of uneasiness and insecurity, a feeling of distrust of Government, and more specifically of the NIH*.

---

*Note: One correspondent quoted Walter B. Cannon, "The investigator may be made to dwell in a garret, he may be forced to live on crusts and wear dilapidated clothes, he may be deprived of social recognition, but if he has time, he can steadfastly devote himself to research. Take away his free time and he is utterly destroyed as a contributor to knowledge."

The course of events since 1967 in relation to Medicare has tended to take away that time, and there have been increasing difficulties in acquisition of grant support. The Social Security Administration held forth the promise that medical school faculties incidentally caring for patients who had, up until that time, been cared for on a gratuitous basis might derive substantial income to replace the dwindling research grant support. Although this was promised in an address published in The Bulletin of the American College of Surgeons by the Administrator of the Medicare Program, nonetheless after many of the medical schools had converted to this method of support of investigative work, the Social Security Administration not only discontinued such payments in such amounts, but demanded return of much of that which had been paid with the explanation that the spokesman had not had authority to make such promises. It became essential, therefore, for the academic surgeons actually to perform the major part of each procedure on ward patients if any financial support from this source was to come into the research foundations of the respective medical schools involved. The surgical faculties were hit worse by this than faculties not required to spend as much time on it. It is against this background that the complaint of the surgical community that preparation of grant requests or responses to RFP's is so disastrously time-consuming. As an example of the result, the bound volume of publications of the members of the Department of Surgery at Downstate fell in 1971 to less than 40% of what it had been four years earlier.

In addition, there developed major invasions into the activity of undergraduate medical curricula, which were fostered by the National Cancer Institute. Finally, the Federal Government put pressures upon the medical schools to increase enrollment, utilizing payment of a fixed sum per head for each additional student brought into the first year class, only to withdraw that support within two years, once the schools were committed to the enlarged enrollment.

The academic faculties, and especially the surgical faculties, feel therefore put-upon in that the survival of their research and surgical training programs is threatened by the following items:

1. A tremendous increment in the time committed to participation in work in the operating rooms,

2. Increasing difficulty in acquisition of research grants,

3. Curtailment as a result of the time available for research activities, including both preparation of requests for grant support and performance of the investigative work for which support has been gained.

4. Strikingly increased costs, this again in large measure the result of legislative foolishness such as the restrictions of the animal care bills which have run the price of dogs from the neighborhood of $11 in 1967 to the neighborhood of $60 in 1974 (Downstate).

5. The growth of centrally targetted projects and the development of the contractual mechanism, both of which are viewed by academia as obstacles placed in the way of the conception and development of original investigative ideas by members of the academic community which have proven so effective during the life of the National Institutes of Health.

It is appropriate to summarize the conclusions of the Special Committee of the two surgical societies, for which purpose a letter from the Chairman, Dr. W. Gerald Austen, is quoted, "I think it would be fair to say that it was essentially unanimous that we were very much for the peer review system and for individual grants, that we were also very much in favor of training grants in research, that we were rather dismayed by the amount of money going for contracts, although we did feel that there were a few areas where this was very appropriate. We felt that there should be a longer lead time for sizable grant proposals and, wherever possible, at least three and possibly five years of support would be helpful in terms of avoiding excessive time spent in reapplication."

The attitudes of these surgical academicians as to specific patterns of policy are as follows:

Item 1. PEER REVIEW. The peer review system was endorsed not only by the Special Committee but by each and every person who was consulted. In terms of cost effectiveness, it is the unanimously and firmly expressed conviction that nothing to equal it has been proposed and that it must be maintained if further progress comparable to that of the last two decades is going to continue.

Item 2. OPEN MEETINGS. Open meetings of Study Sections and other review groups were initially not regarded with great concern by the review committee. With further cogitation and with appreciation of the uneasiness of the staff at NIH that the making of scientific ideas available to anyone who wishes to know about them would be expected to inhibit submission of them to NIH in the hope of support, several members of the Committee and several of the others listed in Enclosure 4 lean toward opening meetings of Study Sections and other review groups only to the extent that some nonmedical individuals (as taxpayers and "consumers") might be appointed.

Item 3. CONTRACTS AND TARGETTED RESEARCH. Concerning contracts, there was agreement that there are certain areas in which this mechanism of support is most effective, such as coordinated technological development (as in the Artificial Heart Program), clinical testing of drugs, clinical testing of techniques and devices, and clinical evaluation of some therapeutic protocols. There was vigorous opposition, on the other hand, to the use of this mechanism or even of targetted research in which there is central direction for support of the search for new fundamental knowledge. The consensus appears to have been beautifully expressed by Dr. Francis D. Moore in a letter which preceded the meeting in Hamilton, Ontario.

> "Before you receive this we will all be meeting together in Hamilton, Ontario.
>
> "However, I can tell you for both of our thoughts, the main thrust of my advice to the NHLI.
>
> "And that is, to keep 'contract research' down to a very minimum. It is absolutely impossible to foster the growth of important new knowledge through the letting of research contracts.
>
> "I was quite shocked recently to attend a meeting of a large number of people interested in one of the National Institutes of Health, only to find that the first few minutes of the meeting were taken up by an impassioned defence of the contract research mode by actually comparing it to the space program!
>
> "It was unbelievable that anyone could be so illiterate as not to have read the innumerable statements by scientists demonstrating the vast difference between an engineering achievement such as the space program, and the discovery of fundamental new knowledge.
>
> "Our contract experience with NHLI has demonstrated the usual pernicious tendencies to maximum interference with the independence of investigators, and the actual stifling of research in new directions."

In those areas in which contracts appear appropriate, it is strongly felt that a duration of more than one year would provide far greater attractiveness to competent investigators, both because of the lesser frequency of preparation of proposals or renewals and because of greater security in holding an investigative staff together. The employees at Pennsylvania State University demanded not to be paid out of contract support because they recognized that the contract is renewable each year, and they felt that this would make their continuing activity under the contract too precarious to permit them to select this as a career. It is recognized that if the contractor is performing satisfactorily, he can be assured of continuity until completion of the agreed upon objectives of the contract, and yet the difficulties in this particular university setting arose from knowledge of short-notice termination of two contracts in the same program in the face of apparently good performance.

Item 4. RESEARCH GRANTS. With regard to research grants, the consensus was that this should be the primary mechanism for lending support to investigative work in non-profit institutions. The reason for this is the greater freedom to explore investigator-originated ideas and to explore new ideas as they develop in work already undertaken without the necessity to gain clarification from NHLI project monitors (who have been all too often not sufficiently possessed of expertise to grasp the full implication of the requests being made).

In the presence of the pressures being placed upon academic surgeons in terms of available time for either research or requesting research support, there were strong feelings favoring some mechanism for decreasing the amount of time required to prepare such requests. As a means to accomplish this end, it was suggested that grants be made for three-year periods at least and most of those interviewed thought five years not an unreasonable duration, provided there was continued productivity. Whether there would be individual research grants or program projects appeared not to be a major item.

Item 5. LEAD TIME. The Committee was unanimous in requesting that the lead time for sizable grant applications be made as long as possible, recognizing the limitations outlined in the response to the Committee dated May 20, 1974. (Attachment 3)

Item 6. THE YOUNG INVESTIGATOR. Categorization of investigators so as to have (1) the beginning group, (2) the general run, and (3) the established investigators appeared attractive initially, but on further exchanges of information has seemed less so. The consensus was that every effort should be made to provide support for the beginning investigator to test his wings. One mechanism for this was suggested by a correspondent not on the Special

Committee, namely a study of what cardiovascular research is being done throughout the medical schools and a definite effort to stimulate academic departments to embark upon cardiovascular research with provision of an institutional research grant to the promising establishments for the specific purpose of lending support to beginning investigators.

Item 7. CONTINUING FLUID SUPPORT FOR LARGE PRODUCTIVE PROGRAMS. There was much feeling among surgical adademicians with sizable programs that the effort to keep abreast of the burden of recurring renewal applications for multiple grants in the laboratory left so little time for prosecution of research and was so detrimental to the expeditious prosecution of that research that there should be a general support grant for the principal investigator with freedom for him to apply his talents wherever the leads in his own laboratory might take him as long as he is highly productive. Another alternative was the establishment of institutional investigative and educational grants of rather fluid nature insofar as the items under study might be concerned but providing core facilities for multiple projects within the institution or department. Such a grant might then very well cover undergraduate programs in investigation, graduate education among resident staff in experimental methods, and research.

Item 8. SUPPORT FOR "HAVE NOT" SCHOOLS. The Committee was concerned that a small fraction of the university centers in this country have gradually amassed the bulk of the investigative expertise and Federal support for medical research to the exclusion of almost a half of the medical schools in the country. As a means to make the country more broadly sound in scientific opportunities and accomplishments, they felt that definitely an effort should be made to provide seed money and proper consultation to utilize it to a maximal degree of effectiveness among the "have not" schools.

Item 9. TRAINING. There was unanimity of opinion that, difficult though it may be, the income from the Social Security Administration is adequate to cover the clinical training of men in surgery, but that such support makes no allowance at all for the education in investigative work in the experimental laboratory which is so essential to preparation for an academic career. The intent in proposing support for training, therefore, is solely for the purpose of providing this educational foundation.

The Study on Surgical Services in the United States (SOSSUS), which has been under way by the American College of Surgeons and the American Surgical Association for more than the past two years and the recent study on Thoracic Surgical Manpower under the auspices of the American Association for Thoracic Surgery, both imply that concentration at the present time should be upon improvement of the quality of the product of surgical education without further enlargement of the numbers being produced. Toward this end, it is felt by many who have provided information for this report that the NIH should make provision for one or two years

of investigational education quite apart from clinical training and ward obligations. As noted, there is in most institutions no mechanism at the present time by which the stipend can be paid at the level of that stage of training ($16,000 to $18,000 a year) and there is very little in the way of resources to provide for expenses incidental to the work these men will be doing. These men are those frankly undergoing preparation for academic careers and should be required to reimburse in terms of services or costs if they elect to follow other pursuits upon completion of training.

Item 10. SURGEON'S ASSOCIATES. A further aspect of concentration on quality rather than quantity in the nation's surgical training program is reduction in numbers of trainees. The large number of men in resident training programs in surgery and cardiothoracic surgery is at the present time dictated mainly by the need for the assistance of such people in running the clinical programs concerned and nowhere nearly enough by the needs of the country at large. At the same time, the tradition has developed that these men, as a condition of receiving the training sought, perform many purely service functions which do not require either the intellectual capacity or the educational backgrounds of the members of the resident staff. A means, therefore, must be found for removing from the responsibilities of the resident staff a host of menial although necessary manipulations and procedures currently being performed by the resident staff in order to cut the number of trainees to the numbers actually needed in the public interest of the United States. For this purpose, the Committee recommends that a proper program in education of surgeons' associates be encouraged and assisted by the NHLI with the end in view that such items as the initial clinical history, the filling out of many of the forms, the scheduling of laboratory and radiological examinations, the provision of purely functional rather than educational contributions to many operations, many dressing changes, etc. can all be done by such surgeons' associates under proper supervision. The education of surgeons therefore could be refined and concentrated upon educational activities.

Item 11. SPECIFIC AREAS FOR RESEARCH. Dr. Ringler's suggestion that the Special Committee consider also specific items of research which might be stressed was also discussed. There appeared to be no solid proposals in this regard, and Dr. W.H. Muller by letter suggested that this is adequately covered in the report of the President's Advisory Panel on Heart Disease.

Item 12. ORGANIZATION OF NHLI AS A CROSS-MATRIX. Dr. Ringler had also requested consideration of the cross-matrix concept of operation of NHLI, in which matters under study might be classed and handled both in the present categorical pattern and also by areas of discipline or expertise, and specifically whether the acadamic surgical community feels there is

sufficient surgical input into the design and operation of the activities of the National Heart and Lung Institute.

The example which entered into this conversation with him was that of an esteemed and effective investigator who applied for a program project grant in order to support a randomized, prospective evaluation of terminal ileal bypass for certain lipidemias. This was delayed for multiple reviews and caused consternation, to say the least, in the academic surgical community (it is now funded).

The concensus of the Special Committee was that many of the amazing advances of the past three decades have had surgical origins and that it would be sound procedure to keep the avenues open for continuence of such contributions as may be expected from the study noted above.

The academic surgical community would cordially welcome an enlarged role in development of policies and in the day-to-day affairs of NHLI, i.e., in participation in development of a surgical component in the envisioned cross-matrix of the operation of NHLI.

COMMENT:

There were other suggestions from those not on the Special Committee which do not seem to me to be directly applicable. One of these was an annual seminar for residents and junior faculty at NHLI to keep these groups abreast of developments. This seemed more appropriately the business of surgical societies. Another was to exert the influence of NHLI to maintenance of a proper balance in the training programs, such as proper balance between other components of the cardiothoracic training and aortocoronary bypass operations, a proper balance between management of intrathoracic tuberculosis and cardiac surgery, and provision of at least a year of thoracic surgical experience to each general surgical resident in the course of his training. This also would seem to be the concern of others than NHLI.

Clarence Dennis, M.D., Ph.D. 

P.S. In a conversation with Dr. Melvin M. Newman, Professor of Surgery at the University of Colorado, a further difficulty was put forward. Dr. Newman is chairman of that university's committee on research involving human subjects. This committee expends 16 man-hours each fortnight in review and advice on this subject. It is regarded by the committee as wasteful of the time of the faculty investigators on the committee to have to spend time with far-fetched problems demanded by directives from NIH such as:

1. Use of buffy coat from blood being discarded from the blood bank because it is over 21 days old.

2. Use of portions of autopsy and surgical specimens sent to the pathologist but remaining after he has used what he needs.

3. Use of glial cells in tissue culture. The cultures have been carried three years, and now the demand comes from NIH that proper informed permission be obtained to continue the cultures.

4. Use of fetuses for investigation of the rates of diffusion of medications past the placenta into the blood stream of the fetuses.

In each of these instances, NIH had demanded review and approval by the committee.