5 March 1946

MEMORANDUM TO THE SURGEON GENERAL, Room 2E288 (Extension 4469) The Pentagon.

Subject: Establishment of a Long-Term Follow-Up Clinical Research Program on Army Material.

1. During the period beginning with the mobilization of the Army in 1940 and continuing to date an enormous amount of material of great clinical value

has accumulated in the records kept in Army hospitals and dispensaries and in medical installations of other branches of the Armed Forces. It can fairly be said that no similar amount of material has ever been accumulated, and it is doubtful whether a similar amount will ever again be available.

- 2. Furthermore, the rigidly controlled Army system of personnel and records has made this material unusually complete. This is particularly true of records of patients who had to appear before boards for disposition and who for that reason were usually studied very intensively.
- 3. It is suggested that this accumulation of material should be turned to practical use by the establishment of a clinical research program, including a follow-up system to determine the natural and post-treatment history of such diseases and conditions as might be selected for the study. Failure to establish such a system would result in an incalculable loss to clinical medicine, as well as to the Armed Forces. From the standpoint of military medicine, the findings would furnish a rational basis for the development of professional procedures and operational policies and would indicate the wisdom of inducting men with certain disabilities because factual data would be available as to their usefulness while in service and as to their pension rights after their separation from the service.
- 4. A recollection of the manpower shortages and other difficulties which frequently occurred in World War II will make clear the usefulness of such data. The military value of follow-up studies was repeatedly proved during the course of that war. Follow-up studies on pilonidal sinus in 1944 showed that existing policies as to surgical treatment were wasteful of manpower and that a change toward a more conservative policy would save over 435,000 man-days per year. A similar study on herniated nucleus pulposus radically altered the management of that condition, and other studies had equally valuable results.
- 5. Peptic ulcer is an illustration of a condition which has not been, but could be, investigated with value both to clinical medicine and to the establishment of policies in the Armed Forces. A follow-up study of cases identified in military personnel would establish the incidence of the disease in certain age groups and the proportion of cases which might be expected to go on to perforation, hemorrhage, cicatrization and other complications over given periods of time. It would probably settle the disputed question as to whether or not benign peptic ulcers undergo malignant changes. It would undoubtedly establish the results of various forms of treatment in respect to mortality, morbidity, recurrence and long-term disability. These and other data, departing from a given base line and followed up over long periods of time dispassionately and in the absence of special pleading, have never been available.
- 6. Similar studies could be made of numerous other conditions such as internal derangements of the knee, chronic osteomyelitis, bone defects, head injuries, pulmonary suppuration, bronchiectasis, foreign bodies in the lung, peripheral vascular insufficiency, malignancies of certain types and in certain parts of the body, and peripheral nerve injuries. At the present time the only one of these conditions in which follow-up studies are being conducted is peripheral nerve injuries. The valuable information gathered from the Peripheral Nerve Registry established in 1944 emphasizes the potential importance of the program proposed. At the clinical research level it furnishes an opportunity to provide an investigative program in which the entire medical profession would participate and from which all would profit.

- 7. In general, the following plan might be followed:
- a. The project would preferably be a joint undertaking of the Army and Veterans Administration.
- b. It could perhaps be set up as a project under the National Research Council and assigned to various sub-committees, as was done with such success in other undertakings in World War II. Whether or not this was done, however, a most important consideration would be the appointment of a carefully selected committee to initiate the project, determine its extent, establish methods of procedure, and exercise a general supervisory function.
- c. It could be financed by grants from the proposed National Research Foundation, legislation for which is now pending, or by a Federal subsidy, depending upon the set-up.
- d. An adequate sample of the mass of material available in each category selected for study would be made from the available material. The records would be photostated and the original records returned to storage for use as other needs for them arose.
- e. The length of the follow-up would be determined upon for fixed periods of time, and in some instances for life, according to the nature of the condition to be studied.
- f. Contacts would immediately be made with the patients in each category through the Veterans Administration, the Army, civilian hospitals, social agencies, and civilian physicians. The mechanism now exists for follow-up studies on patients in the Army hospital system or returned to duty, though it has not been fully utilized for a variety of reasons and it is obviously self-limited.
- 8. Other details of procedure could be worked out by a survey of the problem and the formulation of detailed objectives. It is suggested, however, that, if such a project is initiated, there should be no delay in setting it in motion, while clinical material to be used in the program is still readily available.

/s/ MICHAEL E. DeBAKEY
Colonel, Medical Corps
Surgical Consultants Division.