Director, NHLI
THROUGH: Depty Director, NHLI

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Director, DTA, NHLI

Justification of reorganization of DTA and functional descriptions of the branches of DTA.

The Instrumentation Branch will continue to cover what it has covered heretofore.

The Biomaterials Branch will continue to seek appropriate materials for the blood material interface, appropriate materials in terms of longevity in the body environment and in terms of the flex-life demanded. In addition, it will of necessity delve into the gaining of a proper thorough understanding of the physical-chemical interactions between blood and surfaces with which it does not ordinarily come in contact.

The Devices Branch has been too all-inclusive to permit knowledgable supervision by any single individual. It has required on the one hand the expertise of a thermo-nuclear engineer and on the other the expertise of a rheologist-physiologist. This is a self-defeating administrative structure. For this reason, the Devices Branch is being separated into the two essential components with the intent that each may then prosper in the area of its special expertise.

The Artificial Heart Program, the Medical Devices Applications Branch, and now the Division of Technological Applications have been weakened by a fundamental philosophical incongruity. The original program was established as one in which the research and development were to be conceived and directed from within the Branch. There was some biological input initially. With the death of Dr. Hastings, there ceased to be mature personnel in the office experienced both in the experimental method and in the biologic field. The approaches to the VAB, to the Dow capillary oxygenator, to the blood pumps, and even to the intra-aortic balloon have suffered by absence of this combination of expertise in the office. The use of men two years out of medical school to take an active part in either the initial conceptualizing of new approaches or in direction of activities of contractors after onset of work has been a continuing disaster. For instance, I find no acceptable continuing studies on rheology on a pump costing $2200 each which is being fabricated to do experiments in several areas in which the components of the overall system have not been individually dissected and analyzed. Fifty-six implantations by one contractofralone of a total heart powered electrically without a single animal recovering enough to be taken off the respirator and yet with no documented analysis of the mechanisms for this difficulty represent a disconcerting example of lack of familiarity with proper experimental methods.

We can enhance the stature of DTA and thus f NHLI by placement of each man in DTA in that area for which he has truly the expertise, without imposition of major decisions upon persons not equipped by training or experience to make those decisions, whether they are long-term decisions or day-to-day decisions.

To make this possible and to utilize only scientific monitors who are truly superbly qualified, we must recruit more men of the caliber of Dr. Pitzele, finding slots for them by gradual phasing out of the commissioned officer group, who in general should not have been depended upon in so critical a role.

In line with this logic, the partition of the Devices Branch so that nuclear engineers handle the nuclear engineering component and so that people with experience and training in blood-contacting devices handle that aspect of it is but the constructive reorganization to adopt.

The Implantable Power Branch requires the expertise of a man prepared in nuclear science and engineering, and for this Dr. Harmison is well prepared. It is the plan that the nuclear physicists and engineers concentrate upon manifold problems which revolve about utilization of thermonuclear materials as power sources to be converted to either electrical or hydraulic energy as a means of running blood pumps. The responsibilities of this branch will include also those mechanisms of electrical nature involved in transmission of power across the intact skin, conversion of such transmitted power to usable voltages and frequencies, and storage of said power either in the electrical or thermal form.

The Rheology and Respiratory and Blood Contacting Devices Branch requires direction by a biological scientist well experienced in rheology and in the consequences of turbulence and configurations productive of activation of the clotting cascade. As a means to correct the present shortcomings of the Division in this regard, it is proposed that Dr. Pitzele, with his many years of experience in exactly this field, is the proper person to take charge. Activities in this Branch would therefore cover such problems as cellular aggregation, the effects of design on rheology, disseminated intravascular thrombosis, changes in serum proteins as a result of tissue contacts, the physiologic effects of variations of pulse contour of pumps, a major share of the input to devices through control mechanisms, oxygenators, the effects of flocking on rheology, and the proper configuration of surfaces through which there is to be heat dissipation. As a matter of practical good sense, since this Branch is largely biological, the pathologic changes induced and such matters as of the development, testing and utilization of respirators, oxygenators, and such equipment also are to be handled in this Branch.

The Laboratory Branch will include both the test and evaluation function of the Division and an adjacent laboratory for developmental review. As long ago as March 6, 1969 the Chief of the Artificial Heart program requested that laboratory space be made available to the Artificial Heart Program for the

purpose of providing an in-house laboratory facility under the control of the Artificial Heart Program and responsive to the needs of that program, where members of the staff can quickly build or test a device or try out the technique that is still in the earliest formative stage in the minds of that staff. It was pointed out at that time that such a facility would also be very useful for preliminary or quick testing or inspection by members of that staff of devices or components submitted by Artificial Heart Program developers. It was further pointed out that efforts to use laboratories and personnel under contract to NIH and at some distance away had repeatedly involved delays and had been confronted with elements of unresponsiveness and inflexibility which had seriously impeded progress. This continues to be the situation today.

The Ad Hoc Task Force on Cardiac Replacement in October 1969, included a recommendation that "NHLI be restructured by the addition within the Institute of experimental facilities and personnel for artificial heart research and development." (p.63)

It is the feeling that such a laboratory will provide ability for quick construction and testing of devices or techniques in formative stages, in the process of development, or arising from ideas which the staff of DTA wishes to pursue and in regard to which there have been no responses to RFP's.

As of the present moment, negotiations are in progress with Dr. Fred Leonard, Research Director, Rehabilitation Research and Training Center, George Washington University Hospital. A new building is nearing completion in which there is adequate space to permit a small start with two projects highly important to the Program and with the expertise of the outstanding materials scientist in the Washington area (outside of the NIH) anxious to serve as collaborator. The necessary personnel to man this laboratory are at hand and awaiting the launching of this project. In addition, utilization of this laboratory will facilitate certain testing procedures upon which the DTA has been expending in excess of a quarter of a million dollars a year in each of two laboratories (with unsatisfactory results) in a non-commercial, academic laboratory at a cost of about 20% of the cost heretofore, with expertise not available at the laboratories used earlier. In addition, this laboratory can provide us with personnel and wherewithall for implantation of devices, major and minor.

The possibility of development of a contractual relationship has been carefully explored with our Contract Officer, and there appears to be no difficulty in accomplishing same. This will not only greatly enhance the effectiveness of DTA but accomplish a considerable saving in addition. Finally, the availability of such an opportunity will make it far more straightforward to recruit the type of distinguished scientist which we all wish to have on the staff of DTA by replacement parallel with the expected attrition in commissioned officer personnel in the course of the next year. Finally, as an eager partner there is there a full-time fully trained cardiovascular-

thoracic surgeon, a product of my own training program in New York, to assure active surgical support in the trial of new devices, an item which has heretofore been singularly lacking in large areas of the program.

It is transparent that there are many areas of overlap among these five branches. The Laboratory Branch potentially involves all the other four. For instance, the problem of heat loss into the blood or tissues involves not only waste heat involved with thermo-nuclear devices, but waste heat from other types of pumps or energy convertors as well and will involve therefore the Instrumentation Branch, the Biomaterials Branch, the Implantable Power Sources Branch, and the Rheology Branch. Similar considerations prevail with regard to flocked surfaces, irradiation of plastic materials, and instrumentation which contacts flowing blood.

It is therefore only by virtue of the most cordial and wholehearted intercollaboration that the Program can progress successfully, regardless of the reorganization adopted.

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