STATEMENT of Dr. Michael E. DeBakey, made to the Executive Committee of the Board of Trustees on April 10, 1969

Following my return home on Monday, April 7, from a meeting in Washington on Saturday, April 5, 1969, I received a call from Dr. Ted Cooper, who is Director of the National Heart Institute, telling me that the matter relating to Dr. Cooley's implantation of an artificial heart had reached such proportions in the press that it was necessary for them to make an investigation to determine certain questions:

(1) Was the device used by Dr. Cooley the same as the one developed in our research laboratories under the grant received from the National Heart Institute to support our research on the artificial heart?

(2) If the device was developed in our laboratories, it would be necessary to determine if the guidelines on experimental procedures had been followed. These guidelines of the National Institutes of Health state that any device or drug developed by experimental work supported by a grant from the National Institutes of Health must be approved for use by an institutional committee for research involving human beings before it can be applied in a patient. Dr. Cooper therefore wanted to know if there was compliance of these guidelines.

(3) Dr. Cooper wanted information and data on the results of any experiments that were conducted with use of this device.

I then asked Dr. Cooper if he would write me a letter confirming his request and specifying precisely the questions he wanted answered. He indicated that he would do so and that it would then become the responsibility of the National Institutes of Health to determine what action they might take on the basis of this information.

I knew nothing about this matter until the news was released Friday evening, April 4, after I arrived in Washington and had checked into my hotel. I left Houston Friday afternoon for Washington to attend a meeting of the Artificial Heart-Myocardial Infarction Advisory Committee of the National Heart Institute, of which I am a member. At the meeting on Saturday morning, April 5, Dr. Cooper and other members of the Committee naturally discussed this development, and it was apparent from Dr. Cooper's remarks that the artificial heart implanted by Dr. Cooley was similar to that which we had developed in our laboratories, in his opinion. Dr. Cooper had visited us about two weeks before Dr. Cooley's implantation. At that time, he came here to inform himself personally of various aspects of the research work we were doing under this grant in order to give us as much help as he could before the occurrence of an elaborate project site visit, scheduled for May 7-8 in regard to renewal of our grant of almost $3 million. He therefore came down for a one-day visit with us, and I took him around to the various research laboratories supported by this grant, one of which was the laboratory at Baylor engaged in the artificial heart program.

I showed him the various aspects of the artificial heart research activities in the laboratory, including the fabrication of the pump and some of the problems that we had encountered in its design and development, including some of the results in our animal research work. I had him meet Dr. Liotta in the laboratory and had Dr. Liotta show him various aspects of the fabrication of the pump, including certain modifications we are in the process of making in the pump for better attachment in the animal, since we had had some disastrous technical problems in animals in which we had tried to use it.

Dr. Cooper was also interested, in his call to me, to obtain as much information as possible in regard to the clinical application of this pump by Dr. Cooley, since he was interested in helping to counteract some of the psychologic effects, including lack of confidence and perhaps even antagonism, that this incident would undoubtedly produce in the minds of those scientific members of the project site committee who would come here May 7 and 8 to review our program. In discussing this program with Dr. Eugene Stead, who, as you know, will be joining us soon as a consultant and who has reviewed our application for renewal thoroughly and will be here for the project site visit, I was told by him that he too was concerned about this matter. It is therefore imperative that all the facts that can be obtained be made available to insure the responsibility of the investigators in this renewal application in complying not only with the proper guidelines but also with a sound

scientific basis for clinical application of experimental procedures.

I am sure that you realize that I am in a rather difficult position to make any public statements, since I am not only the Principal Investigator of the Artificial Heart Program, but, as President of the College, am also the responsible Executive Officer of the College. I therefore considered it necessary for me to remain aloof from the public controversy and make no public comments or statements. For this reason, I believe it is necessary to establish the proper procedure to investigate the facts that have taken place in this matter. I informed Mr. McCollum of all the information I had available to me, and he felt that it was necessary to have a special called meeting of the Executive Committee of the Baylor Board of Trustees.

I have available for your review the findings of the Advisory Committee of The Cardiovascular Research and Training Center Grant, under which the artificial heart research program is supported. This Committee is also prepared to give you a report of findings of the Baylor Committee for Research Involving Human Beings. It will also present to you a memorandum, under date of November 4, 1968, from the Baylor Committee for Research Involving Human Beings to all members of the faculty, specifying certain guidelines for clinical experimentation. For your information, too, I may say that all of our affiliated hospitals also have established special committees for research involving human beings.

Mr. McCollum: I think what we might do is have you capsule the events as you know them.

Dr. DeBakey: Briefly, what the Advisory Committee has found is that about three or four months ago, Dr. Cooley went to see Dr. Liotta and discussed with him the possibility of working together to develop an artificial heart for use in a human being. Dr. Liotta, when asked by the Committee why he did not come to me, who, he knew, was responsible as the Principal Investigator, stated that he deliberated about this and although realizing that he was doing wrong, talked it over only with his wife and agreed to go along with Dr. Cooley. He stated that he made this decision because he felt that Dr. DeBakey would not allow this device to be used in human beings and that Dr. Cooley was determined to apply it in human beings.

The second factor we know about is that Dr. David Hellums, who is the Principal Investigator for the Rice University artificial heart grant, which is a companion grant to our own, called me and said that he was shocked to hear the news of the artificial heart implantation by Dr. Cooley. We have been collaborating with the group working on the Rice artificial heart program since 1964. Dr. Hellums then told me that about two months ago, one of his men, Mr. Bill O'Bannon, an engineer on the part-time faculty of Rice and salaried by the Rice grant, came to see him to say that he had had a confidential inquiry about building the driving and control mechanism for an artificial

heart similar to that which Rice had developed for use in our experimental laboratory. When Dr. Hellums asked him who the person was, Mr. O'Bannon stated that he had been asked by the party not to reveal his name. Dr. Hellums told Mr. O'Bannon that he could not approve doing this from the Rice standpoint, but that if Mr. O'Bannon wanted to do it on his own time and work through the Texas Instruments Co. (of which Mr. O'Bannon is part owner), he would have to do it on this basis. Dr. Hellums later learned that Dr. Cooley was the one who asked Mr. O'Bannon to build the pump. He discovered this when Mr. O'Bannon came to see Dr. Hellums on Thursday, April 3, the day before the implantation by Dr. Cooley, and asked permission to run the pump for Dr. Cooley in the operating room the next day. Dr. Hellums told Mr. O'Bannon he could not give this permission. On Friday morning, the day of the operation, Dr. Cooley himself called Dr. Hellums to ask his permission to let Mr. O'Bannon help run the pump which he planned to use in a patient. Dr. Hellums told Dr. Cooley that he could not give his approval because he did not have Dr. DeBakey's approval for it, nor did Dr. Cooley have such approval, since Dr. Cooley admitted to Dr. Hellums that he had not obtained Dr. DeBakey's permission. Dr. Hellums explained to Dr. Cooley that since they had not tested this pump, they could not be responsible for running it. Moreover, it would take more than 24 hours to test the pump.

For your own background information regarding my relationship to the development of this pump, let me state that I first became interested in the development of the artificial heart more than a decade ago and made strenuous efforts through the National Institutes of Health and through Congressional testimony to obtain support for work in this field. Indeed, it was on the basis of my testimony to Senator Lister Hill that funds were finally allocated in 1964 for this purpose.

Following the allocation of such funds, I went to Dr. Pitzer, then President of Rice University, and told him that funds were being allocated for development of an artificial heart and that I thought we should initiate a grant application to the National Heart Institute to obtain funds to support a research program here. I expressed the belief at that time that this should be a collaborative program involving both biologic and physical scientists, and that by Baylor and Rice joining together, we should have the scientific personnel to activate such a program. Dr. Pitzer agreed, and we then submitted companion grants, showing our desire to collaborate. These applications were approved, with me as Principal Investigator for the Baylor program. This collaborative effort has been continued since that time.

In 1964 I appointed Dr. Liotta to the program as an assistant and Dr. William Hall as the director.

We first began working on a complete artificial heart, for total replacement of the human heart, but because of a number of problems which we were unable to solve, we began to concentrate our efforts on a pump that might be used clinically to support the failing left ventricle. This research work ultimately led to the development of the left ventricular bypass pump which was thoroughly tested on hundreds of animals to establish its safety and effectiveness. Thereafter, in 1966, we applied it in a series of critically ill patients and showed its value in these patients. We then continued to modify this pump in the hope that we could improve its design, and also directed our efforts to more intensive study of the blood interface problem, which has been one of the major obstacles to all research workers in this field. As we progressed with the changes in the design of the pump, we evolved a biventricular type of pump in September, 1968, which is essentially similar in design to that used by Dr. Cooley in his clinical experiment. Our pump was tested in the laboratory, from both hemodynamic and design standpoints, at both Baylor and Rice. In the early period of January, 1969, I authorized Dr. Hellums of Rice and Dr. Liotta of our laboratory to begin some experimental animal work on this pump. The purpose of these experiments was to determine the technical feasibility of its replacing the heart, to develop design modifications that would permit its proper technical and anatomic application in the animal, and to study certain physiologic criteria that might be used in the proper

control of the driving mechanism of the pump.

The first four animals in which the pump was applied died on the operating table from various technical problems. As a result of this experience, certain modifications were made in the design of the pump for its proper attachment. These proved to be successful, and in the next three animals, it was possible to apply the pump technically, but the pump did not prove successful in maintaining viability of vital organs in any of these animals. One survived 12½ hours,and died from rupture of the pump; this animal only showed some reflex movements, but was unable to stand and showed no kidney function. The second animal in this series survived about 8½ hours and only showed some reflex movements, was unable to stand, and showed complete renal failure, with progressive anoxia, indicating lung congestion and failure. The last animal in the series showed no evidence of viability from the time the artificial heart was implanted until the pump was discontinued 44 hours later. The animal was essentially a cadaver in which the pump continued to pump blood that was anticoagulated by heparin.

All scientific research workers in this field have long known that the artificial hearts that have been developed by various investigators have all had the same problem in their application to animals, namely, that while it is possible to obtain some evidence of survival of animals for periods ranging up to about two days, there develops progressive damage to the

blood, resulting in irreversible damage to vital organs such as the brain, kidneys, and lungs, producing death from this damage.

Question: Could you use it to keep a person alive for two days in the hope that you could save his life until a heart is available?

Dr. DeBakey: It is important to recognize the fact that on the basis of our experimental evidence, it is not possible that this artificial heart can keep a patient alive in sufficiently good condition for two days to permit recuperability of the damage that takes place over this period to the vital organs, such as the brain, kidneys, and lungs. Moreover, the ethics may be questioned of applying a procedure such as this in a patient without animal evidence of its safety and effectiveness -- on the basis that it might keep a patient alive until a heart donor can be obtained for transplantation -- since it is also not possible to know that such a donor heart will become available for this purpose. We have had a patient at the hospital who has been waiting for a transplantation for more than 2½ months, and whereas we have had several donors made available to us, none of these proved acceptable. Accordingly, it may be necessary to wait for some weeks, or even months, before a donor heart that is suitable presents itself.

The use of desperate measures to save a patient's life is certainly to be applauded, but the application of an untried

procedure to sustain life for 12 to 24 hours is worthless when the damage done by the procedure during this time would vitiate recuperability even if a donor heart became available. What is a more justifiable procedure is to wait until the donor heart becomes available before attempting a corrective operation that might fail. The patient in question, Mr. Karp, had been in the hospital for more than a month, and it would have been better to defer operation until a suitable donor became available for a heart transplantation. The same kind of appeal could have been made for a donor before the operation.

It should be observed that the patient's clinical response to the artificial heart was much the same as observed previously in animals, with progressive damage to the kidneys and even to the brain, resulting in complete renal failure at the time the transplant was performed and complete brain failure, since this was developing progressively and the patient never regained consciousness after the heart transplantation was performed.

In light of the foregoing, it seems to me that we need to obtain factual information regarding this procedure in order to define proper responsibility of the College. We need to determine whether the guidelines of the College for clinical application of experimental procedures have been violated and to make proper assessment of the facts regarding the use of the artificial heart device developed in our laboratories and used by Dr. Cooley in a patient. In other words, we must establish

the facts that will assign the responsibility for what was done, so that we may answer the specific questions asked of us by the National Institutes of Health.