HISTORY OF THE ARTIFICIAL HEART

The artificial heart program was created at the National Heart Institute with special congressional approval in 1963. Its ultimate goal is to develop a totally implantable mechanical heart —including an implantable power source— which can be used to replace a failing natural heart. Since 1964, the program has had a succession of organizational names: Artificial Heart/Myocardial Infarction Program, Medical Devices Application Branch (1970), Division of Technological Applications (1972), and Cardiovascular Devices Branch (1973) of the National Heart and Lung Institute. The program is currently administered by the Devices and Technology Branch (1974), of the Division of Heart and Vascular Diseases, of the National Heart, Lung, and Blood Institute (NHLBI).

The effort to construct heart prostheses followed naturally from the successful design of heart-lung pumps that could be used during open-heart surgery to assume (for short periods only) the functions of both the heart and lung. Many medical and technical advances suggested the feasibility of heart replacement: the implantation of artificial heart valves, the development and widespread use of cardiac pacemakers, increasingly successful blood dialysis as a mechanical replacement for kidney function, and the achievement of kidney transplants in humans and heart transplants in animals. The success of the aforementioned surgical techniques demonstrated the possibility of prosthetic replacement, while the immunological rejection and shortage of donors associated with the transplants helped demonstrate the need for a mechanical heart. Other notable technological achievements included the revolution in miniaturized engineering stimulated by the space program, advances in energy technologies (e.g., the plutonium heat engine), and the development of synthetic materials (e.g., teflon and lycra) with outstanding engineering specifications for wear and flexibility (45).

These developments helped set the stage for the construction of prototype hearts by a number of investigators—Adrian Kantrowitz, Michael DeBakey, and Willem Kolff. Much of the earliest work on the artificial heart was carried out, without Federal sponsorship, in academic and research centers.

The search for the *large* capital outlay necessary to finance the initial R&D for the artificial heart was given impetus by nature of the medical and engineering problems that were encountered: finding hemocompatible materials able to withstand continual wear and flexion, finding a power supply, and developing sophisticated miniaturized control systems. The magnitude of these problems discouraged independent development and created a demand for Government involvement.

The artificial heart program was launched in a period of both economic growth and great faith in the powers of science and technology. Heart researchers, such as Michael DeBakey of Baylor University, were enthusiastic about developing an artificial heart and were optimistic that a successful device might take as few as 3 years but no more than 10 years to achieve. By early 1965, there was a 5-year plan for achieving the artificial heart: roughly 1 year to assess the "state of the art," 1 year to design, test, and develop the system, 2 years to develop heart prototypes, and 1 year to test the model and determine standards for mass production (40).

It was widely believed that the approach to the space race (i.e., systems analysis) could be used as a model for organizing technological projects like the artificial heart. A similar approach, including a built-in rivalry among scientists, was therefore adopted by the National Heart Institute. Several researchers worked on parallel development of the separate subsystems of the heart—energy systems, control systems, blood interface materials—that were to be reintegrated into a working device at a later time (33). The decision was also made, based on the success of the space program, to use targeted contracts to private firms to develop parts and materials for the device, rather than the more common research grant procedure (35). This targeted approach, reflecting the specificity of engineering, was based on the assumption that the