In addition to Federal contracts and grants, some private funding helps to support artificial heart research. For example, the Cleveland Clinic has an NHLBI contract to develop a pump suitable for an implantable LVAD. Supplementing this contract, Parker-Hannifin Corp. provides a philanthropic gift that covers approximately 10 percent of the clinic's heart device research. TRW Corp. produces at its own expense components that are contributed to the clinic. Goodyear Corp. contributes expertise and manufactures the diaphragm for the pumps. It also contributes one full-time employee who works on the clinic's heart device program. This support is part of Goodyear's Aid to Medical Research Program. The Cleveland Clinic is also testing Medtronics' LVADs with that firm's equipment, service, and expertise. Testing and clinical trials of these devices are separate from NHLBI funding.

Federal allocations for the artificial heart program have averaged $10 million since 1964, and the present annual figure is approximately $15 million in contracts and grants. The growth in allocations has not kept up with requests or inflation. Some researchers, such as Yuki Nosé of the Cleveland Clinic, have estimated that a clinically useful, totally implantable LVAD may be ready in 1983, and that a totally implantable artificial heart may possibly be available in 1986. Other contractors say these estimates are optimistic, given present funding, and some claim that a totally implantable artificial heart may not be ready until the year 2000. It could happen, then, that federally funded research will be required for another 10 years. If annual allocations are held at the present level for 10 years, this means an additional $150 million in Federal R&D funds—and $300 million is a potential figure if research continues until the end of the century.

PARALLEL COSTS OF HEMODIALYSIS

Hemodialysis and kidney transplantation emerged as life-extending therapies for victims of ESRD in the early 1960's. Here we examine the experience of hemodialysis financing and distribution in order to draw lessons that have potential for application to the artificial heart.

Systematic funding efforts by NIH on behalf of the kidney program began in 1965 (64). At that time, the artificial kidney-chronic uremia program of the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD) was founded with a contract research program to build a better artificial kidney. The artificial kidney program was mandated by the House and Senate Appropriations Committees with the 1966 budget, 1 year after the artificial heart program was founded in the National Heart Institute. Though the artificial kidney was advanced well beyond the artificial heart at the time, advocates of the artificial heart (such as Michael DeBakey) appear to have been more powerful.

Human kidney transplantation, which following occasional attempts in the 1940's had begun in earnest in the 1950's, developed in parallel with the artificial kidney. The availability of hemodialysis helped the kidney transplantation program by making available pools of potential transplant recipients. NIH funding was available for transplantation research, because the researchers who worked on the immunological problem were well known as basic researchers (64). Information concerning the total sums spent on development of artificial kidney technology or kidney transplantation is not readily available.

In 1960, cost estimates for hemodialysis were made by Belding Scribner and his colleagues at the University of Washington in Seattle (63,64). Minus equipment, the cost per patient for once-weekly dialysis was estimated to be $5,533 annually. The later recognition that dialysis three times weekly would be better medically greatly

increased per patient costs (63). In 1963, at a joint finance meeting of the American Medical Association and the National Kidney Disease Foundation, costs were estimated to be about $20,000 per patient per year. The moral questions involved in the availability of dialysis were brought up at the same meeting. There was concern that 25 to 50 percent of those who needed dialysis were not able to obtain it (43).

In 1964, the Federal Government recognized its potential fiscal role in treatment of ESRD, and the Senate Appropriations Committee said that the Public Health Service (PHS) had the authority to provide demonstration and training funds for artificial kidney programs (but not for patient care) (63). Scribner and his colleagues in Seattle, through community fundraising and private philanthropy, had developed a community treatment center in 1962. The first PHS demonstration and training grant had been given to that center in 1963 (63), to be phased out in 3 years. Also in 1964, NBC television was preparing a documentary that was aired in 1965 contrasting the millions the Government was willing to spend on the space program to the small amount spent for dying individual in need of dialysis. A total of $3.4 million was allotted for support of 14 community dialysis centers. In 1968 and 1969, PHS took action to gradually stop funding these centers.

In 1967, despite these efforts, the Gottschalk committee (an advisory group convened by the Bureau of the Budget) recommended Federal financing of patient care for ESRD through an amendment to the medicare component of the Social Security Act. One month prior to the 1972 election, Congress passed the Social Security Amendments including section 2991 which extended medicare coverage to the treatment of ESRD. Section 2991 was allotted less than 30 minutes of discussion on the Senate floor and given only a few minutes of deliberation in the joint House-Senate Conference Committee. President Nixon signed it into law on October 30, 1972 (63). Senator Vance Hartke, who sponsored section 2991, stated that estimated annual costs at the end of 4 years would be $250 million, with a first year cost of ***$75*** million (63). *

Ronald M. Klar, in the Office of the Assistant Secretary of Health at the Department of Health, Education, and Welfare (HEW), immediately saw problems with this estimate. Through information obtained from nephrologists, Klar made new projections of the costs of the ESRD program based on a new cohort of patients entering the program each year. Each cohort would include about 10,000 patients, 2,000 of whom would be transplanted; there would be about a 20-percent annual mortality rate; and the average annual cost of dialysis would be $16,000. Thus, according to HEW in 1972, the cost in 5 years would be an estimated $592.1 million for 40,000 patients. By the time the program stabilized in 10 years, the cost would be $1 billion annually (64). Table 5 summarizes the 1972 HEW and 1974 Social Security Administration (SSA) estimates of the annual costs for the ESRD program (64).

The House Ways and Means Committee, in 1975, estimated there would be 50,000 to 60,000 patients by 1984 at a cost of $1 billion, and

*The Senate amendment included a 6-month waiting period for patients before benefits should begin, which the House Ways and Means Committee was able to change to 3 months.

Table 5.—Estimated Annual Costs for the ESRD Program (dollars in millions)

Fiscal year	Total patient population	SSA estimates of medicare expenditures (1974)	HEW estimates of total national costs (1972)
1974	9,980	$135	$157.7
1975	18,754	176	281.5
1976	26,746	223	394.5
1977	34,036	278	497.8
1978	40,685	—	592.1

SOURCE: R.A. Rettig and T. C. Webster, "Implementation of the End-Stage Renal Disease Program: A Mixed Pattern of Subsidizing and Regulating the Delivery of Medical Services, " 1977 (64),