VALUING LIVES: THE POLICY DEBATE ON PATIENT CARE FINANCING FOR VICTIMS OF END-STAGE RENAL DISEASE

Richard A. Rettig

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VALUING LIVES: THE POLICY DEBATE ON PATIENT CARE FINANCING FOR VICTIMS OF END-STAGE RENAL DISEASE

by

Richard A. Rettig*

INTRODUCTION

In Public Law 92-603, the Social Security Amendments of 1972, Medicare health insurance coverage for end-stage renal disease** was effectively extended to more than 90 percent of the U.S. population. The 1965 law which established Medicare provided health insurance coverage to the aged--those over 65 years of age, and this included coverage for renal failure.[1] Restrictive patient selection criteria for hemodialysis and renal transplantation*** patients, and limited knowledge of this specific form of the general benefit, however, resulted in relatively few individuals receiving Medicare benefits for end-stage renal disease.

Public Law 92-603, enacted on October 30, 1972, provided Medicare coverage to the under-65 population and did so in two ways. First, those

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*The Rand Corporation, Washington, D.C.

**_Chronic_ or _end-stage renal disease_ is that clinical condition reached when an individual has experienced such a degree of irreversible deterioration of kidney function that--without treatment--death will soon follow. _Renal_ means pertaining to the kidneys, from _ren_, the Latin word for kidney.

***_Hemodialysis_ is the process by which metabolic waste products normally cleared by the kidney through the urinary tract are "washed" from the blood stream by means of an artificial kidney. _Renal transplantation_ is that surgical procedure by which a healthy kidney from one individual is implanted in an individual with end-stage renal disease and the transplanted kidney functions as the individual's own kidneys once did.

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individuals under age 65 who qualified for cash benefits under social security or the railroad retirement system because of a *disability* so incapacitating that they were prevented from working became eligible, after a 24-month waiting period, for Medicare's hospital and supplementary medical insurance protection.[2] This protection included coverage for end-stage renal disease.

A substantial number of potential end-stage renal disease patients, approximately 60 percent of the total, however, could not qualify for Medicare on either the basis of age or entitlement to cash disability benefits. Medicare coverage was extended to this larger group by Sec. 299I of the Act. Sec. 299I stipulated that every individual not yet 65 years old, who was fully or currently insured or entitled to monthly insurance benefits under social security, or who was the spouse or dependent child of such an individual, and who was "medically determined to have chronic renal disease" and to require hemodialysis or renal transplantation, shall, in the language of the Act, "be deemed to be disabled for purposes of coverage under parts A and B of Medicare subject to the deductible, premium, and copyment provisions of Title XVIII."[3]

What is the significance of Sec. 299I? Part of its significance lies in the extension of Medicare coverage for end-stage renal disease to the U.S. population on a near-universal basis, both by virtue of its own coverage and by highlighting the benefits available to the aged and disabled. It is also significant because it is a concrete instance of the willingness of the national legislature to pay a very substantial price to preserve the lives of a very small number of individuals.

In the 1960s, two therapies--hemodialysis and renal transplantation--emerged having the capability of saving the lives of individuals with chronic kidney failure. Clinically, the artificial kidney machine is the first artificial substitute for a whole natural organ and kidney transplantation is the first surgical procedure for transplanting a whole natural organ from one individual to another. These therapies are non-elective procedures for those with end-stage renal disease; if they do not receive this treatment they die.

The number of beneficiaries of end-stage renal disease treatment is fairly small relative to the population. The number of reported dialysis patients alive in July 1970, 1971, and 1972 was 2,874, 4,375, and 5,786 respectively.[4] The total number of kidney transplants reported for 1967, 1968, 1969, 1970, and 1971, respectively, was 428, 625, 787, 996, and 1,172.[5]

Both renal dialysis and transplantation are very expensive therapies, requiring resources normally well beyond the financial means of all but the most affluent. A recent General Accounting Office (GAO) study of the costs of dialysis, based upon 1972 data for 96 center dialysis programs in 11 states and 2 counties and 10 home dialysis programs in 6 states, indicated the following:[6]

Table 1
ANNUAL COST OF DIALYSIS

	Center Dialysis (96)			Home Dialysis (10)	
	Total (96)	Hospital (81)	Non-Hospital (15)	1st Year	2nd Year
Average Charge	$30,100	$30,500	$27,600	$14,900	$7,000
Range		11,500-49,100	12,800-46,800		

NOTE: Data are for 1972.

The costs of transplantation are also significant. Charges for 1973 in 24 facilities analyzed by the GAO ranged from $5,500 to $20,500 and averaged about $12,800. The Department of Health, Education, and Welfare (DHEW) cited costs to the GAO of $14,000 for a living related donor transplant. Included in costs were hospital room, board, ancillary charges, and professional fees.[7]

The costs of therapy to a given individual can vary substantially according to the therapy or combination of therapies received and a number of other contingencies. The general point, however, is that neither therapy is inexpensive, though a *successful* transplant is by far the least costly and most satisfactory mode of therapy.

The extended Medicare coverage for end-stage renal disease went into effect on July 1, 1973. The estimated incurred costs for the first year of the program were $150 million for Sec. 299I beneficiaries and an additional $100 million for patients eligible under the aged and disabled provisions. The estimated incurred costs for the first, second, third, and fourth years for both Sec. 299I and all Medicare renal patients, are shown below.[8]

Table 2
ESTIMATED MEDICARE INCURRED COSTS OF
END-STAGE RENAL DISEASE
(in millions)

	Fiscal Year--			
	1974	1975	1976	1977
Sec. 299I patients	$150	$225	$300	$360
All renal patients	250	350	500	600

It is estimated that the annual costs for renal disease patients will exceed $1 billion by 1984.

The number of renal disease patients who had qualified for Medicare coverage as of March 31, 1975, under all three provisions, was 25,066, of whom 20,764 were living.[9] Essentially 60 percent of the total was qualified on the basis of Sec. 299I. Estimates are that the number of patients alive and receiving renal disease benefits will rise to 50,000 to 70,000 by 1990.

It is interesting to note, by contrast, the situation affecting hemophiliacs, a group for whom Medicare coverage has not yet been made available. Hemophilia is a disease whose central symptom is serious bleeding. The estimated number of patients is 100,000, of whom approximately 25,000 are severely or moderately severely affected.[10] These 25,000 patients require continuous replacement of fresh whole blood, plasma, or clotting concentrates. Replacement materials costs from $2,000 to $5,000 per patient per year. Costs of replacement therapy, and of reconstructive surgery for the most severely crippled, are rarely covered by third-party payments. Therapy capable of preventing bleeding episodes is far more expensive and can range from $20,000 to $40,000 per year. Legislation has been introduced in recent Congresses to make financial assistance for treatment payment available to hemophiliacs.

The provision of Medicare financing benefits to the victims of end-stage renal disease has been much discussed by the public, the press, and policy officials. One main question has to do with the interpretation of the enactment of Sec. 299I. Was it another "chapter in the growing history of Congressional fumbling with health matters," as *The New York Times* suggested editorially?[11] Was it a precursor of a categorical disease

approach to the coverage of catastrophic illness, as an Institute of Medicine panel worried?[12] Was it the result of astute inside lobbying of the Congress by the National Kidney Foundation?[13] Was it, as Zeckhauser has argued, a "myth-preserving action" demonstrating the greater willingness of society to expend resources for identified lives than for statistical lives?[14] Or was it the practically inevitable next step in a series of partial federal government responses to the existence of life-saving therapies so expensive they were simply beyond the financial reach of the victims?

In this paper we examine the above questions and the decision to enact Sec. 299I in the light of the policy debate which preceded it. Four characteristics of that debate are significant:

- o The debate was lengthy, beginning in the early 1960s and resolved in 1972;
- o The critical importance of paying for the cost of therapy was always clearly understood;
- o Strong resistance to expanding the federal government's responsibility to include patient care financing was encountered at every major juncture in the debate; and
- o The resolution of the debate in the enactment of Sec. 299I occurred after very limited discussion and was inconclusive with respect to any definitive interpretation.

That the debate was lengthy and the issues clearly understood from the outset is indicated in the next section. The factors affecting the evolving policy debate over time are analyzed in Section II. The proce-

dures by which the resolution of the debate occurred are set forth in Section III. The implications of this case study are discussed in the final section.

I. THE LONG POLICY DEBATE

In order to understand how the society grappled with value-of-life decisions posed by Sec. 299I, it is important to recognize that the nature of the end-stage renal disease issue was clearly understood at least a decade before the matter was resolved. The U.S. government did not move quickly to the decision it made in 1972. It is also important to note that although the particular issue of the moment wore many faces specific to particular federal policies and programs, the centrality of the patient-care financing question was never in doubt.

The use of the artificial kidney machine for providing long-term intermittent hemodialysis for preserving lives of individuals with end-stage renal disease became possible in 1960. In that year, Dr. Belding H. Scribner, a physician at the University of Washington School of Medicine, and his colleagues invented a vascular access device known as a *cannulae* and *shunt*. This device made it possible to hook patients to the artificial kidney machine for the purpose of cleansing their bloodstream of the products of metabolic waste and then to unhook them at the end of 10 or 12 hours of treatment.[15]

Scribner inserted the cannulae and shunt in his first patient on March 9, 1960, and immediately began dialysis. Scribner was so enthusiastic about his technique that he took ten "how to do it" kits to Chicago the next month, where he demonstrated for his medical-scientific

colleagues the process of patient cannulation.[16] Clyde Shields, his first patient, also made the trip. Scribner's own account of that meeting indicates that there was general agreement that the cannulation technique was promising but that considerable pessimism existed regarding the biochemical aspects of dialysis. Questions dealing with the potential patient load revealed substantial differences of opinion, but most thought the load would be considerable. Efforts to determine that load were deferred to a later date. "The question of public release of information and fund raising was not discussed in detail," Scribner wrote, "because it is just too early to say much."[17]

On May 19, 1960, Scribner wrote George M. Wheatley, M.D., a vice president of Metropolitan Life Insurance Company in New York City, to inquire about prospective patient load data: "It is becoming more and more clear that by this technique of continuous hemodialysis and the technique of cannulation of the blood vessels, we are going to considerably alter the course of terminal illness in patients with chronic uremia."[18] Clearly, moving this new medical technique from clinical research to widespread medical use was of great importance to Scribner within weeks of his first patient being placed upon the machine.

Costs also came quickly into focus. July 1960 estimates by Scribner of costs for treating 15 patients came to $99,000--$16,000 for equipment, $40,000 for once-a-week dialysis, and $43,000 for medical personnel.[19] Minus equipment, per patient costs were $5,533 per year. The recognition that thrice-weekly dialysis was medically more desirable later exposed these estimates as quite low. Even so, it was clear that substantial costs were associated with this new procedure.

By 1962, cost considerations and the related scarcity of facilities, permeated all discussions of dialysis. Harold Schmeck, writing in *The New York Times* about the Seattle experience, called the emergence of hemodialysis "one of the most dramatic stories of medical triumph and tragedy in recent history."[20] The triumph lay in the fact that "a handful of men and women who should be dead, by normal medical criteria, are living and leading nearly normal lives." The tragedy lay in the fact that "because facilities for cure are limited, inevitable death of kidney disease was in store for thousands of others." Annual costs of treatment were estimated to be $10,000 per patient.

In early November 1962, a *Life* magazine article by Shana Alexander described the dilemma created by the existence of a life-saving therapy and the scarcity of facilities to provide it.[21] Treatment costs were estimated to be $15,000 per patient year. The article went on to describe the anonymous, seven member, lay committee in Seattle which was charged with deciding which individuals should have access to the limited number of machines *after* medical evaluation of prospective patients. Factors identified as important to the committee in their determinations included the patient's age and sex, marital status and number of dependents, income, net worth, emotional stability--especially in accepting treatment, educational background, occupation, past performance, future potential, and personal references. The value-of-life dilemma was conveyed in stark terms to an audience of millions.

At a joint conference in June 1963 between the American Medical Association and the National Kidney Disease Foundation, the Seattle presentation enumerated "adequate funding" and preparation as the first of several prerequisites for a successful hemodialysis treatment program.[22]

Costs, it was indicated, could reach "upwards of $20,000 per patient per year," and initial capitalization for a ten-bed center was estimated to be $300,000 to $500,000. The financial workshop report indicated that it "has asked more questions than it has been able to find answers for at this point." The workshop on socioeconomic and moral questions, however, chaired by a Jesuit priest, put the problem in clearer perspective:[23]

> At this moment there are only a certain number of people who are able to be helped through the technique of hemodialysis. In the immediate future, also, just a small number of people will be able to be treated. No matter what the decision of our conferences about the medical and financial factors, the implementation of a full-scale program will take a number of years. Therefore, we in this country will be faced with the moral problem of having at hand a method of saving life which is not available to all who need it.

Finally, the implications of hemodialysis for the federal government were also recognized early. In 1964, the Senate Appropriations Committee indicated that the Public Health Service had the statutory authority to provide demonstration and training funds for artificial kidney programs. That authority, however, did not extend to patient-care financing:[24]

> The Federal Government has borne the cost of treatment for its legal beneficiaries and shared these treatment costs when it has been in connection with research investigation or demonstration. Traditionally, payment for treatment of illness has been the responsibility of the patient or the local community. If the Federal Government were to share the full cost of lifetime treatment for all who suffer from these chronic diseases and conditions, the financial burden would be excessive.

This statement reflected full comprehension of the policy issue.

It should be clear from the above analysis that the value-of-life issues raised by the emergence of hemodialysis were understood generally and with respect to their implications for the federal government essen-

tially a decade before the passage of Sec. 299I. Why ther did it take so long to resolve the matter? In the following section, the answer to that question will be developed through an analysis of the factors influencing the policy debate.

II. MAJOR FACTORS AFFECTING THE POLICY DEBATE

Six major factors were important in affecting the lengthy policy debate on patient-care financing. These factors were:

- o The unfolding clinical development of the two life-saving medical procedures--dialysis and transplantation;
- o the changing distribution of power within the medical-scientific community;
- o the "technical logic" of federal policy development;
- o the evolution of the federal role in health;
- o the vicissitudes of politics; and
- o the importance of identified lives.

A. The Unfolding Clinical Experience

The evaluation of a new medical procedure by the medical-scientific community depends upon a number of factors. Those general factors that have been identified as most important to this case are the location of a procedure on the *experiment-therapy continuum*, the quality of life provided patients by the procedure, the therapeutic alternatives, and the aesthetic nature of the therapy.

Fox and Swazey have suggested that it is appropriate to speak of an experiment-therapy continuum for any given medical procedure.[25] A procedure may be clearly experimental or clearly an established therapy,

but new procedures are frequently in some intermediate position and moving from the experimental to the therapeutic. Clinical investigation, they note, involves the interplay between research and therapy, and the balance between the two "shifts as the new treatment evolves."

The precise location of a new medical procedure along this continuum, quite obviously, will have a large bearing upon the policy debate about how the federal government should react to the procedure. If it is experimental, then research is clearly indicated. If it is established therapy, however, other responses might and probably will be called for. But the position of a given procedure on this continuum at a particular time is difficult to establish.

Two sources of ambiguity complicate this assessment. First, Fox and Swazey point out, there are semantic difficulties: "Physicians do not have standardized and unevocative terms to designate the stages of development of a new therapy clearly and objectively."[26] No *a priori* criteria exist by which the medical community can make such judgments.

Second, clinical investigators confront a role of structural ambivalence created by their dual orientation to the provision of therapy to sick patients and their concurrent commitment to "the advancement of scientific understanding" of clincial medicine. Clinical investigators differ markedly in their emotional involvement in both the investigative and therapeutic aspects of their dual role. The dilemma confronting the clinical investigator has been described in this way:[27]

> The research physician's attempt to equilibriate his clinical and investigative responsibilities is related to a basic problem: determining how experimental and/or therapeutic a new operation, drug, or other procedure is at a given time in its development and for a given class of sick persons.

Consequently, among clinical investigators the "scientist" is likely to emphasize the unknowns and uncertainties of a new procedure, to stress the limits of knowledge, and to regard it as experimental for a longer time than a "physician." By contrast, the "physician" is likely to emphasize the prospective benefits of a new procedure and deemphasize the associated uncertainties.

The policy debate over end-stage renal disease was affected by differences of opinion within the medical-scientific community as to where the therapies of dialysis and transplantation were along the experiment-therapy continuum. For instance, when Scribner first introduced his cannulation technique in 1960, John P. Merrill, M.D., who had extensive experience with dialysis in connection with the transplantation program at Peter Bent Brigham Hospital in Boston, suggested that patient weight loss and mental deterioration were likely to occur on long-term dialysis. George E. Schreiner, M.D., of Georgetown University, one of the pioneers in the use of dialysis with acute renal failure, supported Merrill's views.[28] Subsequently, many physicians attempting to replicate the Seattle experience were unable to do so. Charges were made that Scribner kept his patients alive only by heroic dedication and energy and not by clinical understanding of the dialysis experience.

In June 1963, at the meeting sponsored by the AMA and the National Kidney Disease Foundation mentioned above, Merrill essentially announced that hemodialysis could be regarded as an established therapeutic procedure. He said:[29]

> My colleagues and I at Peter Bent Brigham and others have used Dr. Scribner's technique and while difficulties were encountered at first, we have found that it is now possible to use this method. It is important to emphasize this fact about hemodialy-

> sis because it is no longer in the experimental stage. It is now a practical method, as far as some physicians are concerned, by which to keep chronic uremia patients alive. I believe the problem of hemodialysis must be looked at in this light.

Schreiner, however, speaking at this same meeting, was far more conservative. "So at the outset," he said, "let me emphasize that no matter what you have read or heard, there are problems connected with the use of these techniques, both in a research setting and on a community-wide basis."[30] The medical problems he identified were hypertension, psychiatric problems, metastatic calcification, peripheral neuropathy, resistant anemia-repeated transfusions that had raised "concern among professional men in the field." The community was hardly of one mind on the status of hemodialysis. Since that conference considered the financial questions posed by dialysis, as well as its moral-ethical implications, differences of opinion within the medical-scientific community entered directly into the policy debate.

The differences between Merrill and Schreiner can be explained in large measure as a function of their differing orientations to kidney transplantation. Renal transplants, initially on identical twins, were pioneered at Peter Bent Brigham in Boston beginning in the early 1950s.[31] In 1963, it was realized that the use of immunosuppressive drugs could aid in the immunological rejection problem confronting transplants that involved a cadaveric rather than a living-related kidney. It did not take the transplanters long to recognize that dialysis was capable of keeping potential transplant recipients--who had experienced loss of kidney function--alive while waiting for a cadaveric kidney to become available.

The development of kidney transplantation also raised the question of where that procedure was on the experiment-therapy continuum. The implications of the status of both dialysis and transplantation were addressed in an editorial in *Modern Medicine*.[32] The editor, Irving H. Page, M.D., described chronic dialysis as "an interesting and important *experiment*." (italics added) He also stated categorically "that it should be perfectly clear that we are not ready for large-scale kidney transplantation" until the rejection problem had been overcome. He was exceptionally critical of recent initiatives within the Public Health Service and the Veterans Administration to establish dialysis centers around the country. Then, to his physician audience, he argued: "We have a responsibility to help guide other human beings *through life* and not to hold out hope of a normal life-span when this hope is not justified."[33] (italics added)

The debate was not settled in late 1964. In an article primarily describing the Seattle experience with home dialysis, *Medical World News* quoted Norman G. Levinsky, M.D., director of Boston City Hospital's renal service: "Chronic dialysis is properly considered a clinical experiment rather than an established mode of treatment at this time."[34] Levinsky went on to describe dialysis as a stopgap treatment to keep patients alive while they awaited transplantation or some other form of treatment.

The experiment-therapy discussion was not confined to the medical-scientific community but entered directly into the public debate of the issues posed by dialysis and transplantation. In 1965, in hearings before the House of Representatives Appropriations Committee, Congressman Melvin Laird asked a physician witness, Dr. Edward Kass, "Do you consider dialysis a research program or a treatment program?"[35] Kass responded: "I

would consider dialysis now at the point in between--I think it's what I would call pilot plan or operational research program." Laird turned to a Philadelphia physician, Dr. Theodore Tsaltas,* and asked him if he agreed. "I believe that chronic dialysis has gone beyond the actual experimental stage," Tsaltas replied, "and it is now at the point where we can apply it to save lives. The kidney machine is no longer an experiment--it can no longer be classified as an experiment because it works--it is now a scientific fact not a theory--it keeps people alive."

Not until late 1967, in the report of the Gottschalk Committee, did both dialysis and transplantation receive "official" medical-scientific sanction as established therapies. The report stated: "The Committee believes that transplantation and dialysis techniques are sufficiently perfected at present to warrant launching a national treatment program and urges this course of action."[36]

The debate described above indicates that both dialysis and transplantation were evaluated in reference to the experiment-therapy continuum. Consensus was a long time in developing. Among the clinical investigators, Scribner represented the polar extreme of the "physician" committed to providing therapy to dying patients while Levinsky represented the "scientist" given to seeing the limitations of the dialysis procedure. Also suggested is the dimension of conflict, not fully articulated here, between those committed to hemodialysis as a major mode of therapy and those who saw it as basically an adjunct to transplantation.

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*Tsaltas' own life was being sustained by the artificial kidney and the physician administered the hemodialysis treatment directly to himself.

Another issue in the debate within the medical-scientific community was the quality of life provided to patients by these procedures. Were these therapies "life saving" as their proponents argued, conveying to beneficiaries a new lease on normal life? Or were they merely "life prolonging," as their critics claimed, having a number of unresolved associated clinical problems created by the ministration of therapy? On this matter, as well, the medical-scientific community was divided.

A third issue raised by the emergence of dialysis and transplantation, but especially by dialysis, focused on preventive versus treatment approaches to end-stage renal disease. The scientifically-oriented members of the community were greatly concerned with the emphasis upon the curative or palliative approach and urged that there be an appropriate research investment into the etiology of end-stage renal disease that would lead to effective means of prevention. The basic weakness of this argument was that it involved a trade-off between the future promise of prevention and the existing reality of treatment. Great uncertainty existed regarding when that promise might be redeemed, and medical scientists advocating the research approach were vulnerable to charges of self-interest in advancing it.

A final consideration should be raised, namely, the aesthetic evaluation of the therapies. Lewis Thomas, M.D., has written of the "high technology" and "half-way technology" of medicine. The former "comes as a result of a genuine understanding of disease mechanisms, and when it becomes available, it is relatively inexpensive, relatively simple, and relatively easy to deliver."[37] Half-way technology, however, is represented by "the kind of things that must be done after the fact, in

an effort to compensate for the incapacitating effects of certain diseases whose courses we are unable to do very much about. It is a technology designed to make up for disease or to postpone death."

Thomas categorizes both hemodialysis and renal transplantation as half-way technologies. Most physicians would agree. Beyond this, especially with respect to dialysis, many would liken the artificial kidney machine to the "iron lung" stage of treating poliomyelitis. The poliomyelitis story involved the development of a vaccine capable of preventing this viral-caused disease, a vaccine that made obsolete the clumsy technology of iron longs.[38] This experience, it should be recognized, has a profound aesthetic attraction for the medical-scientific community. It demonstrates for many the absolute superiority of scientific solutions over technological fixes in medicine. Attitudes toward the artificial kidney, this author believes, have been shaped in large measure with that analog in mind.

What should be done about patient-care financing for victims of end-stage renal disease? The medical-scientific community's orientation to the question depended heavily upon its assessment of the clinical experience with both therapies. One reason the overall policy debate took as long as it did was related to the time required to secure sufficient consensus within the medical-scientific community to sanction action by the government.

B. Changing Power Distributions Within the Medical-Scientific Community[39]

It should be remembered that no therapy existed for end-stage renal disease prior to 1960. Those interested in the kidney--its functions

and pathologies--were primarily research-oriented medical scientists.* The prevailing view of dialysis among the research-oriented members of the medical-scientific community was that the procedure was experimental, the quality of life provided by it was highly unsatisfactory, and it represented the "iron lung" phase of medicine. These views are still prevalent among many medical-scientists today.

In the early 1960s, the medical-scientists exercised dominance over all the relevant medical-scientific institutions within which the policy debate over the implications of dialysis and transplantation took place. For instance, within the National Institutes of Health key leadership positions were occupied by research-oriented renal physiologists and the relevant NIH study sections were dominated by those who were strongly committed to medical research. The influence of these individuals extended to the major voluntary health associations, including the renal section of the American Heart Association and the National Kidney Disease Foundation (later the National Kidney Foundation). And they made their influence felt in these various medical-scientific councils.

The research-oriented group was aided for a time by the difficulties that other physicians had in replicating the Seattle results. When Scribner and his colleagues first began using the artificial kidney, Seattle was the only medical center in the country where such treatment was available. Although the Seattle group was successful from the outset in sustaining the lives of patients, other groups in the 1960 to 1962

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*Renal physiologists, in fact, included among their ranks some very prominent men of academic medical science, many of whom emerged in the 1960s in positions of leadership in major medical schools.

period had difficulty replicating their experience. Charges were made that Scribner invested so heavily in "tender loving care" for his patients that the Seattle experience did not constitute a scientific test of the new procedure. From the Seattle perspective, failure by others to replicate their successful experience was attributed to a greater orientation toward research than toward patient-care or, conversely, the lack of strong interest in establishing long-term hemodialysis as a reality.

From late 1962 through the mid-1960s, a number of young physicians trekked to Seattle to learn how to perform dialysis. Frequently, these younger men were less strongly committed to academic medicine than the renal physiology research community that dominated the scene. These younger physicians believed that lives could be prolonged through hemodialysis and they wanted to participate. The institutional impacts of this were substantial. A program of delivering dialysis therapy to eligible veteran beneficiaries was initiated within the Veterans Administration in 1963, and a number of VA physicians received on-site training in Seattle. Similarly, by the time the Public Health Service initiated a grant program to support center dialysis facilities in 1965, a number of the physicians heading up those twelve grant-supported projects had been to Seattle to learn how to dialyze patients.

From approximately 1962 through 1966, it is possible to observe differentiation of medical-scientific community along four dimensions. In *functional* terms, a predominantly research-oriented community now included a significant and growing number of clinicians who were providing dialysis therapy. In terms of *age*, a younger group of physicians were coming into positions of importance within the kidney disease field. Relative to major *medical centers*, movement was away from the university

research centers and toward treatment-oriented centers located in close relationship to a university medical center. Finally, in *specialty* terms, nephrology emerged as a clinical and academic specialty alongside the academic specialty of renal physiology.

A similar pattern can be observed relative to renal transplantation. The surgical techniques of transplantation were established in a few major centers like Peter Bent Brigham in Boston, Medical College of Virginia in Richmond, and the University of Colorado in Denver.[40] Important differentiation, however, followed the introduction of immuno-suppressive drugs for control of the rejection phenomenon in 1963-1964, and there emerged a number of major "second generation" transplant centers, such as, the University of California at San Francisco, Stanford University, and, somewhat later, the University of Minnesota.

What effect did this differentiation have on the policy debate? First, the differentiation of the medical-scientific community occurred as both therapies became increasingly regarded as established, rather than experimental, procedures. Second, the differentiation of the professional community from one dominated by researchers to one having an increased number of clinicians meant that there was a concommitant shift in values from a science-oriented to a patient-oriented view of the clinical situation. Finally, this complex pattern of differentiation meant that there was an increasing number of "identified physicians" distributed broadly across the country who were beginning to interact as constituents with the political-administrative community as participants in the policy debate. In the main, they tended to be advocates for an expanded governmental role.

As professional differentiation occurred with the development of the two therapies, the institutions of medical-science changed also. The 1963 joint American Medical Association-National Kidney Disease Foundation conference constituted an *ad hoc* arena for discussing the issues that had been raised by Shana Alexander's *Life* magazine article. The conference was sponsored by the AMA, an organization not known for favoring government intervention in the financing of medical care, and by the N.K.D.F., which tended to be dominated by its Scientific Advisory Board. Although there was substantial discussion of establishing a series of dialysis research and treatment centers, the conference adjourned without making any recommendations on this matter to the federal government.[41] Conservatism toward dialysis as a treatment was the prevailing view.

In November 1964, the National Institutes of Health held a conference "to elucidate the technical aspects of hemodialysis in which improvements could be made."[42] Slightly more than 40 persons attended and the emphasis was clearly on research. Interestingly enough, two prominent clinicians--Scribner and Merrill--were not present, the former because he had not been invited. In response, Scribner, with support from a local Seattle manufacturer, hosted a "Working Conference on Chronic Dialysis" one month later, which approximately 160 people attended.[43] The composition of this conference and the nature of its agenda indicate a far stronger orientation toward patient-care problems than characterized the NIH meeting.

These three meetings represented an *ad hoc* response to the need for institutional arenas in which to discuss the problems created by dialysis. Permanent institutional changes were also sought. For example, in 1969

a Medical Advisory Board was created within the National Kidney Foundation, in large measure to offset the research influence of the Scientific Advisory Board. As another example, dissatisfaction in the early 1970s within the American Society for Artificial Internal Organs at the limited portion of the agenda allocated to dialysis and renal transplantation led to the establishment of the Council on Dialysis and Transplantation. This free-floating group later attached itself to the National Kidney Foundation.

These changing patterns of organization within the medical-scientific community represent various factors at work. One important factor was the manifest desire of clinicians to address the patient-oriented problems of dialysis and transplantation in settings that were not dominated by the research-oriented members of the community. Secondarily, they reflect the desire to establish various platforms from which representations can be made to the political-administrative community. Over time, these changes altered the power balance among scientists and clinicians and led to increased demands for government provision of treatment services from the interested clinician community.

C. The "Technical Logic" of Federal Policy Development

In retrospect, one can observe a logical development of both dialysis and transplantation as each emerged from biomedical research and was introduced into patient care. That "logic" can be seen with respect to research and development, demonstration and training, and capacity-building within the Department of Health, Education, and Welfare (DHEW). In addition to these stages of development within DHEW, we must mention the activities of the Veterans Administration. Finally, we take account

of the situation that this policy development produced on the eve of enactment of Sec. 299I.

1. Research and Development

The support of biomedical research has long been a widely sanctioned role for the federal government in health.[44] In the mid-1960s, soon after dialysis and renal transplantation appeared, "identified" research programs were established within the National Institutes of Health.

The possibility of using immunosuppressive drugs to control the rejection by the host of a transplanted kidney was suggested to the scientific community in 1959 and was taken up quickly by medical scientists engaged in experiments with kidney transplantation.[45] The first application to humans was in 1961. Within a short time, control of the immunological rejection phenomenon in kidney transplantation by immunosuppressive drugs had displaced the earlier use of whole-body irradiation in clinical research. In 1964, as a result of this work, the Committee on Appropriations of the House of Representatives added $2 million to the budget request of the National Institute of Allergy and Infectious Diseases "to start a real program in the study of immunological defense mechanisms as they relate to the rejection, by one person's body, of transplanted tissues from the body of another person."[46] The Senate Appropriations Committee of that same year concurred: "This rejection phenomenon," it noted, "rather than surgical technique, is today the most serious obstacle to successful organ transplants."[47] The Transplant Immunology Program, within NIAID, was established in direct response to the implications of research results and in an effort to pursue those implications.

The establishment of the Artificial Kidney/Chronic Uremia (AK/CU) Program within the National Institute of Arthritis and Metabolic Diseases (NIAMD) occurred more slowly. Scribner testified in 1962 about the need for research funds to improve hemodialysis, and the Senate did add an additional $1 million to the NIAMD fiscal 1963 budget request "for expanded research in diseases of the kidney."[48] It also recommended that "a considerable portion" be devoted to further research on the artificial kidney. Although the 1962 Senate Appropriations Committee report described hemodialysis as a "brilliant triumph of medical research,"[49] its 1963 report more modestly referred to it as "an excellent example of practical accomplishment."[50] Neither the Senate nor House appropriations committees saw fit in either fiscal 1964 or 1965 to take additional action.

Substantial pressures were brought to bear upon both the Congress, the National Institutes of Health, and the executive branch during these years to create a program of research on the artificial kidney. Finally, in connection with the fiscal 1966 appropriation, the House recommended $2 million more than the NIAMD budget request, for "the development of a better artificial kidney than the machines which now exist."[51] The Senate Appropriations Committee, impressed with the need for "simpler and less costly techniques," added an additional $1 million to the House allowance to enable research and development work to proceed "with all possible speed."[52] Not even for research and development for a better dialysis machine, however, did the federal government move very quickly.

2. Demonstration and Training

A thornier policy question arose in connection with funding dialysis centers through Public Health Service funds. Scribner and his colleagues

in Seattle had established a community treatment center in 1962. Through a combination of support from private philanthropy and community fund-raising, an active dialysis center was in existence when the 1962 *Life* magazine article appeared. In 1963, a Public Health Service grant was made to this center to assist it in meeting its financial obligations.

The policy discussion generated by this PHS grant dealt with several considerations, two of which were addressed by the Senate Appropriations Committee in its report on the fiscal 1965 appropriation. First, the committee pointed out that chronic illness and aging formula grant funds were available "for the States to use at their discretion for the support of community dialysis centers"; furthermore, the Public Health Service had the *authority* under the Community Health Services and Facilities Act of 1963 to use funds for community dialysis centers. Second, the committee report made clear that such funds were legitimate for demonstration and training but not for payment for treatment of illness.[53]

There was an underlying issue that troubled the Senate Appropriations Committee. The two grants that had been awarded before 1964, one to Seattle and the other to Downstate Medical Center in Brooklyn, were step-funded over a three-year period so PHS funds would be phased out during that time. It was assumed by PHS officials that community financial support would be established at the end of the three years. The Senate, especially Senator Lister Hill (D-Ala.), was skeptical that community support would be forthcoming. In 1964, the committee indicated that it had decided against an amendment proposed by Senator Henry M. Jackson (D-Wash.) to provide $1 million for two additional centers.

In 1965, in connection with the fiscal 1966 appropriation, the House Appropriations Committee recommended an additional $2 million

beyond the budget request of $1.4 million for supporting hemodialysis centers. The committee's report noted that this amount fell short of the $5 million recommended by the PHS advisory groups. The Senate committee concurred with the House in providing a total of $3.4 million for the support of 14 community dialysis centers.

The members of the House and Senate appropriations committees, where much control over federal government health policy resided in the 1960s, knew what they were doing. They were prompted to action in 1965, in part, by the knowledge that NBC Television was preparing a documentary program for release that fall which would contrast the millions of dollars being spent on the space program with the apparent unwillingness to spend money to save lives on earth.[54] However, the Senate, in setting forth the legal authority for PHS action, limiting the scope of that action to demonstration and training, and providing modest funds for 14 community dialysis centers reflected great reluctance to accept federal government responsibility for paying for the costs of treatment.

Indeed, the federal government moved to further limit its involvement in community dialysis centers in 1968 and 1969. The Health Service and Mental Health Administration, under whose authority the kidney centers program was then being administered, took action to terminate grant support. A May 1969 memorandum from the director of the Kidney Disease Control Program to HSMHA indicated that support had terminated for four centers, one other center was soon to go off federal funding, fourth-year funding extensions to the original three-year grants had been negotiated with seven centers on the condition that this support was to be terminal, and fourth-year support was not anticipated for two other centers.[55]

3. Capacity-Building

The development of hemodialysis centers around the country led to streams of legislative proposals for expanding federal government programs from 1965 onward. Senator Jackson was the foremost advocate of such legislation in the Senate; Representative Roybal, among others, in the House. But this flurry of proposed legislation literally went nowhere. No hearings were held on any legislation during the period from 1965 through 1969. All legislative action was effectively channeled through the appropriations committees.

Reluctance to see an expanded role for the federal government in hemodialysis was not limited to the legislative branch, as the above analysis may suggest. In early 1969, the director of the Regional Medical Programs Service, in a memorandum to the Deputy Administrator of HSMHA, wrote the following in response to a request for comments on proposed legislation to support treatment of end-stage kidney disease:[56]

> I judge that the major question we should ask ourselves as we review the proposed legislation is this: "Can we and should we at this time make an all out effort to establish facilities for the treatment of all patients with end-stage kidney disease who can benefit from hemodialysis?" My answer is no.

After recommending a strategy directed at prevention, early detection, and early treatment of kidney disease, this official described the proposal to finance treatment of end-stage renal disease through Social Security as "quite unsound." He cogently summarized his views on the central issue:[57]

> Our present system of health care controls costs in cases like this by setting up barriers to adequate care by making accessibility and financing difficult or impossible. The cost in dollars, facilities, and health manpower of a national kidney

> program which would remove these barriers to patients with end-stage kidney disease are so great that for the time being we may have to leave them erect.

No clearer statement of the nature of the policy debate within the bureaucracy is to be found.

Kidney disease legislation was finally enacted in 1970. The legislative authority for the Regional Medical Programs Service was amended to read, "The Heart Disease, Cancer, Stroke, and *Kidney* Disease Amendments of 1970." (italics added) The DHEW kidney disease program initiated in the chronic diseases division of the PHS in 1965 was now legally nestled in RMPS, where it had been administratively lodged since 1969. This established a means whereby community dialysis centers could receive financial support through the 55 regions of the RMPS. Policy control was centralized, but funds for centers were allocated on a decentralized basis through the regions. The net effect of this arrangement was to increase the dialysis *capacity* at the local community level, even though there remained great reluctance at the highest levels of the federal government to adopt legislation that would provide directly for patient-care financing.

The apparent progression from research and development through demonstration and training to capacity-building is obviously a reconstruction of events. Obviously, the "technical logic" of DHEW policy development looks more rational in retrospect than it did at the time. It is true, however, that federal health policy within the statutory framework of the Public Health Service Act was strongly oriented toward medical research and concurrently engaged in a search for effective means to bring the results of research into medical practice. Within this framework, policy

consistently stopped short of assuming a federal government role for payment of patient treatment costs. Policy toward end-stage renal disease was clearly constrained by these broader considerations.

4. The Veterans Administration

The U.S. Government did assume responsibility for treatment payment for *veterans* who were eligible for medical benefits from the Veterans Administration. In 1963, the VA announced the initiation of a program to establish dialysis units in thirty VA hospitals around the country.[58] This was done over the next few years and by July 1, 1972, the VA was dialyzing 16 percent of the total reported dialysis patients in the country.[59]

The VA reached the decision to provide dialysis treatment largely within its own organization. It did request apportionment of construction funds for refurbishing hospitals to create dialysis units, however, from the Bureau of the Budget (BOB) in 1965. This prompted much discussion within BOB about the implications of the request. Consultations between BOB and the Office of Science and Technology led to a decision, implemented in 1966, to establish a committee of experts to advise the Bureau on government-wide policy toward dialysis and transplantation.

This group, known as the Gottschalk Committee, after its chairman, Carl W. Gottschalk, M.D., of the University of North Carolina, issued its report in September 1967.[60] The report, among other things provided BOB with a basis to urge combined dialysis and transplantation units within VA hospitals and to promote home dialysis--a less costly mode of treatment--as an alternative to hospital-based dialysis. The legal basis of VA action in providing dialysis treatment was clear. To reverse

the VA policy decision once it had been made would have been a momentous political task. Even so, the VA action was greeted with some scrutiny by the Bureau of the Budget and stimulated BOB to explore more fully the policy implications of available treatment for end-stage renal disease.

D. The Evolution of the Federal Government's Role in Health

The policy debate on payment for treatment of end-stage renal disease occurred in parallel to the larger debate about the appropriate role of the federal government in the provision of health services. This larger debate, moreover, occurred not within the framework of the Public Health Service or the Veterans Administration but with respect to the Social Security system. In 1965, Congress added Titles XVIII and XIX to the Social Security Act, thus establishing Medicare and Medicaid programs and the principle that the aged and indigent deserved government-financed health insurance. This major policy departure in the federal health policy was necessary, but not sufficient, to provide a statutory basis for patient-care financing for end-stage renal disease.

In 1967, the Gottschalk Committee recommended financing patient-care for end-stage kidney disease patients through an amendment to Title XVIII (Medicare) of the Social Security Act.[61] The Committee argued that the general recommendation by the Johnson Administration on *disability* be the basis for inclusion of payment for kidney disease patients, although the disability recommendation was not enacted in 1967. The disability recommendation did result, however, in a study being undertaken within the Social Security Administration in 1968. This study laid the groundwork for providing Medicare health insurance benefits to the most severely disabled.[62] The provision of benefits to the most severely disabled did

not occur, however, until the passage of the Social Security Amendments of 1972, the same legislation that included Sec. 299I.[63]

The language of Sec. 299I reflects the importance of this expansion of the federal health insurance role. After stipulating the conditions of eligibility--under 65, fully or currently insured or entitled to monthly benefits, medically determined to have chronic renal disease--the provision said such individuals *shall be deemed to be disabled* for purposes of coverage under Medicare. It is quite unclear what formula the lawyers might have required had not the expansion of Medicare benefits to the disabled been occurring simultaneously.

It should also be remembered that Senator Russell B. Long, chairman of the Senate Finance Committee, was then, as now, advocating health insurance for catastrophic illness. Kidney disease was seen as a catastrophic illness, easily exhausting the financial resources of all who required therapy.[64] Therefore, in addition to being included under the general language of the disability provision, financing of treatment for end-stage renal disease was also seen as the first step toward providing catastrophic medical insurance through Medicare.

As long as kidney disease programs were authorized and funded under the authority of the Public Health Service Act, it was possible to contain the government's responsibility to activities that stopped short of patient-care financing. It was necessary to shift the context of the policy debate from that framework to that provided by Title XVIII of the Social Security Act. Even this was not sufficient to ensure the commitment made in Sec. 299I. The ability of the Congress and its staff to relate end-stage renal disease to disability and prospectively to catastrophic health insurance was also necessary. Looking backward over

the entire debate that preceded Sec. 299I, the policy consensus at any given time on the appropriate federal government role in health must be seen as constraining or facilitating value-of-life decisions like that of Sec. 299I.

E. The Vicissitudes of Politics

The policy debate described here was pervaded at all times by political considerations. For example, in late 1965, Neal Bricker, M.D., then of Washington University in St. Louis, was elected chairman of the Scientific Advisory Board (SAB) of the National Kidney Disease Foundation. Reflecting the priorities of the research-oriented community, Bricker and the SAB took a series of steps that indicated strong opposition to the endorsement of community dialysis centers by the NKDF.[65] In October 1965, Bricker wrote the SAB outlining his future plans and made essentially no mention of dialysis treatment centers. In December, he announced that the SAB had voted to discontinue the newsletter "Developments in Dialysis," then being published and distributed under NKDF auspices. And in January 1966, Bricker and the SAB fired the executive director of the NKDF, who had become controversial through his advocacy of expanding dialysis treatment centers. In late March, however, the SAB met and considered the legislation sponsored by Senator Jackson, which would substantially expand community dialysis centers. The group voted to endorse community dialysis centers. "What brought us around?" Bricker was quoted as saying. "Reality. The realities are that there is probably going to be an extension and expansion of dialysis activities by Congress, and if the foundation put itself in the opposition, that would be bad."[66] Physicians, like the Supreme Court justices obviously are attentive to political events.

Politics intruded into the work of the Gottschalk Committee in several interesting ways. One of the reasons conveyed to the committee for undertaking the 1966 study was that dialysis was seen by BOB and the White House as a potential post-Vietnam spending initiative if peace should break out![67] Another interesting sidelight is that the committee was not asked to do a *cost-benefit* study of providing treatment for end-stage renal disease, but a *cost-effectiveness* study of how to provide such treatment.[68] BOB saw the experts as having competence on the latter question, while the former question was to be reserved for senior policy makers.

F. The Importance of Identified Lives

It has been argued that identified lives call forth substantially greater investment of public resources than statistical lives. While this clearly appears to be the case, it is nevertheless worthwhile asking how a particular set of identified lives come to be important in this way. The fact that hemophiliacs are treated differently from victims of end-stage renal disease by the government, as indicated above, suggests that some attention should be directed to the processes by which identified lives lay claim to government resources.

The policy debate preceding the enactment of Sec. 299I does not reveal an automatic reflexive response by the government to the victims of end-stage renal disease. Rather, it suggests a "tipping process" at work. Specifically, it appears that publicity of lives lost for the lack of scarce medical resources had to occur, including specific dramatization of identified lives. Beyond this, it was necessary for the cumulative effect of an increasing number of government programs to be

felt. Finally, the number of patients being kept alive had to increase to the point where they simply could not be ignored. The greater portion of this paper has been addressed to the second factor, so the first and third factors need only be mentioned, and briefly, here.

Publicity of the situation of kidney disease victims was essential to the process of their identification. But it was not sufficient. Scribner, for instance, thought that the effects of the 1962 *Life* magazine article and 1965 NBC documentary would be immediate and would generate intense public demand for a strong federal government commitment to providing treatment to those with chronic kidney failure. The limited response in both cases came as a great surprise to him. It should also be mentioned, however, that there was over these years substantial local newspaper and television coverage which further publicized the plight of the individual with end-stage kidney disease.

Publicity included dramatization of particular identified lives. In 1965, Dr. Theodore Tsaltas, the Philadelphia physician who was dialyzing himself, testified before the House Committee on Appropriations to great effect, testimony later seen on the NBC TV documentary.[69] In 1966, on a visit to Seattle, Representative John E. Fogarty, chairman of the House committee, observed Mr. Ernie Morelli dialyzing himself in his home. In November 1971, Mr. Shep Glazer, of New York City, testified and was dialyzed before the House Ways and Means Committee in November 1971 and apparently contributed to the willingness of Representative Wilbur Mills (D-Ark.) to support a kidney disease amendment to Medicare.[70] Without question, the publicity and dramatization of these identified lives affected the policy debate, the extent of their influence with legislators at any given time is unclear.

How many patients were dialyzed prior to the 1972 legislation? The Gottschalk Committee had data on 247 individuals who had begun dialysis treatment in PHS-supported programs from 1960 to March 1967, of whom 42, or 17 percent, had died.[71] The committee estimated that this number amounted to one-fourth to one-third of all those who had begun treatment since 1960, or roughly 750 to 1,000 patients. Using the 17 percent mortality rate, the estimate was that approximately 620 to 830 dialysis patients were alive in March 1967.

Data from the National Dialysis Registry for the years ending June 30, 1970, 1971, and 1972 indicate the numbers of patients being kept alive on dialysis:[72]

Table 3
ESTIMATED PATIENTS ALIVE ON DIALYSIS

1970	2,874
1971	4,375
1972	5,786

The question is: when and under what circumstances does the number of identified lives become so large that patient-care financing becomes an imperative?

The prior analysis has indicated a number of the factors which influenced the extended policy debate on patient-care financing for end-stage renal disease. The evidence reveals great reluctance by the government to assume the financial responsibility for paying patient treatment costs. It is useful, then, to turn to the manner in which the policy debate was resolved.

III. RESOLUTION OF THE DEBATE

In early 1971, at the outset of the 92nd Congress, the Nixon Administration proposed a number of major amendments to the Social Security Act. The bill which was introduced in the House of Representatives as H.R. 1 dealt with consolidation of 54 federal-state programs for the needy aged, blind, and disabled, the establishment of more effective cost controls on Medicare and Medicaid, the provision of health care to Medicare and Medicaid recipients through health maintenance organizations, and various modifications of the social security benefit structure. But "by far the most significant and the most needed provisions of H.R. 1," in the words of Elliott Richardson, then Secretary of Health, Education, and Welfare, were "those which reform the family welfare system and replace it with a new national program."[73]

The welfare reform debate was very protracted, especially in the Senate.[74] In addition to the Administration's proposal, Senator Russell B. Long (D-La.), chairman of the Finance Committee, was advocating a more conservative welfare reform bill and Senator Abraham Ribicoff (D-Conn.) was proposing a more liberal version. None of the three parties had the votes to prevail over the other two, nor were any two able to compromise differences. By mid-summer 1972, it was clear that welfare reform legislation had effectively been killed.

The prolonged debate on welfare reform had consumed so much time that passage of any bill was threatened. Since H.R. 1 contained many important provisions beyond welfare reform, no one wished the Congress to fail in enacting legislation. This commitment to have a bill was reinforced by the desire to avoid the experience of 1970. Then the House had refused to meet with the Senate in a joint conference committee late

in the session because there was so little time to negotiate important differences prior to the November election. This time, both House and Senate were determined to have legislation on the President's desk before election day, November 7, 1972.

At no point in the extensive hearings on H.R. 1 did either the House or the Senate hear testimony on renal disease. It is true, however, that the House Ways and Means Committee heard testimony in November 1971, in connection with hearings on national health insurance, which urged that end-stage renal disease be included in any such program.[75] Moreover, in December, Representative Mills introduced a bill that would have amended the Social Security Act to provide patient care financing for chronic renal disease patients, a bill more notable for signaling Mr. Mills' intentions than for the care with which it was drafted. But neither the Ways and Means Committee hearing nor the Mills legislative proposal was part of the legislative history of H.R. 1. Furthermore, there was no activity within the Senate Finance Committee during this time which remotely related end-stage renal disease to H.R. 1.

The end-stage renal disease amendment was not considered until the provisions of the entire H.R. 1 bill were being debated seriatim on the Senate floor. On a Saturday morning, hardly a normal legislative workday, September 30, barely one month before the November election, Senator Vance Hartke (D-Ind.) was recognized at 11:30 a.m. to propose an amendment on chronic renal disease. Thirty minutes of time was allocated to the immediate consideration of the kidney amendment. During the brief debate on the Senate floor, only Senator Wallace Bennett (R-Utah) spoke against the provision. With nearly half of the Senate absent, the measure was adopted by a vote of 52 "Yeas" and 3 "Nays."[76]

The remaining steps of the legislative process were traversed with comparable speed. The conference committee of the House Ways and Means Committee and the Senate Finance Committee met for only a single day to consider differences on the entire bill. The kidney disease amendment received no more than ten minutes' discussion and the Senate proposal was accepted in its essentials with a slight modification in one provision. Both House and Senate accepted the conference committee report on October 17, and President Nixon signed H.R. 1 into law as Public Law 92-603 on October 30, 1972. The kidney disease provision was included as Sec. 299I. In this way, the nation resolved an extended policy debate over kidney disease that reached back a decade or more.

IV. IMPLICATIONS

What interpretation is to be placed upon the extended debate on patient care financing for end-stage renal disease and on the manner of its resolution? *The New York Times* viewed the enactment of Sec. 299I as an episode in which the Congress did not really know what it was doing. In a news story of January 11, 1973, it quoted Senator Hartke's remarks of September 30, 1972, on the floor of the Senate. At the time the Senator said:[77] "Final cost estimates for this vital amendment are now being worked out. Preliminary estimates indicate an annual cost of approximately $250 million at the end of 4 years with the first full-year cost at about $75 million." The Senator also said: "The $90 to $110 million that this amendment will cost each year is a minor cost to maintain life."

Richard D. Lyons, a *Times* reporter who had been primed by DHEW officials, challenged the Senator's estimates. He wrote:[78]

> Original cost estimates ranged from $35 million to $75 million in the first fiscal year of operation. The debate record in both houses shows that the highest estimate was $250 million in the fourth year. Yet calculations made by Federal experts after passage set first year costs at $135 million, rising to $1 billion annually a decade from now.

Lyons quoted several prominent Senators and Representatives to the effect that they would not have supported the provision had they known the full magnitude of the anticipated costs.

This story was the basis for a Sunday editorial on January 14, 1973, in which the *Times* criticized the Congress for not knowing what it was doing and for not recognizing the implications of its decision.[79]

> The point is not that victims of renal disease are unworthy of help, but the Government resources have to be allocated to meeting many needs. If a billion dollars has to go to prolonging the lives of thousands of kidney disease victims, that is a billion dollars that cannot go to eradicating slums, improving education or finding a cure for cancer.

The editorial concluded by stating that "society has a right to expect that the legislators will understand what they are doing and know the magnitude of the commitment they are making when they pass special interest legislation, whether for kidney disease sufferers or anybody else."

The implication that Congress was not fully informed in its action, though challenged by the National Kidney Foundation, has achieved some currency. A report in 1975 by the Subcommittee of Health and the Subcommittee on Oversight of the House Ways and Means Committee developed he data cited above in Table 2 on incurred costs of the end-stage renal disease program, costs substantially greater than estimated by Senator Hartke.[80] A further report by the Subcommittee on Oversight explicitly

juxtaposed the estimates for Sec. 299I only, which were available to the conferees and those then available to the subcommittee for the 3rd and 4th years of the program in the following manner:[81]

Table 4
ESTIMATED INCURRED COSTS OF SEC. 299I
THIRD AND FOURTH YEARS

	1972	1975
Fiscal Year	Data available to conferees (cash disbursement)	Revised latest estimate (incurred cost)
1976	$198,000,000	$300,000,000
1977	$252,000,000	$360,000,000

The underestimation of costs has been clearly established. The implication remains that the Congress did not fully understand what it was doing in the passage of Sec. 299I.

Another interpretation of the events surrounding the passage of Sec. 299I is that it was the work of the National Kidney Foundation. There is substantial evidence indicating this to be the case.[82] From 1969 onward, when Dr. George E. Schreiner became president of the NKF, the organization has employed a Washington representative, Mr. Charles Plante, to promote the interests of the NKF on Capitol Hill. After Senator Long introduced his proposal for catastrophic health insurance in 1970, Schreiner, Plante, and others were instrumental in persuading him that it required modification for kidney disease patients. Though the catastrophic proposal was never part of H.R. 1, the chairman of the Senate Finance Committee was favorably predisposed to do something for end-stage renal disease well before September 1972. NKF officials, moreover, were personally involved in drafting the language of the Hartke amendment which became Sec. 299I.

At the micro level, it is clear that Congressional proponents of the end-stage renal disease provision miscalculated first and subsequent year costs. It is far from clear that the Congress was ignorant of the implications of what it was doing. There had been an extended policy debate on patient care financing, as indicated in this paper, to which many members of Congress had contributed. The National Kidney Foundation had, with others, done much to inform the Congress of the need for financial coverage for renal disease victims from 1969 onward. It is difficult indeed under the circumstances to presume the Congress unaware of the implications of its action, even though the procedures by which it did act hardly constitute a model of thorough legislative deliberation.

At a higher level, however, the question of how to interpret the meaning of Sec. 299I remains. Zeckhauser has argued that the end-stage renal disease provision represented an instance in which society demonstrated itself unwilling to sacrifice lives for dollars. He writes:[83]

> The attractiveness of a process for making policy choices will be enhanced the more closely it accords with valued beliefs. When risks of lives are involved, an important valued belief is that society will not give up a life to save dollars, even a great many dollars. Rarely is this belief, widely held albeit mistaken, put to a clear test. When it is, it may be desirable for society to spend an inordinate amount on each of a few lives to preserve a comforting myth. Such a myth-preserving action was taken when the federal government assumed the costs of renal dialysis. The specific individuals who would have died in the absence of the government program were known. The lives at stake in this policy context were identified lives. They can be contrasted with the nonpersonalized, statistical lives that are saved, for example, by expenditures to construct highway safety barriers. If lives are sacrificed for dollars, the valued belief that society will not make such sacrifices is more likely to be jeopardized when the specific identities of the victims are known. An effort to preserve this valued belief may explain in part the frequently noted difference between the resources expended to

> save statistical and identified lives. Society, acting collectively, shows itself willing to pay much more to save the latter.

There are two problems with this interpretation. First, no evidence is cited to establish Sec. 299I as a "myth-preserving" action. Second, no criteria are provided to enable us to judge what constitutes a "clear test" of the willingness of the government to sacrifice dollars for lives.

A more complex interpretation is suggested by the discussion of the Hartke amendment on the Senate floor.[84] A central concern was that access to life-saving therapy was denied to many because of lack of dollars. A "tragic irony" of this particular situation was that the life-saving therapies had been developed by federal government investment in medical research. The end-stage renal disease provision would remove inequities between the wealthy and those unable to pay for therapy, and between eligible workers and their spouses and children. It would also remedy the current law under which one could become disabled by virtue of the disease but be denied disability status because of the need for dialysis therapy. The nature of end-stage renal disease, moreover, was such that it struck without warning and without reference to barriers of age, sex, race, or geography. More affirmatively, many afflicted with end-stage renal disease could be rehabilitated and returned to work. The performance of the therapies was steadily improving. The costs, it was argued, were not unreasonable, and unit costs of therapy were improving.

In a more fundamental vein, the Senate recognized an opportunity to compensate for the past and a need to realistically confront an inevitable future. Senator Jackson (D-Wash.), referring to the Seattle experience in allocating scarce dialysis resources, expressed the hope "that we would make an effort here, at least a beginning, to approve the amendment, so

that we can do better than we have done before."[85] Lives had previously been sacrificed for dollars but that situation should now be changed.

Senator Bennett, argued against the provision on the ground that it added further costs to H.R. 1, already an expensive bill, and that "a more reasonable way to handle this amendment would have been to delay action until it can become a part of a broader health insurance bill."[86] Senator Long, responding to Bennett, commented on the future:[87]

> The next Congress will tackle health insurance issues, and I am sure during that debate we will deal with health insurance problems in general, and I hope that specifically we will deal with the problem of insuring against catastrophic illness. I am cosponsoring this proposal at this time because these very unfortunate citizens with chronic renal failure cannot wait for Congress to debate these broader issues. They need help--it is critical--and that help must come now as many of them, without assistance, simply will not be alive for another 2 years.

That the end-stage renal disease provision might be an entering wedge in the debate on catastrophic health insurance did not lessen the force of the Senator's argument.

Several strong impressions of this debate on patient care financing for end-stage renal disease stand out in retrospect. First, over the entire length of the protracted debate there were always strong voices of opposition to a treatment payment program. These voices were found within the medical-scientific community, the executive branch, and the legislative branch. Their opposition is eloquent testimony to the fact that policy-makers are not always prepared to save lives at any cost.

Second, a basic asymmetry was manifested throughout this complicated policy debate. The proponents of an expanded federal government role were able to carry their case to the public in a variety of ways, while the opponents made their case in "sotto voce" fashion. This asymmetry

may be a passing historical phenomenon and we may now be entering a period in which policy-making officials are more willing to debate both sides of value-of-life issues in full view of the public. Given finite scarce resources, it would seem salutory if such a development were occurring.

Finally, in the instance of end-stage renal disease, it seems only reasonable to conclude that the enactment of Sec. 299I was the near-inevitable outcome of a whole series of federal government actions which occurred prior to 1972. While it was not inevitable that the end-stage renal disease provision be passed in 1972, the prior commitment of the federal government to R&D, demonstration, and capacity-building within DHEW, and to patient care financing of eligible veterans meant that sooner or later the decision would be taken. Though one could hope for more thoroughness in the deliberative process by which the Congress reached this decision, it is pure speculation whether the outcome would have been any different. That speculative task, however, is a worthwhile effort for all those concerned about situations similar to end-stage renal disease which may arise in the future.

FOOTNOTES

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1. U.S. House of Representatives, Committee on Ways and Means, *Background Information on Kidney Disease Benefits Under Medicare,* Committee Print, 94th Congress, 1st Session, June 24, 1975, p. 3. Hereafter, Ways and Means, *Background Information.*

2. *Ibid.*

3. Public Law 92-603, "Social Security Amendments of 1972," 92nd Congress, October 30, 1972, pp. 135-136.

4. See Research Triangle Institute, *The National Dialysis Registry: Second Annual Progress Report, July 1, 1969 - June 30, 1970,* August 1970; *Third Annual Progress Report, July 1, 1970 - June 30, 1971,* July 1971; and *Fourth Annual Progress Report, July 1, 1971 - June 30, 1972,* July 1972. The national dialysis patient load reported in January 1971, January 1972, January 1973, and January 1974, respectively, was 16.6 cases per million population, 24.4 per million, 37.4 per million, and 46.9 per million. See National Institutes of Health, *Proceedings of the 4th, 5th, 6th, and 7th Annual Contractors Conference of the Artificial Kidney Program of the National Institute of Arthritis and Metabolic Diseases,* Washington, D.C., 1971, 1972, 1973, and 1974.

5. See National Institutes of Health, *U.S. Kidney Transplant Fact Book: Information from ACS/NIH Registry, 1972,* Washington, D.C., 1972. There are several indications that data supplied to the American College of Surgeons/National Institutes of Health Organ Transplant Registry underreport the kidney transplants performed in the U.S. by nearly 50 percent. For an analysis of this problem see Sr. Josephine Sullivan, "The Role of Data In End-Stage Renal Disease Programs," M.S. Thesis, Hospital and Health Services Administration, Ohio State University, 1975.

6. See Comptroller General of the United States, *Treatment of Chronic Kidney Failure: Dialysis, Transplant, Costs, and the Need for More Vigorous Efforts (Department of Health, Education, and Welfare),* Washington, D.C., U.S. General Accounting Office, June 24, 1975, pp. 38-39.

7. *Ibid.,* pp. 43-44.

8. *Op.cit.,* Ways and Means, *Background Information,* p. 15.

9. *Ibid.*, p. 6.

10. See the testimony of Margaret W. Hilgartner, M.D., and Louis N. Friedland, in U.S. House of Representatives, Committee on Ways and Means, *National Health Insurance*, Hearings, Vol. 5, 93rd Congress, 2nd Session, June 14, 1974, p. 2400.

11. "Medicarelessness," editorial, *The New York Times*, January 14, 1973.

12. National Academy of Sciences, Institute of Medicine, *The Report of the Panel on Implications of a Categorical Catastrophic Approach to National Health Insurance*, Washington, D.C., June 1973.

13. "The Kidney Care Issue: A Test for National Health Insurance," *Hospital Practice*, April 1973, pp. 40, 49-52, 59.

14. Richard Zeckhauser, "Procedures for Valuing Lives," *Public Policy*, Vol. 23 (Fall 1975), pp. 447-448. While I disagree with Zeckhauser's interpretation of the meaning of the end-stage renal disease decision, his emphasis on the importance of process is fully shared. The case of the policy debate on end-stage renal disease actually serves to point up the importance of process.

15. The announcement of the invention of the cannulae and shunt was made in three papers published in American Society for Artificial Internal Organs, *Transactions*, Vol. VI (1960): Belding H. Scribner, John E. Z. Caner, Rachit Buri, and Wayne Quinton, "The Technique of Continuous Hemodialysis," pp. 88-103; Wayne Quinton, David Dillard, and Belding H. Scribner, "Cannulation of Blood Vessels for Prolonged Hemodialysis," pp. 104-113; and Belding H. Scribner, R. Buri, J. E. Z. Caner, R. Hegstrom, and J. M. Burnell, "The Treatment of Chronic Uremia by Means of Intermittent Hemodialysis: A Preliminary Report," pp. 114-122.

16. The demonstration of the invention actually occurred in Scribner's hotel room in a special session arranged by Dr. George E. Schreiner to which approximately 10 people were invited. This session was held during the annual meeting of the American Society for Artificial Internal Organs. The three papers cited in fn. 15 were not formally presented at the time, but were submitted afterward at Schreiner's request.

17. Memorandum, From: Belding H. Scribner and Colleagues, To: Persons Concerned with Hemodialysis of Patients with Chronic Renal Disease, "Report on the Chicago Meeting," April 13, 1960.

18. Letter from Belding H. Scribner, M.D., to Mr. George Wheatley, May 19, 1960.

19. Memorandum, From: Belding H. Scribner, M.D., To: Walter S. Tuesley, Director, Seattle Foundation, "Community Dialysis Center for King County (Preliminary Considerations)," July 5, 1960.

20. Harold M. Schmeck, Jr., "Panel Holds Life-or-Death Vote in Allotting of Artificial Kidney," *The New York Times*, May 6, 1962, p. 1.

21. Shana Alexander, "They Decide Who Lives, Who Dies," *Life*, Vol. 53, November 9, 1962, pp. 102-104 ff.

22. See "Suggestions Regarding Activation and Operation of Community Hemodialysis Centers for the Treatment of Chronic Uremia," pp. 20-28, American Medical Association and National Kidney Disease Foundation, *Proceedings, Conference to Consider the Treatment of Patients with Chronic Kidney Disease with Uremia*, New York City, June 20-22, 1963.

23. *Ibid.*, p. 51. Hereafter, *A.M.A. - N.K.D.F. Conference Proceedings.*

24. U.S. Senate, Committee on Appropriations, *Departments of Labor, and Health, Education, and Welfare, and Related Agencies Appropriations Bill, 1965* Report No. 1460, 88th Congress, 2nd Session, August 17, 1964, p. 20.

25. Renee C. Fox and Judith P. Swazey, *The Courage to Fail: A Social View of Organ Transplants and Dialysis*, Chicago, University of Chicago Press, 1974, esp. pp. 60-83.

26. *Ibid.*, p. 64.

27. *Ibid.*, p. 63.

28. This is reported in Scribner's memorandum of April 13, 1960 (fn. 7 above).

29. John P. Merrill, M.D., "Current Status and Future Prospects in the Treatment of Patients with Chronic Uremia," p. 37, in *op.cit., A.M.A. - N.K.D.F. Conference Proceedings.*

30. George E. Schreiner, M.D., "Definition of the Problems Involved in Large-Scale Hemodialysis Treatment," p. 45, *ibid.*

31. This story is told in Francis D. Moore, M.D., *Transplant: The Give and Take of Tissue Transplantation*, New York, Simon and Schuster, Revised edition, 1972.

32. Irving H. Page, M.D., "Prolongation of Life in Affluent Society," *Modern Medicine*, October 14, 1963, p. 89.

33. *Ibid.*, p. 91.

34. "Crucial Test for Hemodialysis," *Medical World News*, Vol. 5, November 6, 1964, p. 99.

35. Quoted on the N.B.C. Television News documentary, "Who Shall Live?" November 1965.

36. U.S. Bureau of the Budget, *Report of the Committee on Chronic Kidney Disease*, Washington, D.C., September 1967, p. 2. Hereafter the *Gottschalk Committee Report*.

37. Lewis Thomas, "Guessing and Knowing: Reflections on the Science and Technology of Medicine," *Saturday Review*, January 1973, p. 54.

38. The story of poliomyelitis is told in: *Tom Rivers: Reflections on a Life in Medicine and Science*, an Oral History Memoir prepared by Saul Benison, MIT Press, Cambridge, 1967; James A. Shannon, M.D., "NIH-Present and Potential Contribution to Application of Biomedical Knowledge," U.S. Senate, Committee on Government Operations *Research in the Service of Man: Biomedical Knowledge, Development, and Use*, Document No. 55, 90th Congress, 1st Session, pp. 72-85, November 2, 1967; John R. Paul, M.D., *A History of Poliomyelitis*, Yale University Press, New Haven, 1971; Burton A. Weisbrod, "Costs and Benefits of Medical Research: A Case Study of Poliomyelitis," *Journal of Political Economy*, Vol. 79, No. 3, May-June 1971, pp. 527-544; Saul Benison, "The History of Polio Research in the United States: Appraisal and Lessons," pp. 308-343 in Gerald Holton, ed., *Biography of Twentieth Century Science*, New York, Norton, 1972; and Saul Benison, "Speculation and Experimentation in Early Poliomyelitis Research," *Clio Medica*, Vol. 10 (April 1975), pp. 1-22.

39. This section is based on interviews conducted since 1973 with many of the individuals involved in these events. The interpretation is, of course, mine alone.

40. *Op.cit.*, Moore.

41. See pp. 65-69 of *op.cit.*, *A.M.A. - N.K.D.F. Conference Proceedings* for an indication of the inconclusive nature of the conference.

42. National Institute of Arthritis and Metabolic Diseases and National Heart Institute, *Proceedings of the Working Conference on Chronic Dialysis*, Seattle, Washington, University of Washington, December 3-5, 1964.

43. *Proceedings of the Working Conference on Chronic Dialysis*, University of Washington, Seattle, Washington, December 3-5, 1964.

44. For background on the history of the National Institutes of Health see Stephen P. Strickland, *Science, Politics, and Dread Disease*, Cambridge,Mass., Harvard University Press, 1972. See American Medical Association, *Report of the Commission on Research*, Chicago, Illinois, February 1967, for an official view of organized medicine on medical research.

45. *Op.cit*, Moore, esp. pp. 128-265.

46. U.S. House of Representatives, Committee on Appropriations, *Departments of Labor, and Health, Education, and Welfare, and Related Agencies Appropriation Bill, 1965,* Report No. 1316, 88th Congress, 2nd Session, April 10, 1964, p. 35.

47. *Op.cit.,* Senate Appropriations Committee, *Labor, DHEW Appropriations, 1965,* Report No. 1460, p. 54.

48. U.S. Senate, Committee on Appropriations, *Departments of Labor, and Health, Education, and Welfare, and Related Agencies Appropriation Bill, 1963,* Report No. 1672, 87th Congress, 2nd Session, June 29, 1962, p. 40.

49. *Ibid.,* p. 39.

50. U.S. Senate, Committee on Appropriations, *Departments of Labor, and Health, Education, and Welfare, and Related Agencies Appropriations Bill, 1964,* Report No. 383, 88th Congress, 1st Session, August 1, 1963, p. 57.

51. U.S. House of Representatives, Committee on Appropriations, *Departments of Labor, and Health, Education, and Welfare, and Related Agencies Appropriation Bill, 1966,* Report No. 272, 89th Congress, 1st Session, April 29, 1965, p. 17.

52. U.S. Senate, Committee on Appropriations, *Departments of Labor, and Health, Education, and Welfare, and Related Agencies Appropriation Bill, 1966,* Report No. 537, 89th Congress, 1st Session, August 3, 1965, p. 56.

53. *Op.cit.,* Senate Appropriations Committee, *Labor, DHEW Appropriations, 1965,* Report No. 1460, pp. 19-20.

54. *Op.cit.,* N.B.C. Television documentary.

55. Memorandum, From: Acting Chief, Kidney Disease Control Program, To: Administrator, Health Services and Mental Health Administration, Through: Acting Director, Division of Chronic Disease Programs, RMPS, Director, Regional Medical Programs Service, "Fourth-Year Funding - Chronic Hemodialysis Grants," May 20, 1969.

56. Memorandum, From: Director, RMPS, To: Mr. Irving Lewis, Deputy Administrator, HSMHA, "Comments on proposal for legislation to support treatment for end-stage kidney disease," April 22, 1969.

57. *Ibid.*

58. *Op.cit., A.M.A. - N.K.D.F. Conference Proceedings,* p. 67.

59. *Op.cit., National Dialysis Registry: Fourth Annual Progress Report,* pp. 5, 14.

60. *Op.cit., Gottschalk Committee Report.*

61. *Ibid.*, pp. 1, 14, and 85-99.

62. Advisory Council on Health Insurance for the Disabled, *Health Insurance for the Disabled Under Social Security*, Washington, D.C., 1969.

63. *Op.cit.*, Ways and Means, *Background Information*, pp. 2-6.

64. U.S. Congress, *Congressional Record--Senate*, September 30, 1972, p. S16462.

65. This section is based upon interviews with participants and various documents in their files.

66. "Renal Group Eases Policy on Dialysis," *Medical World News*, Vol. 7, April 8, 1966, p. 83.

67. Interview with Carl W. Gottschalk, M.D.

68. *Ibid.* and *op.cit.*, *Gottschalk Committee Report*, pp. 137-157.

69. *Op.cit.*, N.B.C., "Who Shall Live?"

70. See "Statement of Shep Glazer, Vice President, National Association of Patients on Hemodialysis," U.S. House of Representatives, Committee on Ways and Means, *National Health Insurance Proposals*, Hearings, Part 7, 92nd Congress, 1st Session, November 3 and 4, 1971, pp. 1524-46.

71. *Op.cit.*, *Gottschalk Committee Report*, pp. 47-49. The Committee also had data on 231 Veterans Administration patients who had begun dialysis since 1963, of whom 47 had died at the time of the report.

72. *Op.cit.*, *National Dialysis Registry: Second, Third, and Fourth Annual Progress Reports.*

73. U.S. Senate, Committee on Finance, *Social Security Amendments of 1971*, Hearings, Part 1, 92nd Congress, 1st Session, July 27, 1971, p. 30.

74. See M. Kenneth Bowler, *The Nixon Guaranteed Income Proposal: Substance and Process in Policy Change*, Cambridge, Massachusetts, Ballinger Publishing Company, 1974.

75. U.S. House of Representatives, Committee on Ways and Means, *National Health Insurance Proposals*, Hearings, Part 7, pp. 1524-46 and Part 10, pp. 2226-29, 92nd Congress, 1st Session, 1971.

76. *Op.cit.*, *Congressional Record--Senate*, pp. S16396-16402.

77. *Ibid.*, p. S16397.

78. Richard D. Lyons, "Program to Aid Kidney Victims Faces Millions in Excess Costs," *The New York Times*, January 11, 1973.

79. *Op.cit.*, "Medicarelessness," *The New York Times*.

80. *Op.cit.*, Ways and Means, *Background Information*, p. 15.

81. U.S. House of Representatives, Committee on Ways and Means, *Reports on Administration by the Social Security Administration of the End-Stage Renal Disease Program Established by Public Law 92-603 (with additional views) and on the Social Security Medicare Research Studies*,

82. *Op.cit.*, *Hospital Practice*.

83. *Op.cit.*, Zeckhauser, pp. 447-448.

84. *Op.cit.*, *Congressional Record--Senate*, pp. S16396-S16402.

85. *Ibid.*, p. S16401.

86. *Ibid.*, p. S16401-S16402.

87. *Ibid.*, p. S16402. A panel of the Institute of Medicine later expressed apprehension that the kidney disease provision pointed in the direction of disease-by-disease coverage of catastrophic illness. The panel expressed "unanimous agreement that coverage of discrete categories similar in kind to end-stage renal disease would be an inappropriate course to follow in the foreseeable future for providing expensive care to those who are unable to afford it"; see *op.cit.*, National Academy of Sciences, Institute of Medicine, pp. 6-7. Though this fear has not materialized, and though there is no strong indication that the Congress intends to move in this direction, the existence of other diseases with expensive therapies, like hemophilia, means that this possibility is ever present.