6. Policy Issues

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Developments in the industry have been greatly influenced by a number of Federal policy decisions. Most notably, the decision to extend Medicare coverage to end-stage renal disease (ESRD) patients regardless of age set off a dramatic chain of events. The population of beneficiaries grew from roughly 11,000 at the onset of the program to **77,000** today. The industry supplying these patients with equipment and disposable grew with this population.

At present, policy debates continue on a number of issues of critical importance to the market as well as to the patients. The following three sections consider the three major policy areas: reimbursement, research, and dialyzer reuse.

REIMBURSEMENT POLICY

In May of 1983 the Department of Health and Human Services issued final rules for new reimbursement rates for the ESRD program (93). These new rules have caused a great deal of controversy and are expected to have important effects on the industry. This section considers these new rules, discussing their historical antecedents, their form and rationale, and their possible effects.

History of Reimbursement

As dialysis techniques for treating chronic kidney failure were developed in the 1960s, effective treatment of the life-threatening disease became a possibility. Unfortunately, resources were scarce and treatment choices, often involving life or death decisions, had to be made. In response to this dilemma, the U.S. Bureau of the Budget in **1967** created a Committee on Chronic Renal Disease. The committee, known as the Gottschalk Committee, was charged with developing recommendations to deal with these problems. It issued a recommendation that (94):

> . . a national program be initiated for the treatment of end-stage renal disease with the aim of providing, at the earliest possible date, treatment in the form of chronic dialysis and/ or transplantation for all the American population for whom it is medically indicated.

The committee suggested that the program be financed by amending the Social Security Act "to cover the permanently disabled regardless of age" (94).

From the late 1960s until 1972, *over* 100 bills were submitted in Congress to deal with the ESRD problem (73). However, it was not until 1972 that the issue was fully addressed. Section 199I of the Social Security Amendments of 1972 extended Medicare health insurance coverage to those people under age 65 suffering from chronic renal disease and requiring dialysis or transplantation. The effective date for the coverage was July 1, 1973 (108). As of 1982, the program covered about 93 percent of the ESRD patient population (20).

In establishing the actual reimbursement levels for dialysis under Medicare, the Social Security Administration's Bureau of Health Insurance had little to go on. The non-Medicare medical market varied widely in reimbursement practices (72). The decision was made to pay 80 percent of the average cost to a hospital-based facility or 80 percent of the reasonable charges for a free-standing facility, up to a "screen" or limit, of $133 per treatment. If routine laboratory services were included in the facility's costs, the screen was raised by $5; if the supervisory services of a physician were included in the facility's costs, the screen was increased by $12 more to $150. These rates were in effect from 1974 until just recently when they were supplanted by the new rates discussed below (108).

In 1982, prior to the new rules, nearly all free-standing facilities were being paid at the rate of $138 per treatment (the $133 plus $5 laboratory charge) (20). Most hospital-based facilities re-

quested and were granted exceptions to the screen, on the grounds that their costs were higher; and the average payment to hospitals had risen by 1980 to approximately $159 per treatment (110).

Under the previous system, physicians could choose from one of two systems of payment, the initial method and the alternative reimbursement method. Under the initial method, reimbursement for supervisory care was paid to a facility as part of its reimbursement rate, as mentioned above. The physician was then paid by the facility for these supervisory services. Other nonsupervisory services were paid on a fee-for-service basis. Under the alternative reimbursement method, physicians were paid a comprehensive monthly fee per patient. For patients dialyzed in facilities, the fee was based on a calculation of the customary or prevailing charges for a followup visit, multiplied by 20. In 1982 the fee averaged roughly $220 per month. For supervisory home patients, the weighting factor was 14 rather than 20, to reflect the presumed lower physician service requirements of patients on home dialysis. This fee came to an average of $154 per patient per month in 1982 (20,110).

These payments to physicians and facilities reflect payments under the patients' Medicare coverage. Patients have been enrolled under Parts A and B of the Medicare program. Part A (Hospital Insurance) covers, with some benefit limits, the reasonable and necessary services received in a participating facility. These would include inpatient dialysis. ESRD patients generally receive dialysis on an outpatient basis. This is covered by Part B (Supplemental Medical Insurance). ESRD beneficiaries pay a monthly premium and are entitled to payment of 80 percent of reasonable charges or costs above a deductible. Physicians' fees are paid on the same basis. Patients are responsible for the remaining 20 percent of charges. However, most patients are privately coinsured for this 20 percent, and hospital facilities often waive the 20 percent for those who are not (64).

Home dialysis has been covered under this same basic arrangement. Medicare pays **80** percent of acceptable costs for supplies and equipment and physicians' services, above the deductible. Some inequities in defining supplies were corrected early in the program so as not to penalize home dialysis patients (72). Then, in 1978, passage of Public Law 95-292 offered another incentive. If the patient obtained home dialysis and equipment from an approved facility that reserved the equipment for the exclusive use of patients on home dialysis, the reimbursement rate would be 100 percent. At the same time the law set a target rate for home dialysis reimbursement to facilities of no more than 70 percent of the national **average payment** for in-facility dialysis. The target rate did not apply to CAPD but notably did include payment for home dialysis aides. (The 70 percent limit was raised to 75 percent by the Omnibus Budget Reconciliation Act of 1981 (108)).

Kidney transplantation is paid for by both parts of Medicare. Hospital insurance (Part A) covers various inpatient hospital services associated with the transplant. This includes the cost of obtaining a suitable kidney, Coverage also extends to the care of a patient who donates a kidney. The surgeon's services are covered by Part B. After the deductible is met, Medicare medical insurance pays 80 percent of the recognized charges for a surgeon's services (108).

The New Reimbursement Rates

The costs of the ESRD program have increased dramatically. From $229 million in 1974, expenditures rose to about $1.8 billion in 1982 ($1.2 billion in constant 1974 dollars) (20). This continued growth has generated considerable concern, even though, as Rettig has pointed out, the increase was due more to an increased patient population, which more than tripled over this period, than to an increase in costs per patient (72).

A major impetus for change was the passage of the End Stage Renal Disease Amendment of 1978 (Public Law 95-292). As noted above, a major purpose of the law was to increase incentives for home dialysis. In addition, section 1881 of the law directed that a system be established for "prospectively set" reimbursement rates. Implementation of this provision proved rather time-consuming. In 1979 draft regulations were developed proposing a single rate for outpatient dialysis covering both hospital and free-standing facilities.

However, in 1980 the Health Care Financing Administration (HCFA) proposed a dual rate system, one for hospitals and a different one for free-standing facilities. This proposal was a recognition of the difference in payment rates that had developed from Medicare's practice of granting to hospital facilities of numerous exceptions to the payment screen (73). Although the Reagan Administration indicated in 1981 some preference for a single rate, a final compromise, the Omnibus Budget Reconciliation Act of 1981 (Public Law 97-35) indicated preference for a dual composite rate: one rate for hospitals and one for free-standing facilities, but each would apply whether patients were dialyzed in the institutional setting or at home (73,108).

By early 1981, the Department of Health and Human Services had developed specific proposed rates. The reimbursement rate was to average $132 for hospital-based facilities and $128 for free-standing facilities. Rates would be allowed to vary to reflect local labor costs. As a result, payments could vary from a low of $114 to a high of $148 for hospitals and from $109 to $143 for free-standing facilities (20,93).

The method by which these figures were generated is illuminating. In response to the 1978 legislation HCFA conducted audits of 38 free-standing facilities and 67 hospitals. *Median* cost per in-facility dialysis treatment was estimated at $108 for free-standing facilities and $135 for hospital-based facilities. In response to the 1981 legislation calling for composite rates, audits were then conducted on 25 large home dialysis programs. From this audit a median cost of $97 per treatment was estimated. These costs were then weighted by the percentage of patients estimated to be dialyzing in-facility and at home. The hospital rate was then raised by **$2.10** "to account for an apparent excess in hospital overhead costs resulting from Medicare hospital accounting requirements." Then 5 percent more was added to hospital costs to account for "the possibility that the methodology used may have failed to recognize fully the legitimate costs of hospitals or shortcomings in the audited data" (20).

For physicians the proposed changes eliminated the initial method of payment and modified the alternative reimbursement method. The payment would be the same for in-facility and home patients and was calculated as a weighted average. For patients, one direct change was to eliminate the 100 percent reimbursement option for home dialysis equipment. However, as is suggested below, indirect effects could be more substantial.

In congressional hearings in 1982, critics pointed out various perceived problems with the proposals (110). Opponents criticized the quality of the audits, the sample size, the underlying assumptions, the philosophical rationale, and much else. Overall, HCFA received 507 petitions and 4,265 comments on the rules, 3,675 of these from patients (93). The statistical procedures underlying the calculations did seem suspect. Partly in response to that, HCFA pledged additional audits. Nevertheless, the final rules, which were published in the Federal Register on May 11, **1983,** and which became effective August 1, 1983, showed very little change from the proposals. The average reimbursement rates of $131 for hospitals and $127 for free-standing facilities were $1 lower than those stated in the earlier proposal. However, this difference simply reflected updated information on the geographical wage differentials that were used in rate calculations (93).

Effects of the Rates

The legislation mandating new rates spoke of their "prospective" nature. Fixed rates are designed to encourage facilities to control costs. Any excess of the rates over incurred costs can be kept by the facility; any deficit in costs must be absorbed. In addition, the composite nature of the rates is meant to create an incentive for movement toward increased home dialysis. HCFA believes that as many as 40 percent of the ESRD population could be on this presumably less expensive modality. Indeed, Carolyne Davis, the Administrator of HCFA, stated that "the promotion of this incentive is the most important objective of the 1981 legislative provisions and of our regulations" **(20).**

Thus, the regulations are aimed at providing some overall cost-control incentives and at shifting treatment to the home setting. In neither case

is this motivation entirely new. A screen on Medical payments for dialysis treatment has been in effect for a decade. For free-standing facilities the $138 screen was, in effect, a prospectively set rate. Indeed, if the HCFA audits are accurate, these facilities were enjoying an operating profit of about $30 per treatment. Cost reductions could have been translated into profits for these facilities, precisely as called for in a prospective reimbursement system. For hospitals, of course, the screen could be circumvented by the exceptions process. Nevertheless, although Administrator Davis describes the previous system as cost-based (20), the screen did at least impose some administrative discouragement to increasing costs. Apparently, it has made some contribution toward shifting patients toward the more cost-efficient proprietary facilities. Rettig argues that the screen was "imaginative" and "the primary reason for steady per-patient costs" (72). HCFA's plans to be stricter in granting exceptions (93) should enhance the screen's effects.

The incentive for home dialysis is in some respects ironic. In 1972 home dialysis was the choice of approximately 40 percent of the patients, but the initial Medicare regulations discouraged it, contributing to the relative decline in this treatment choice (72). The 1978 legislation was a clear move toward providing a home incentive. The new regulations also encourage it but in a somewhat different fashion.

A rationale for discussing reimbursement in this report is the expectation that reimbursement rates will, by affecting patient and provider behavior, affect the dialysis equipment and disposable market. This section considers effects by evaluating the likely responses to the rules' objectives of encouraging cost control overall and home dialysis in particular.

Cost Control

A prospective reimbursement system provides an incentive to reduce costs. One **way** to reduce costs is by lowering the costs of materials and equipment used in the dialysis process. Another is to reduce labor costs, Providers can reduce their costs by pressuring manufacturers to lower the prices they charge, There may be some opportunities here, through strenuous bargaining or forming cooperative buying ventures. GAO suggests that HCFA might negotiate with suppliers (105). If such efforts did lower prices overall, then costs to providers would, of course, decline accordingly.

Manufacturers naturally could suffer from such developments. Profits, especially in areas such as dialyzers, are apparently being squeezed. In fact, those providers paying high prices may be in effect subsidizing other activity. Continued buyer pressure on prices will undoubtedly contribute to the predicted industry shakeout.

Such cost-reduction pressures may be viewed perhaps more positively as providing an incentive for innovative advances. Rettig, for example, cites the development of large surface area dialyzers, which increase the surface area exposed to the blood, reducing required time on dialysis and thus providers' costs, as a technical change that may have been prompted by Federal Government cost-control efforts (72). More generally, a recent study notes that prospective reimbursement systems have provided hospitals with a moderate incentive to adopt cost-saving innovations (75), Such concerns about costs offer a useful signal to manufacturers (53).

Materials costs can also be reduced by increased reuse of dialyzers. The key impetus behind reuse, of course, has always been the effort to control costs, Despite medical claims that reprocessing may actually lead to salutary medical effects, cost considerations are likely to remain the force behind this practice. It appears that as long as current professional opinion remains generally supportive of carefully controlled reuse (e.g., Sadler, 1983 (77)), reimbursement pressures will make the practice increasingly attractive to providers,

Note that this may be especially true since reuse was not explicitly considered in the HCFA cost calculations and no adjustments were made to reflect reuse. The HCFA did note that 25 percent of the independent facilities examined reused dialyzers while only 1 percent of the hospital-based facilities did. It was further suggested that dialyzer reuse does contribute to the cost differences observed (20). If a hospital's costs are

otherwise comparable to the HCFA figures, reuse offers a potential for generating a surplus.

The potential effects of reuse on the dialyzer market were discussed earlier in this report. The pressures generated from reuse could, however, provide a special incentive to manufacturers. Manufacturers insist that today's dialyzers were designed for single use only (117). Yet reuse is a fact. Cost pressures may stimulate design changes that enhance the efficiency or reduce the costs of reprocessing.

Another potential source of cost savings is labor costs. Labor probably constitutes **50** percent or more of the cost of dialysis treatment (91). Thus, reductions in labor costs could generate considerable savings. A potential reduction in labor has been the cause for some concern that care will be shortchanged. The American Association of Nurses and Technicians, for example, expresses a fear that the useful services of social workers, dietitians, and nurses will be reduced **(3).**

The effects on the dialysis equipment and supplies industry of such actions are not clear-cut, but are probably not detrimental. Labor, equipment, and supplies are to some extent substitutable. As has occurred elsewhere, automation may substitute for certain labor requirements. This, of course, would have positive effects on the producers of the automated equipment. With reuse, there is a complex interaction at work. Reuse does seem to raise a facility's labor costs (e. g., by requiring extra handling of dialyzers) while it reduces material costs. At the same time automated dialysis machines could reduce some of these labor requirements.

Input costs could be reduced by a facility's focusing on "healthier" patients. "Sicker" patients, with special medical problems, require more labor, more care in general. The possibility that hospitals' higher costs are due to their "sicker" patients case mix has been debated. Only limited data are available and they are subject to alternative interpretations. However, a recent study by Plough, et al., does suggest that the case mix in hospital-based facilities includes more severe cases than those in free-standing facilities (69) (see also, (53), (109), and (110)).

Incentives for Home Dialysis

As noted above, a major objective of the new reimbursement plan is to encourage home dialysis. Under the previous system, the expenses for home dialysis were reimbursed according to the actual costs incurred. This was the case whether patients dealt with suppliers directly or through a facility. For facilities, the composite rate now provides some incentive for encouraging this modality. Cost data generally suggest that home dialysis is, on the average, less costly per treatment than dialysis in facilities. Recalling the figures presented earlier in the case study, home hemodialysis is clearly less costly in terms of direct outlays because of the time required for unpaid aides. Similarly, CAPD, a popular home modality, appears less expensive if the costs of patient hospitalization are not included. Since hospitalization costs of this sort are funded under Part A of Medicare, they pose no rate-based disincentive to home dialysis. Thus, on balance, if patients affiliated with a facility are moved to home hemodialysis or CAPD, the hospital has an opportunity to receive a surplus.

The objective of the changes proposed in physician reimbursement was essentially to eliminate the disincentive to home dialysis in the preexisting system, where physicians were reimbursed less under the alternative reimbursement method for home patients than for in-facility patients. This payment differential was based on the view that home patients required less of the physicians' time. Under the compositive alternative reimbursement method, physicians' fees are independent of location, and there is no longer any direct financial reward for setting treatment in the facility.

For patients the situation becomes rather complex. Under the new rules patients may still choose to buy their own supplies and be reimbursed under the prior procedures. However, the new plan eliminates the option to receive 100 percent reimbursement for purchase of a home dialysis machine, Furthermore if home patients now purchasing on their own do choose to operate through the facility, they would risk being responsible for 20 percent of a fixed amount that is higher then 20 percent of the home dialysis costs they are now

incurring. Yet HCFA has suggested that one objective is to direct home patients into affiliating with and receiving all equipment and supplies from a facility (20,87). If there is indeed a profit margin for facilities from home patients, facilities would have an incentive to encourage patients to buy through them. Moreover, greater volume purchases may enable the facility to bargain for lower prices from suppliers. One industry source suggests that, as a result, the percent of patients dealing directly with suppliers on an assignment of benefits basis should fall from approximately **70** percent today (105) to less than 10 percent within 1 year (91).

Under the new plan, the patient has no extra financial incentive and perhaps even weaker incentive than previously for home dialysis. The potential profit incentive built into the composite prospective rate is not for patients. This is quite different from, say, a voucher type system, in which the patients, rather than the facilities, are allocated a fixed dollar amount and then given the option of choosing a treatment from among competing alternatives.

Overall, the strongest incentive for home dialysis belongs to the facilities. This is important, of course, and should create some movement toward increased home dialysis. What effects would this have on the industry? If the movement were simply from in-center hemodialysis to home hemodialysis, the effects would probably be to increase sales. Equipment and disposable requirements would be technically similar. However, patients at home would not be able to share machines as would be the case in facilities. Without this opportunity to economize on machines, more machines would be demanded for any given patient population.

However, most new home patients are choosing CAPD (14), This has led many analysts to predict significant growth in this market. Firms such as Baxter Travenol that have a firm foothold in the market may gain at the expense of others that do not. At the same time, many firms focusing on hemodialysis will be encouraged to diversify into CAPD products (47,79). Depending on the relative success of the firms, changes in industry structure are certainly possible. Much, of course, will also depend on how present uncertainties about CAPD's cost and clinical efficacy are resolved.

RESEARCH POLICY

The research activities of the Federal Government have played an important part in the development of knowledge on the causes and treatment of ESRD. The National Institutes of Health (NIH) funded early work on maintenance dialysis and supported research on transplantation as well. The Veterans Administration (VA) and the Public Health Service provided resources for the demonstration of maintenance dialysis therapy. The research support continues today, but some difficult policy issues are evident.

The primary source of research on kidney disease-related research is NIH. Within NIH, the institute doing most of this research is the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK), formerly the National Institute of Arthritis, Metabolism, and Digestive Diseases. Other institutes also support kidney-related research as it relates to their special responsibilities. These include the National Cancer Institute, the National Heart, Lung, and Blood Institute, the National Institute of Allergy and Infectious Diseases, the National Institutes of Dental Research, the National Institute of Child Health and Human Development, and the Division of Research Resources. Overall, the total amount spent on kidney-related research was estimated at about $90 million in 1982 (78). This might be compared with the approximately $73 million spent by NIH on kidney and urinary diseases in 1979 and the $47 million spent in the area in 1976 (101).

This research would be expected to have some long-term effects on the incidence and treatment of ESRD. Perhaps a clearer idea could be obtained by focusing attention on NIADDK, whose over-

all contributions to improving dialysis treatment appear to be significant. According to testimony before Congress by the institute's Acting Director, Lester Salans, in 1982, NIADDK's activities "have produced, directly, or indirectly, most of the innovations and developments which undergird today's maintenance dialysis treatment . . ." (78). The list of these innovations presented in table 14 is impressive. Certainly, these developments have had an effect on the equipment market, particularly the dialyzer market, for NIADDK contributed to the development of the hollow fiber dialyzer.

An examination of trends in funding, however, suggests that NIADDK's direct contributions to the market are likely to decline. Table 15 shows figures for **1979-83** for the Chronic Renal Disease Program, a subdivision within NIADDK's Kidney and Urologic Diseases Program. After an adjustment for inflation, overall spending for the Chronic Renal Disease Program fell by roughly 12 percent. In the area of maintenance therapies, which includes applied research on hemodialysis, peritoneal dialysis, hemofiltration, and other aspects of therapy, research fell by **83** percent from 1979 to 1983. Furthermore, within NIH as a whole, maintenance therapies took up only about **6** percent of the ESRD-related research **(119).**

Table 14.— Innovations in Dialysis Treatment Attributed to the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases

- Development of hollow fiber-dialyzers.
- Enhancement of efficiency of flat-plate dialyzers.
- Introduction of "single-needle" dialyzers.
- Determination of protein levels for diets for dialysis patients.
- Establishment of national registry of patients on dialysis (responsibility later assumed by HCFA).
- Development of specific absorbents for uremic wastes.
- Development of wearable artificial kidney for self-treatment.
- Improvement in prevention and treatment of chronic bone pain and bone fractures in patients
- Development of treatment measures for chronic anemia i n patients.
- Development of concept of hemofiltration.

SOURCE Adapted from L B Salans Acting Director, National Institute of Arthritis Diabetes, and Digestive and Kidney Diseases National Institutes of Health test imony at hearin g *The* Errol *Stage Renal Diseases Program (Part* 2— Treatment *Standards and Methods)* before the Subcommittee on Government Operations U S House of Representatives Apr 28 1982 (Washington DC U S Government Printing Off Ice, 1982)

This decline in dialysis research appears quite conscious. Congressional testimony puts forward the view within NIH that needs are changing. Particularly noteworthy is the "movement . . . of industry into this [dialysis] field." Given the research base provided by NIH, the view holds, private industry is now ready to take the major responsibility for research in dialysis. Thus, NIH becomes able to focus more heavily on alternatives, such as the underlying causes of the disease and on transplantation. Along with this shift comes an emphasis on investigator-initiated research and a reemphasis on contracts aimed at particular programs (78).

To many observers, such as Blagg, the result is a "deficiency in dialysis research" (12). They can point to various projects with worthwhile objectives that cannot be accomplished because of a lack of funds. They can also point to successes of the sort referred to in table 14 to indicate that past federally funded research in dialysis has been fruitful. For industry, the change in emphasis is important. The NIH research has served as a useful complement to the industry's own research and development (R&D) activities. As the Federal research contribution in this area diminishes, industry will probably find its own research efforts in dialysis becoming more costly.

From an economic perspective, expenditures on dialysis research have to be compared with alternative uses of these funds. A choice must be made as to how much to spend on all research overall, then which specific project should receive funding. Rarely is there adequate quantitative information on benefits and costs on which to make these judgments. In the absence of such information it is appropriate to rely, as NIH has, on the scientific community for judgments on which projects have scientific merit and on Congress and the executive branch for judgments as to which projects have special social merit.

This is a complex but sensible method for deciding research priorities. However, the situation in dialysis is complicated by assumptions underlying the NIH decisions. NIH is suggesting that research on dialysis may indeed be worthwhile but that industry can be expected to step in to see that sufficient research is performed. Is

Table 15.— Research Support for Chronic Renal Disease Program of National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, 1979-83

	Fiscal year											
	1979		1980		1981		1982		1983		Percent change 1979-83	
	Current $	Percent	Current $	Percent	Current $	Percent	Current $	Percent	Current $	percent	Current $	Constant $[a]
Pathophysiology	$2,986,058	32 "/0	$2,745,229	35 %	$3,050.031	370/o	$3,698,842	42 %	$6,221,596	53%	+ 108	+ 46
Transplantation	1,933,590	21	2,652.601	34	3,488,265	42	3,915,709	44	4,428.662	38	+ 129	+ 61
Maintenance therapies	4,435,899	47	2,412.880	31	1,779,284	21	1,192,758	14	1,043,157	9	– 77	–83
Total	$9,355,547	100%	$7,810.710	100%	$8,317,580	100%	$8,807.309	100%	$11,693,415	100%	+ 25	–12

[a]Conversion to constant prices was accomplished by using implicit GNP deflator (a price index) for Federal Government purchases of goods and services (U S Department of Commerce Bureau of Economic Analysis Survey *of Current Business*, March 1984)

SOURCE: L B Salans Acting Director, National Institute of Arthritis Diabetes and Digestive and Kidney Diseases, National Institutes of Health, testimony at hearing *The End-Stage Renal Diseases Program (Part 2–Treatment Standards and Methods)* before the Subcommittee on Government Operations House of Representatives Apr 28 1982 (Washington DC: U S Government Printing Off Ice 1982) and G H Hirschman. Chronic Renal Disease Program, National Institutes of Health Bethesda MD, personal communication March 1984

this a reasonable expectation? In some respects it is. If, as NIH asserts, a strong technological base has already been provided, then industry may be expected to perform the development work required for commercializing worthwhile new technologies. Nevertheless, a diminishing NIH research base is apt to be viewed by firms as offering diminishing attractive commercial opportunities. A further difficulty is that an industrial firm will make judgments on R&D based on the expected return to the firm rather than on the overall value of the innovation to society. As various authors have suggested (e. g., **(6)** and **(56)),** there are numerous projects where the returns to society may be high but where the returns to the private firm may be so low as to make the project unattractive. This results because an innovator is generally unable to appropriate fully the gains of an innovation. As the market reacts to these innovations, competitors and even customers manage to secure for themselves part of these gains.

The end result is that private firms may, from a social perspective, underspend on R&D and may choose a socially suboptimal mix of R&D projects. Policies to correct this problem need not, in general, include direct Government grants for R&D, but they may involve various other incentives such as tax breaks. However, for some studies, particularly those of an evaluative nature, potential conflicts of interest may call for direct Government involvement. For example, clinical trials of hemodialyzer reuse or of CAPD may be more valuable and widely accepted if funded by impartial sources. And further, such purely evaluative studies are apt to be especially characteristic of projects where the benefits to society are well beyond what the firm is likely to gain for itself.

A related difficulty here is the potential for differences of opinion among Government agencies with respect to who should fund particular research. An example is the controversy, discussed in congressional hearings in **1982 (107)** as to which agency, HCFA or NIH, should fund research on reuse of hemodialyzers. NIADDK had funded a study, completed in June **1981,** on multiple use (see (22)). However, in the testimony, the Institute's view is expressed that, because the issue had now emerged as primarily one of economic impact, HCFA would be best suited to fund additional clinical trials; HCFA, on the other hand, viewed its research role as purely economic and "appropriate only after clinical issues have been resolved" (119).

An intradepartmental ESRD workgroup set up to help resolve such differences subsequently recommended that the Food and Drug Administration be given the responsibility for the clinical trials **(20,40).** Meanwhile, many questions about reuse remain unanswered. This example suggests that an appropriate Government research program in ESRD should clearly delineate not only research objectives but also research responsibilities.

DIALYZER REUSE AND THE FEDERAL GOVERNMENT

Federal Government policies have had an important influence on the practice of reuse of dialyzers. These policies include the reimbursement policies discussed earlier, which provide incentives for cost control and, thus, cost-saving techniques such as reuse. However, other policies have had a more direct influence. These include funding of research on reuse and actions related to the regulation of medical devices.

Various research efforts that deal with reuse have been supported by Federal funds. For example, the Artificial Kidney-Chronic Uremia Program within NIH sponsored work on the reuse of coil dialyzers (e. g., see (85)). This study concluded that reuse of coils did indeed appear safe and cost effective. The National Institute of Arthritis, Metabolism, and Digestive Diseases also partially supported research on reuse by Dr. Karl

Nolph and his associates (9,65,118). This work evaluated reuse of coil and hollow fiber dialyzers under various conditions.

In 1978 Congress passed an amendment to the Social Security Law (Public Law 95-292) requiring the Secretary of Health and Human Services to conduct a "study of the medical appropriateness and safety of cleaning and reusing dialysis filters by home dialysis patients. " Subsequently, NIADDK did sponsor a study evaluating dialyzer reprocessing (see **(22)).** The Centers for Disease Control also did work that indicated that reuse was not associated with the increased incidence of hepatitis B infections among dialysis patients and staff (see (28)). Thus, the Federal Government has contributed to the development of knowledge on reuse. The Federal Government's interest in reuse remains high. However, as noted in the previous section, there are differences of opinion as to which Federal agencies will support or conduct the research.

A key role in the history and future of reuse belongs to the Food and Drug Administration (FDA). This role is associated with the FDA's regulatory functions under the 1976 Medical Device Amendments to the Food, Drug and Cosmetics Act. These amendments give FDA authority to regulate medical devices in order to assure that they are safe and effective. The regulations apply to all medical devices and in general appear to pose no special or unusual problems for dialysis equipment. Reuse is affected because regulatory authority extends to dialyzers and to equipment utilized in dialyzer reprocessing.

As noted earlier, most dialyzers are labeled by the manufacturer as being for single use. Under the regulations, any relabeling would require the manufacturer to seek FDA approval. Given the extensive clinical experience with reuse, the FDA may eventually determine that specific dialyzers, when reprocessed according to rigorous reprocessing procedures provided in the manufacturer's labeling, are as safe and effective as dialyzers not previously used (113). Although FDA's response cannot be assured and seeking FDA approval would involve some administrative expenses, manufacturers' reasons for not seeking to relabel stem largely from considerations other than FDA. One may simply be their belief that reuse is medically inappropriate. Another reason may be concern about the market's reaction: Relabeling may stimulate even further the practice of reuse and contribute to declining demand for new dialyzers. Finally, manufacturers may have concerns about product liability, Labeling a dialyzer as suitable for reuse could make manufacturers liable for any damages to a patient from reuse. However, although the legal situation is potentially complex, manufacturers do have reason to know that dialyzers are reused and, thus, maybe liable regardless of labeling (36).

Of course, regardless of the labeling, reuse has become a common practice. The FDA is obviously aware of this. Its position regarding reuse of dialyzers (and other disposable) was stated in a policy guide for field staff issued in 1977 and revised in 1981 (99,100). The FDA indicates that "the user should be able to demonstrate that a device considered for reprocessing can in fact be adequately cleaned and sterilized without affecting the characteristics and qualities of the device and, moreover, that the device will remain safe and effective for its intended use. In addition the institution or practitioner who reuses the disposable device must bear full responsibility for its subsequent safety and effectiveness" (116).

Although the FDA "neither condemns nor condones dialyzer reuse" (116), it has made some efforts to contribute to the evaluation of the practice. The FDA was one of the sponsors of a National Workshop on Reuse of Consumables in Hemodialysis in 1982. This workshop reached a consensus for the development of guidelines for hemodialyzer reuse.

The FDA has also authorized the marketing of an automated dialyzer reprocessing device. Under the Medical Device Amendments, entirely new devices may be subject to premarket approval by the FDA. However, if a device is "substantially equivalent" to a device marketed prior to the enactment of the amendments, then a manufacturer can submit information required for premarket notification (106). In this latter case the FDA will consider whether the device is similar to and as safe and effective as the preexisting device. The reprocessing device was deemed sub-

stantially equivalent and allowed to be marketed. Such permission does not constitute FDA approval of the device (116).

Overall, FDA response to reuse has been cautious. It recognizes that reuse is widespread and, from available evidence, not a hazard to the public health. At the same time it is reluctant to endorse formally a practice which most experts agree should be the subject of further clinical trials. The FDA has chosen to monitor the activity and to emphasize the responsibility of providers to ensure safety and effectiveness.

However, the literature on reuse suggests that the practice's safety depends critically on the quality of the reprocessing. This suggests that in the future FDA might want to step in to assure that reprocessing is done appropriately. The manufacturing industry would be expected to be generally supportive, since it has argued, as noted earlier, that clinics and hospitals reusing dialyzers should be subject to good manufacturing practices guidelines. This has not yet been done, but California has recently passed legislation requiring the establishment of appropriate reprocessing methods (44). Furthermore, if independent reprocessing service companies do become important, they may be viewed as falling under GMP guidelines. As suggested earlier, however, this need not pose a serious threat to the economic viability of such reprocessing activities.