1.
Introduction and Summary

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INTRODUCTION

End-stage renal disease (ESRD) afflicts approximately 96,000 people in the United States (25, 102). In the course of treatment for this disease, most patients and their providers use an array of products produced by the hemodialysis equipment and supplies industry. This case study offers an analysis of this relatively new U.S. industry. Its existence is a consequence of modern medical advances that have made hemodialysis a viable treatment for ESRD. Moreover, it would be difficult to think of another industry that has been so clearly and directly shaped by Federal policy.

Federal policy continues to be critical to the industry's development. Recent Federal initiatives have changed the rules under which treatment for ESRD is reimbursed. Federal policy makers are also being asked to evaluate certain current practices in treatment. The decisions made will influence, to a significant degree, the structure and economic performance of the industry. In light of his, the case study is particularly timely.

SUMMARY

Treatment Approaches

The two major treatment options for ESRD are transplantation and dialysis. At present transplantation is a solution for a small minority of patients, but with major advances of the recent past in transplantation techniques and immunosuppressive drugs, [1] its use may grow in the future. Nevertheless, at present the vast majority of patients undergo regular dialysis treatment, during which the patient's blood is cleansed of accumulated waste products.

in 1983, 86 percent of dialysis patients (61 ,722 people) chose a form of dialysis known as hemodialysis (102). In this modality the patient's blood is pumped from the body by a machine, subjected to dialysis, and then returned to the body in a continuous extracorporeal blood loop. Dialysis occurs as the blood passes through a dialyzer, or artificial kidney. Patients must undergo this treatment about three times per week in sessions running about 3½ to 5 hours each. This can be accomplished in a hospital-based center, in a free-standing facility, or at home.

A major alternative form of dialysis, chosen by 12 percent (8,688 people) of ESRD patients in 1983, is continuous ambulatory peritoneal dialysis (CAPD) **(102). In CAPD,** dialysis occurs within the patient's body across the peritoneal membrane. CAPD requires a manual exchange of fluid every 4 to 6 hours, but it can be done at home and it frees the patient from dependency on a dialysis machine. Although patients experience some risk of developing peritonitis, the modality has been growing in popularity.

The Market

The market for dialysis equipment and disposable has undergone rapid growth since 1972 when Congress passed legislation extending Medicare coverage to patients with ESRD, regardless of age. Since its inception the number of beneficiaries of this program has grown by more than 700 percent (from about 11,000 to 89,000 people[2]). As

[1] For further information, see U.S. Congress, Office of Technology Assessment, *The Use of of Immunosuppressive Drugs in Kidney Transplantation*, Staff Memorandum, Washington, DC, March 1984.

[2] Approximately 7 percent of the 96,000 ESRD patients are not Medicare beneficiaries.

of 1983, program costs were estimated at more than $1.7 billion annually (102).

The firms that produce dialysis equipment and disposable now have total sales of roughly $500 million. They sell their products to hospitals, to free-standing facilities (proprietary and nonproprietary), and to patients themselves. According to traditional economic measures, the industry is highly concentrated (i.e., only a few sellers have a large market share). At the same time the number of separate buyers is large. However, although profits in the industry were apparently quite attractive several years ago, they have been increasingly squeezed. Data presented in this case study indicate that prices have fallen; for example, over the past 5 years, the prices of dialyzers, which have constituted about 40 percent of the industry's sales, have fallen, after adjusting for inflation, by 34 percent.

The difficulties firms have experienced in the dialyzer market in recent years are the result of a combination of factors. It seems clear that there has been overcapacity in the industry. Firms expanded production during the good times only to find that overall demand for new dialyzers leveled off and now is actually decreasing. The decrease has resulted in part from buyers' attempts to reduce costs, and those efforts, in turn, have been stimulated by Federal efforts to control the costs of the ESRD program.

Future prospects for the industry as a whole are uncertain. The cost-control pressures are likely to persist. The dialyzer market, in particular, is likely to continue to decline as dialyzer reuse continues and patients move to modalities, such as CAPD (continuous ambulatory peritoneal dialysis), that do not use dialyzers. Firms supplying dialyzers are likely to respond, in part, with diversification within and outside the dialyzer area. In addition, they will probably attempt to develop equipment that can effectively reduce the costs of treatment.

Major Policy Issues

Future prospects for the industry will largely depend on the resolution of some major policy issues. Three areas of policy in particular were considered in the case study. They are: the reimbursement procedures for dialysis care, the Federal contribution to research on ESRD, and the practice of "reuse" of dialyzers. The case study draws some conclusions in each area.

Reimbursement

Perhaps the most notable and most controversial of these issues is the new Federal reimbursement rules for the ESRD program that were established in 1983. These rules are aimed at controlling program costs, in particular by encouraging home dialysis. The rules are likely to have a myriad of direct and indirect effects on the nature of care and thus on the hemodialysis equipment and disposables industry.

The rules have been hailed as the initiation of prospectively set rates. Although the new rules do involve prospective reimbursement—pre-set payment "screens"or maximums known in advance to facilities and patients—so did the previous payment procedure, albeit perhaps to a lesser extent. Under the previous rules, if costs differed from the screen, the facility incurred a loss or surplus accordingly, but hospitals (although not independent facilities) were almost routinely granted exceptions to the screen. Nevertheless, there is some evidence that overall the screen did stimulate cost-control efforts.

It is likely that the new rules will have some of the desired effect. Since exceptions will apparently be granted much less readily, facilities now have a stronger financial incentive to control costs. Moreover, because home dialysis is less costly to the facility, but is reimbursed at the same rate as dialysis performed in the facility, there is a clear incentive to have patients treated at home. Whether the present rates are the most appropriate way to achieve this goal is debatable. The rates themselves seem to have been developed through a less than rigorous statistical procedure, and they offer no clear direct incentive to patients and only limited incentives to physicians for home dialysis. Thus, they could conceivably create conflicts between the facilities that wish to lower costs (and generate surpluses) and physicians and patients. Such conflicts are not apt to enhance the quality of care or, indeed, to contribute to efficient care.

Patients have no direct financial incentive to go home, because the patient's required payment is independent of the setting. Although the Health Care Financing Administration (HCFA) has noted that facilities may want to share some of their profits from home dialysis cases with the patients themselves, it is unclear to what extent facilities will take up this idea (93).

If the objective is to encourage home dialysis, stronger incentives should be directed at patients, who, after all, must make the ultimate choice of setting. If patients were offered a financial incentive to dialyze at home—by being allowed to share in the cost savings attributed to home dialysis—they might be more inclined to choose this setting. Such an incentive, which allows patients themselves to balance benefits and costs, does not appear to have been seriously considered (20). Congressional legislation in 1978 did try to eliminate one financial disincentive to home dialysis by allowing for payment to home dialysis aides. This payment was attractive because home dialysis generally requires the assistance of a trained aide. Although a spouse or other close friend or family member can provide such assistance, a notable time burden is imposed. Payment to an aide is meant to reflect the time costs incurred. However, this congressional provision apparently was not effectively implemented, On balance under the new rules, home dialysis may contribute to the facilities' financial interests but not directly to the patients'.

The impact of these rules on the equipment and disposable industry depends on how effective the rule changes are in achieving their stated objectives. If facilities feel the pressure to reduce costs, they will in turn put pressure on their suppliers. Suppliers will thus have an incentive to compete more than previously on the basis of price and less on the basis of other attributes of the product. At the same time, suppliers may be stimulated to develop cost-reducing innovations. If the effect of the rules is to shift patients to newer modalities such as CAPD, the industry will also respond. Industry resources will be shifted toward those products offering the greatest profit potential, which depends ultimately on the patient base associated with the product.

On balance, the industry will certainly *survive* the new rules, although its form and structure may undergo some change. Profitability will depend on how facilities and patients respond to the rules and on how creative] y the industry can react.

Federal Research

The second major policy issue concerns research. The Federal Government has supported considerable research on ESRD and has contributed to development of many of the products sold by the equipment and disposable industry. However, this Government research contribution has declined, particularly in the area of maintenance dialysis, the area most likely to affect the industry. The long-term consequences are likely to be a decline in innovation in the industry.

Federal-Government-supported research provides a base from which industry can build. As the research base diminishes, private industry has less on which to build. The profitability of its research and development (R&D) activities may diminish, and as a result less R&D will be done. In the long run, the quality and cost efficiency of care depend on such R&D. Private incentives may not generate the socially optimal amount of R&D.

In assessing research, one must recognize that there are competing uses of scarce funds. This case study has no basis on which to conclude that the ESRD program is more worthy of funds than other programs. It is therefore appropriate that some administrative decisions be made on the basis of available expert opinion and perceived social goals. However, the activities of the various agencies responsible for research should be coordinated to assure that whatever objectives are agreed upon are pursued efficiently and effectively.

Dialyzer **Reuse**

The third major issue facing the industry involves dialyzer reuse. Increasingly, dialyzers, which are labeled by manufacturers for single use only, are being reprocessed and used again, often multiple times. This reprocessing involves a rinsing of the used dialyzer, followed by cleaning and disinfection or desterilization. Critics of the practice express concern about the possible adverse

consequences for patients. These may result from the diminished performance features of a reused dialyzer as well as from the introduction of chemicals used in reprocessing. However, at present, medical opinion views reuse as an acceptable practice, as long as the reprocessing is done with appropriate care. From an economic perspective, reuse appears attractive. Cost savings are undoubtedly present—but only if there are no substantial, negative, medical consequences to the practice. If reuse is associated with increased morbidity or mortality, such costs would have to be included in any cost analysis. Although projected direct cost savings are large, they could be outweighed by the indirect costs of adverse medical consequences.

Again, the current economic argument seems to support reuse. It seems to follow as well that Federal policy be directed toward seeing that reuse be done appropriately. The Government through the Food and Drug Administration could encourage the adoption of guidelines for reprocessing, for the costs of inadequate reprocessing could be severe. Since increases in reuse are likely, poor reprocessing procedures may result. In essence, care should be taken that reuse, one result of cost-control measures, does not, on balance, increase the full social costs of the ESRD program.

Note that these arguments are not contingent on the possible negative effects increased reuse may have on particular manufacturers. Clearly, reuse will pressure firms, particularly weaker firms, to lower prices, thus decreasing profits. In the short run, the lower price seems attractive, particularly to providers, On the other hand, these price reductions could result in firms' exiting from the market, which might ultimately result in a less competitive industry and higher monopoly-like prices. However, such pricing would require at least tacit coordination among remaining manufacturers and might be hampered by the international nature of competition and the possibility for cost competition among treatment modalities. Overall, such concerns seem remote.

The manufacturers of hemodialysis equipment and disposable belong to an unusually dynamic industry, which experienced rapid growth and attractive profits during one phase of its relatively short existence and decreased profits and sales, notably at least in dialyzers, in its current phase. Clearly more changes are in store.

Federal policy has played a critical role throughout. The market grew with the onset of Medicare coverage and has responded to ongoing Federal efforts at controlling the costs of the coverage. It is a market that in many respects is the creation of Federal policy. Its future shape remains intimately tied to that policy.

The remainder of this case study presents evidence pertaining to the conclusions above. Chapters 2 and 3 describe the available treatment approaches to ESRD and their equipment requirements. Chapters 4 and 5 analyze the industry. Finally, policy issues emanating from the industry are raised and discussed in chapter 6.