1. Summary and Policy Issues

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SUMMARY

The Study

Wheelchairs, for many disabled persons, are essential medical devices for work, mobility, and recreation. The characteristics, prices, and durability of these chairs are critical both to the quality of life of their users and to the costs incurred by the users, insurers, and government agencies.

This case study focuses on how Federal Government policies affect innovations[1] in wheelchair characteristics. In this chapter, these findings are summarized. In subsequent chapters, wheelchairs and their market (ch. 2), the role of the Federal Government (ch. 3), and relevant economic theories of innovation (ch. 4) are described. Findings of a telephone survey of wheelchair manufacturers (ch. 5) are reported, and case studies of innovation based on a field visit (ch. 6) are presented.

The Device and Its Market

One American in 200 (approximately 1.2 million total in 1977) is a wheelchair user (36). Just under half the users in 1977 were nursing home residents, and this user population is expected to grow by an annual rate of 1.5 percent (25). In 1982, an estimated 338,000 wheelchairs of all types were sold in the United States, for total retail sales of $126 million. Wheelchairs fall into four categories: 1) general-purpose manual wheelchairs, 2) power (electric) wheelchairs, 3) sports wheelchairs, and 4) power alternatives (vehicles that function as wheelchairs, but often look more like golf carts than chairs), General-purpose manual chairs are, by far, the largest segment sold. Manual wheelchairs serving rental or institutional needs (transport within a health care institution) represent 250,000 of the total annual number of chairs sold.

[1] For this report, an "innovation is any product or product modification that substantially improves the quality or decreases the cost of a product, while introducing a technology, material, or concept not previously found in any similar product on the market (see ch. 4).

Until 1978, the market was dominated by one manufacturer, Everest & Jennings, Inc. (E&J), which had 90 percent of U.S. sales. However, in that year, E&J settled an antitrust suit and relocated its plant. This situation slowed deliveries and weakened E&J's market position, offering other manufacturers the opportunity to strengthen their market shares. As a result, by 1983, there were approximately 53 manufacturers and importers of wheelchairs in the United States (37). Since 1978, E&J's sales have slightly declined in absolute terms, but much more in market share. In 1983, Invacare Corp., whose sales have risen rapidly, overtook E&J as the leader in number of industry sales, although E&J remained first in dollar value of wheelchair sales. (E&J projected its total 1983 sales, including non-wheelchair products, at $65 million.) The importance of these and a few other large firms suggests that the wheelchair market is oligopolistic.[2] Few details on market shares by type of wheelchair or manufacturer are available.

Purchase costs of a wheelchair vary from $200 to $3,000, depending on the type of wheelchair (manual, power, sports, or power alternative), the number of accessories and custom features, the quality of the construction and materials, and the manufacturer.

Maintenance and repair costs of wheelchairs are substantial. Over an average 3- to 4-year wheelchair lifetime, cumulative repair costs are sometimes more than initial purchase costs. The most frequently needed repairs are replacement of tires and upholstery. Maintenance and repair costs vary among models, however, and stainless steel chairs even come with a lifetime warranty on the frame. Comparison of costs of different wheelchair models is more meaningful if total annualized costs are computed. Total annualized costs

[2] In an oligopoly, a few suppliers dominate the market, and competition is limited by the knowledge that an action by one firm will prompt a reaction by the others.

of a wheelchair are the sum of: 1) the purchase price divided by a factor based on expected years of use, and 2) the annual repair and maintenance costs. For power chairs, this cost amounts to $1,6000 per year, of which over half is maintenance and repairs (calculated in ch. 2).

The wheelchair market is dominated by third-party reimbursement. The influence of third-party reimbursement is direct for prescription wheelchairs and indirect for institutional and rental chairs. About half of all wheelchair purchases are at least partially funded by government and another 40 to 45 percent by private insurers. Only 5 to 10 percent are paid for totally by the user. The largest single purchaser of wheelchairs is the Veterans Administration (VA), which reportedly purchased 11 percent of wheelchairs in 1976 (17). The extensive amount of third-party reimbursement steers innovation to devices that can expect to receive such funds. The policies of the different insurers vary; and, although all of them will pay for a wheelchair that is "medically necessary, " the meaning of this term varies. Some payers, such as the VA and Medicaid in Massachusetts, consider wheelchair alternatives, or accessories that provide psychological benefit to the user, to be medically necessary. Others, such as Medicare, will pay only for the most minimal type of equipment needed to provide mobility and to meet other physical needs of an individual patient. Wheelchair repairs are covered (or provided) in full to eligible users under the VA, Medicaid, and the health maintenance organization surveyed for this study. They are also covered by Medicare, subject to maximums, deductibles, and 20-percent coinsurance. However, the private insurer interviewed for this study, Blue Cross of Massachusetts, did not pay for repairs. Payers appear to consider only initial purchase costs, not lifetime costs, in deciding which wheelchair to supply.

The emphasis on price over performance in the reimbursement procedures for general manual wheelchairs has probably discouraged innovation. As manufacturers have difficulty selling a higher priced, higher quality, manual wheelchair, they probably have little reason to produce one.

Federal Policies

Wheelchair users are protected by the Rehabilitation Act of 1973, which generally prohibits discrimination on the basis of physical or mental handicap and requires that public buildings be accessible to handicapped people. Undoubtedly, the physical modifications of buildings and grounds, transportation systems, and many private accommodations and increased public concern have stimulated demand for wheelchairs.

Government research and development (R&D) efforts on wheelchairs appear modest in relation to the number of users. Available data show 1983 R&D expenditures specifically directed at wheelchairs to be $750,000 by the National Institute of Handicapped Research, $511,000 by the VA, and $50,000 by the National Aeronautics and Space Administration.

The Federal Government is a major purchaser of wheelchairs not only through the VA, but also through Medicaid (which probably spent nearly $32 million on wheelchairs nationally in 1982) and Medicare. Specific data on Medicare expenditures for wheelchairs are not available.

Wheelchairs themselves are covered under legislation concerning medical devices. The Food and Drug Administration (FDA) classifies and regulates the marketing of medical devices, including wheelchairs. Only manual wheelchairs for short-term indoor use are in Class I. All other currently marketed wheelchairs fall into Class II, while the most risky chair, a curb-climber, falls into Class III. FDA is working on developing performance standards for wheelchairs in cooperation with

[3]There are three FDA regulatory classes of medical devices according to the potential risks they pose: Class I, general controls, encompasses devices for which general controls are sufficient to provide reasonable assurances of safety and effectiveness. Class II, performance standards, contains devices for which general controls are considered insufficient to assure safety and effectiveness, and information exists to establish performance standards. Class III, premarket approval, applies to devices for which Class I general controls are insufficient, information does not exist to establish a performance standard, *and* the device supports life, prevents health impairment, or presents a potentially unreasonable risk of illness or injury (35).

the Rehabilitation Engineering Society of North America. These standards are not expected to be completed for several more years, however.

FDA investigates claims for unsafe products that are brought directly to it. When a series of claims requires action, FDA usually attempts to have the manufacturer voluntarily correct the problem, if possible, and recall defective products.

The Federal and State judicial systems serve as judges of product liability. Manufacturers are generally liable for injuries caused by negligence in design or manufacture or, in many cases, inadequate performance of their products. Although most manufacturers subject their products to extensive testing, accidents still happen. Physicians, therapists, and dealers are also at risk for negligence or failing to inform users properly regarding risks of and alternatives for the products they prescribe or sell. As a result, users may be hesitant to try substantially new products. The fear of product liability suits causes manufacturers, physicians, therapists, and dealers to hesitate to make, fit, or sell products that are significantly different from those already established. These fears of liability retard the innovative process.

Manufacturer Survey

Eleven wheelchair manufacturers were surveyed by telephone interview regarding their innovations in the last decade, their R&D efforts, their marketing methods, and the effect of government policies on their operations. The researchers found that most innovations have been refinements of existing products, with an emphasis on usefulness to active users.

Most respondents called their R&D departments crucial to the success of their companies. The 15 innovations identified in the survey were reportedly developed with private R&D. The few manufacturers that provided quantitative data on their R&D effort gave a median of 4 percent of sales. If this share applied to the industry generally, it indicates a total annual private R&D effort of $5 million, several times larger than that of the Federal Government.

Other findings of the survey involved marketing, reimbursement, and legal issues. Dealers were the important target for marketing (mentioned by *82* percent of respondents), followed by institutions and users. Trade shows were the most commonly mentioned marketing tool. Marketing strategies aimed at the end users were most significant for innovative products of small companies. Reimbursement policies were important primarily to manufacturers of innovative products. Products that are fairly typical of their kind tend to be assured of third-party coverage. The high cost of an innovative product, lack of clear-cut product liability laws, and the vulnerability of the manufacturer to frequent and successful lawsuits were cited as major obstacles to innovation.

Case Studies of Innovations

The authors studied the Power Rolls® IV, made by Invacare Corp., as an example of a successful past innovation. This innovation was pushed from conception to market in approximately *2* years. The product resulted from market research that examined products that were currently available and needs that were not being met, as identified by the end users. However, reimbursement policies and product liability were also considerations and played limiting roles in the design and production of the product. Although the Power Rolls® IV offered several advantages over current products, it was designed to be competitively priced to broaden third-party reimbursement. It was extensively tested for safety and durability. A strong sales force successfully gained the interest of dealers. In the first *3* years that it has been available, the Power Rolls® IV has gained 25 percent of the U.S. market for powered wheelchairs.

The second innovation studied was a curb-climbing wheelchair available in parts of Europe, but not the United States. According to this study, five significant factors that limited innovation in this country were: product liability, R&D funding, reimbursement policies, user preference, and technology transfer between countries. Product liability, reimbursement policies, and import duties also discourage the import of this product.

POLICY ISSUES

Monitoring Durability and Computing Annualized Costs of Different Wheelchairs

When purchasers of wheelchairs face a choice among alternative models and manufacturers, they need to determine which choice provides the best value for the money. A model with a higher initial purchase price may save money later through lower repair costs. In order for government and other purchasers to evaluate different wheelchairs properly, systematic data are required on the length of useful life and maintenance costs of wheelchairs.

The VA and the National Institute of Handicapped Research might undertake such analysis. VA facilities and certain users could be identified as "monitoring sources" to maintain careful records of the timing, nature, and cost of repairs and the type of use for the chair. Costs could be summarized as annualized cost per year of use. This reporting would be analogous to the annual cost of electricity indicated on the label of a new refrigerator. VA therapists and statisticians could select the chairs to be evaluated and choose veterans to serve as a representative sample of users. Organizing this monitoring effort like a research study may be desirable. Participants must be informed of the benefits, responsibilities, and risks (none known) of participation.

Since wheelchairs differ in features and quality, the one with the lowest annualized cost is not necessarily the appropriate one. But third-party payers could demand some justification before reimbursing for costs considerably above the minimum for a similar product. If models of wheelchairs with the lowest annualized cost were reimbursed most easily and quickly, then the other manufacturers might be encouraged to increase quality so as to decrease maintenance and thus total annualized costs. If such effects occurred, both quality and cost-containment goals could be served. The VA, for example, could also consider basing its procurement program on similar annualized cost analyses, rather than only on purchase price and past impressions.

It maybe argued that a reimbursement system that encourages high-quality products will also encourage costly products—a problem for a medical care system that is trying to limit spending. One way in which the reimbursement systems, especially Medicare, have attempted to limit their costs has been to base reimbursement rates on costs for previous, rather than current, years. If an innovation raises costs, the increase is not recouped for at least 2 years. Simply basing reimbursement rates on current prices could have a beneficial effect on innovation. If manufacturers knew that their products would be reimbursed at something close to their charge and that better performance could command a higher price, they might be encouraged to implement some of the innovative ideas they currently have. However, as more costly innovations would be introduced, the average price on which the reimbursement rate is based would rise and spending would increase.

A possible approach would be to borrow the concept of price indexes from payment systems for hospital care. Payment rates could be adjusted annually for changes in prices of inputs (labor and materials), complexity, and productivity. Manufacturers would then have the security of knowing that they could sell their products at a fair price. But such an approach would require that payers acquire additional technical expertise and would still entail continuing increases in prices and expenditures.

The problem remains of how to pay for higher quality products while encouraging manufacturers' efforts to maintain quality. One possibility would be to categorize products on the basis of quality, as determined through effectiveness analyses. Products that are more effective could be reimbursed at a higher rate, or at a greater percentage of the average cost of all wheelchairs. Manufacturers would then have to make a better product to receive a higher level of reimbursement. This system should be less expensive over the long run, since repair and replacement costs (part of the quality evaluation) would be less. A second possibility would be to reimburse at a higher rate for products that carried extended war-

ranties (excluding normal wear and abuse), placing manufacturers at risk for the durability of their products.

Prescribing and Paying for Significantly Valuable Wheelchair Features Under Government Programs

New technology in wheelchairs that maybe significantly valuable to users may not be developed and diffused. When manufacturers have some assurance of a reasonably sized and predictable market for an innovation, they are usually much more likely to implement it. A serious impediment to the diffusion of new technology in wheelchairs is that many prescriptions are written for a "standard wheelchair, " which allows reimbursement only for one of the least expensive models available. Since the Federal Government pays for almost half the wheelchairs purchased, its policies affect the industry as well as the patients. Medicare's policies are extremely important, not only for chairs it pays for directly, but also as a bellwether for the private insurance industry.

Officials of the Medicare and Medicaid programs could consider encouraging physicians and therapists to prescribe more sophisticated types of wheelchairs if they substantially improve the user's ability to function independently. The Medicare program could communicate this information in a letter to therapists and dealers who currently receive Medicare reimbursement. At the same time, the Medicare program should be sure that providers are aware of the kinds of features for which Medicare or Medicaid would be willing to pay and the kinds of justifications that these features require. Currently, justification is based on medical necessity, but guidelines could be spelled out. If a chair with some special feature, such as lighter weight or removable armrests, results in significantly better function for its user but is unaffordable for the user, Medicare could encourage the therapist to prescribe and justify it, and the dealer to order it.

Currently, the Medicaid program allows no copayments by a wheelchair user. By contrast, the Medicare program allows copayments for more sophisticated wheelchairs, other than the required 20-percent share by the purchaser, only if the purchaser advances the full price of the wheelchair directly.

Many dealers and manufacturers could offer more convenience and amenity options as "accesseries, " such as especially comfortable or durable upholstery. If improved seating is therapeutic, it could be so indicated and billed to a third party. If the accessory was purely an amenity, it could be written up and billed to the user as a separate item, but, if ordered at the same time, could be installed on the wheelchair at the factory. For example, cloth upholstery might be offered as an accessory in place of the standard vinyl upholstery. This practice would allow users to customize their wheelchairs with features that could not necessarily be justified on the basis of medical necessity. The cost of a basic wheelchair would still be billed to the insurer and only the accessory billed to the user. To prevent overcharging, Medicare and Medicaid might require that they be notified about the nature and price of such accessories,

For features *prescribed by the therapist*, the extent of justification required by Government and private insurers would entail tradeoffs between *maximizing the independence and comfort of the client and containing cost for the payer*. For example, suppose a handicapped person could be provided either a standard manual wheelchair costing *$400* (retail) or a prescription manual wheelchair costing $1,000, the 1983 estimated industry average prices for their respective categories. (Based on estimated annual industry sales of 300,000 and 70,000 units respectively (including rental and institutional chairs), over 75 percent of manual chairs are standard (1).) The prescription chair, however, allows a user to have the design, dimensions, weight, type of armrests, etc., tailored precisely to his or her requirements. The *$600* difference in initial purchase cost translates to a differential in annualized cost of about *$250* per year. If the prescription wheelchair allowed even a moderate improvement in function, the small investment might appear cost effective.

Physicians and therapists should be encouraged to think carefully about the tradeoffs between cost and performance. To clarify these issues, payers

and prescribers may wish to establish a joint force to write prescribing guidelines for cases that are clear cut; remaining cases would be left to individual judgment.

Subsidizing Selected R&D Activities

Although several manufacturers would like the Federal Government to award them contracts for specified R&D projects, this contracting role must be carefully defined. Appropriate criteria for Government support of R&D might include the following: 1) relatively large social gain, i.e., innovations that substantially improve the user's ability to function independently; and 2) relatively large expected social gain compared to the manufacturer's gain from this innovation. Examples of the latter are development efforts that would be difficult to appropriate by patent, or those where the manufacturing setup cost is modest. Economic theory suggests that in cases such as these, private companies would be reluctant to innovate because the innovations could be copied easily.

Government-supported R&D currently focuses heavily on basic research and on transfer of high technology to wheelchairs, Since manufacturers say that they cannot afford such research, funding agencies may wish to continue supporting it. However, the level of support could be based on the expected utility of results. Market research could be undertaken to determine what is most important to the end users. In addition, it would be useful for agencies that support research to understand how a new product will be paid for prior to committing resources to an R&D investment. Further analysis on the impact of reimbursement policies on purchasing practices is needed to determine whether the products that are developed through Government research will ever reach a significant market.

The general-purpose manual wheelchair seems to be the object of relatively little research, despite the fact that it constitutes the majority of the market. Here, R&D costs for manufacturers and strict price limitations by third-party payers virtually preclude innovation that enhances quality. This chair would seem to be a prime subject for Government R&D, particularly ideas not patentable, such as the use of a novel material in an existing wheelchair design.

Government funding of R&D by manufacturing companies is one way in which new products could be made more readily available to the public. Transfer of technologies from other industries, such as high-performance batteries or microprocessors, could be encouraged through Government funding of R&D in sophisticated wheelchairs. Manufacturers might then make such innovations available at a lower cost to the consumer, since the manufacturer's costs for R&D would be shared by the Government, and the Government could make the process available to competitors. It would be valuable to make market research a component of development work funded by the Government to assure that an adequate market exists for a proposed innovation.

Encouraging and Expediting the Development of Standards for Wheelchair Performance

Although the VA has issued performance standards for its own procurement of manual and power wheelchairs, there are no standards for other purchasers or for the industry as a whole. In the *absence* of *performance standards, it is not clear whether the less expensive wheelchair which is usually purchased represents a better buy or an inferior- product.* If standards are not forthcoming, better information would be useful. If the results of monitoring data described above were made available to dealers and therapists, they and the users would be better able to choose the appropriate chair.

Standards that refer to performance, rather than design, and that are flexible are less likely to stifle innovation. Performance standards could be based on the weight carried, the kinds of stress tolerated by the wheelchair, the frequency of repairs allowed, and other performance issues. Performance issues include safety, battery longevity for power chairs, rolling resistance, and brake design. Penalties for noncompliance by manufacturers could be clearly defined. These penalties could include guidelines for recompensing the in-

jured party in an accident involving a noncompliant chair, as well as stiff fines, or automatic disallowance of Medicare or Medicaid reimbursement.

Responsibility for improving wheelchairs and assuring their safety seems to be shared among all involved parties: Government and independent associations for setting and enforcing standards, manufacturers for thoroughly testing products before marketing, dealers for selling equipment with proven safety, third-party payers for evaluating a product's safety and effectiveness, therapists and physicians for properly assessing and prescribing the wheelchair appropriate for the user's needs and abilities, and consumers for using the equipment correctly. Appropriate actions by all of these parties would minimize wheelchair accidents.