

Appendixes

Appendix A.—Incontinence Product Manufacturers: Characteristics and Opinions

This appendix examines the characteristics and opinions of manufacturers of incontinence products. It includes data collected directly from manufacturers of the devices and from various secondary sources such as the Medical Devices Register of the Food and Drug Administration. As would be expected from the wide range of devices available for treatment of incontinence, urinary incontinence products are made by a heterogeneous assortment of firms. Some incontinence products are designed for broad consumer use; others are designed for very discrete types of incontinence, have a high unit cost, and require surgical implantation. Any effort to describe “the incontinence products industry” must recognize this diversity. Two approaches to this dilemma were used: a survey of a representative sample of manufacturers and a more detailed description of a highly specialized product, the artificial sphincter (see app. D).

To facilitate systematic collection of data from manufacturers, a questionnaire was designed and pretested in telephone discussions with a small number of manufacturers. A careful search through various secondary sources, supplemented by discussions with some manufacturers, was used for compiling a list of manufacturers of urinary incontinence products. In all, 48 companies were identified. Most of them were contacted by telephone to seek their consent to participate in this survey. Questionnaires were sent to 38 companies that agreed to respond. Frequent telephone followup was required to obtain an acceptable response rate. Twenty-one companies replied, giving a response rate of approximately 55 percent. A copy of the questionnaire is shown in appendix C. The analysis based on this survey has a number of limitations. The most significant include:

- Potential selection bias among those who responded to the survey. It is possible that companies responding to the survey may have differed significantly and systematically from those not responding. If they did differ, the analysis would suffer from some biases.
- Variations in quality and quantity of responses. Although many of the questions were answered by only a few respondents, the analysis of the importance of the physician’s role, the promotional tools used, the relative use of advertising and samples, and the obstacles to growth are based on all 21 responses. The question on barriers to entry was answered by 19 companies (90 percent of respondents). However, the question on proportion

of incontinence products purchased by different segments of the population was answered by only 12 companies (57 percent of respondents), and the question on cost of research and development was answered by only 6 companies (28 percent of respondents). The confidence in the analysis of the last two questions is therefore very limited.

- Variations in respondents. The questionnaire may have been completed by people at different levels and positions in the companies surveyed. This could have caused some differences in the perspectives of the respondents.

These survey limitations must be kept in mind while reviewing the analyses in this appendix.

Industry Structure

The substantial size of the incontinence product market appears to have attracted numerous companies into this field. Although it is difficult to pinpoint the exact number, at least 48 companies are involved in the manufacture of one or more incontinence products. A list of these companies is provided in appendix B.

These companies vary dramatically in their size, the number of products manufactured, etc. In many cases, it is virtually impossible to isolate the incontinence component of a much larger corporation. For example, O. M., Inc., employs only seven people and has a total sales volume of \$50,000. Proctor & Gamble, on the other hand, employs 25,000 people, and the sales volume of its “Attends” disposable pants was said to be \$100 million in 1982. Of these 48 companies, 26 are small (1 to 100 employees), 13 are medium (101 to 1,000 employees), and 9 are large (more than 1,000 employees). Most of the companies manufacture more than one type of incontinence product. The most common combination is pants and pads. Of the 20 companies that manufacture pants, 16 (80 percent) also manufacture pads. Of the 24 companies that manufacture pads, 16 (67 percent) also manufacture pants.

- Pants: The disposable and reusable pants market has as many as 20 manufacturers. Despite the number of manufacturers, the market is dominated by a few large companies such as Proctor & Gamble, Bard Home Health, Kimberly-Clark, Dundee, and Whitestone Products. The impressive record of the disposable baby diaper industry in the United States is expected to be dwarfed

both \$6 billion in sales of adult incontinent pants projected by the year 2000 (140).

- **Pads:** Some 24 companies manufacture disposable or reusable pads. Once again, a few large companies dominate: Kendall Co., Bard Home Health, Johnson & Johnson, Dundee, and White-stone Products.
- **Catheters:** At least 17 companies manufacture either in-dwelling or condom catheters. The large companies in this category are Seamless Hospital Products, American V. Mueller, and Bard Home Health.
- **Electrical Stimulators:** Only two companies manufacture electrical stimulators: Mentor Corporation, a small company in Minneapolis that employs 85 people and Myodynamics, Inc., a privately owned company in Carson, CA.
- **Artificial Sphincters:** American Medical Systems is the leading company for this product, which is described in greater detail in the case history (app. D).

Table A-1 summarizes the companies in the incontinence-product market.

Costs of Research and Development

The amount of time and money spent on research and development (R&D) varies considerably from one product type to another. Accurate information on R&D costs is difficult to obtain from manufacturers, but it is clear that both the time involved and the costs associated with R&D for pads and pants are considerably less than those associated with R&D for the other product types. For example, typical R&D for pads and pants takes about 6 months to 1 year and costs approximately \$6,000 to \$100,000. For catheters, on the other hand, typical R&D takes 1 to 3 years and costs approximately \$100,000 to \$500,000.

Other sources of R&D support might come from public funds, such as Government research agencies. The National Institute on Aging has shown recent in-

terest in urinary incontinence and supports research on the topic but has not funded the development of specific devices. The National Center for Health Services Research might be considered a potential source of support for tests of efficacy but has not funded such work in incontinence.

Marketing and Distribution

Companies historically have marketed incontinence products as medical devices rather than as consumer products. Most companies (85 percent) reported on the survey that they use distributors and/or dealers to reach the users. Three companies that do not use distributors or dealers, and three companies that do, sell directly to the users. Thus, only six companies (29 percent) sell directly to users.

Most brands are available throughout the United States; however, some brands are available only in certain regions. Over time, these companies can be expected to begin national distribution. The previous lack of retail distribution, despite the large number of incontinent people in the community, may be attributable to the social stigma attached to incontinence. This situation is changing as new marketing strategies focus on the consumer. The marketing situation has been comparable to that of feminine sanitary products about 40 to 50 years ago. At that time, the subject was not discussed, despite the fact that a huge demand existed for the product. Feminine sanitary products were sold by some pharmacists but were wrapped in plain paper and never displayed. Now these products are commonly sold in supermarkets and advertised on television.

Mail order has become an increasingly effective channel of distribution for many different products in the United States, including urinary incontinence products. Catalog sales of incontinence products by Sears Roebuck and Montgomery Ward, for example, include a wide range of product types and have grown rapidly. This channel of distribution is especially useful for

Table A-1.—Incontinence-Product Industry Structure

Product	Company size			Total
	1-100 employees	101-1,000 employees	1,000 + employees	
Pads		7	6	24
Pants	;	7	3	20
Catheters	8	5	4	17
Electrical stimulators.	1	1		2
Artificial sphincters	1			1
Others.	1	2		3

SOURCE: J. Ouslander and R. Kane, University of California at Los Angeles, 1984.

stigmatized products because people can purchase the product without disclosing their problem.

Pricing

Price is one of the important mechanisms used by some companies to capture an increased share of the market. Although one would therefore expect prices to be fairly uniform within a given product type, this is not the case. Some companies have not used pricing as a major tool. Instead, they have opted for product differentiation so that they can charge a different price and consequently have greater sales, greater profitability, or both. This product differentiation is accompanied by considerable price variation, even

within a product type. For example, the price of reusable pants sold by Sears Roebuck varies from 57.49 (nylon fabric with vinyl coating) to \$8.49 (vinyl brief with cotton-flannel lining) to \$10.49 (vinyl coated nylon tricot with cotton-flannel lining).

The typical wholesale price range in 1983 for each product is given below:

Pants:		
Disposable		So. 46 0.80 each
Reusable		\$7.00 \$14.00 each
p a d s		
Disposable		\$0.12 \$0.70 each
Reusable		\$7.00 \$10.00 each
Catheters		\$1.00 \$2.00 each
Intravaginal electrical stimulators		\$600.00 each
Artificial sphincters		\$2,450 each