

PROFILE OF THE PRESCRIPTION DRUG WHOLESALING INDUSTRY

EXAMINATION OF ENTITIES DEFINING SUPPLY AND DEMAND IN DRUG DISTRIBUTION

FINAL REPORT

EXECUTIVE SUMMARY

The U.S. Food and Drug Administration (FDA) is examining the drug wholesaling and distribution industry as it reviews policies applying to the distribution of prescription drugs. This study profiles drug wholesalers and drug distribution patterns. It also characterizes the pharmaceutical purchasing organizations and their impact on prescription drug prices and distribution.

Drug wholesalers consist of the Big Five full-line wholesalers (including McKesson HBOC, Inc., Bergen Brunswig Drug Company, and Cardinal Health, Inc.), regional wholesalers, and numerous smaller sub-regional/specialty wholesalers. In addition, there are "secondary wholesalers" that take advantage of manufacturers' sales on drugs to purchase discounted products and then resell these products throughout the distribution chain.

ERG identified several models that apply to the distribution of pharmaceuticals. In the most common model, covering a majority of drugs, manufacturers sell drugs to the Big Five drug wholesalers, who then sell them to dispensing organizations, such as retail chain stores, independent drug stores, and health care facilities. These drugs reach the ultimate consumer with a minimum number of transactions or physical shipments. In some cases, manufacturers sell directly to health care facilities or drug stores, eliminating any role for wholesalers. According to a compilation by PhRMA, 20 percent of all pharmaceutical drug sales went directly to dispensing organizations.

A more complex model of distribution is initiated, however, when manufacturers offer price discounts on various prescription drugs. Frequently, manufacturers hold short-term sales for individual drugs in order to reduce inventories or to meet quarterly sales targets. Large distributors, and especially secondary wholesalers, who are willing to risk substantial capital to acquire the discounted goods, purchase these sale drugs. These purchasers then turn the product over quickly by selling it to their networks of customers, which might include both larger and smaller distributors, and some drug dispensing organizations. In this model of drug dispersion, however, the sale drugs might change hands more than one-half dozen times before reaching a drug dispenser (i.e., a retail pharmacy or a hospital).

SECTION ONE

PROFILE OF THE PRESCRIPTION DRUG WHOLESALING INDUSTRY— THE SUPPLY OF WHOLESALE DRUG PRODUCTS

This section examines the market characteristics of the prescription drug wholesaling and distribution industry. Section 1.1 outlines the applicable Federal and State regulations governing the distribution of prescription drugs. Subsequent sections describe the components and characteristics of the entities that distribute wholesale drug products. Section Two examines the organization of purchasers of wholesale drugs. These sections also provide data on the number of companies and distribution of sales for each of the market players addressed.

This report generally refers to the companies being profiled as "wholesalers," in keeping with the terminology most commonly used in the industry. In fact, it is recognized that most wholesalers also perform substantial distribution functions and, therefore, can also be called "distributors." This report,

however, will generally use the term wholesalers to refer to the larger companies that engage in wholesale purchasing and reselling of pharmaceutical products. While most of these wholesalers also perform distribution functions, their activities do not always primarily involve distribution in the sense of moving products closer to their eventual point of consumption. For example, some discount wholesalers could theoretically purchase an entire lot of distressed product and resell it, in its entirety, to another company, without "distributing" the product to smaller companies. The term "distribution" will be used to refer to the physical activity that generally is one of the primary functions of the wholesalers, namely, to divide large-volume purchases among customers for them to eventually resell to retail customers or to smaller wholesalers.

Much of the material collected for this report is derived from conversations with industry sources that did not wish to be quoted or for whom their identification posed a possibility of revealing sensitive material. Thus, some statements about the operation of the drug distribution industry are not attributable to specific sources.

1.1 Regulatory Framework for the Distribution of Prescription Drugs

Federal regulations define distributor requirements for reporting on the source of their drug purchases to their customers. States impose basic licensing requirements on drug distributors.

1.1.1 Federal Regulations

At the Federal level, the Prescription Drug Marketing Act (PDMA) of 1988, as modified by the Prescription Drug Amendments of 1992, establishes requirements for the distribution of prescription drugs. Section 503 [e] [1] [A] of the Act requires each person, who is engaged in the wholesale distribution of a prescription drug and who is not the manufacturer or an authorized distributor of record for the drug, to provide the person receiving the drug a statement identifying each prior sale, purchase, or trade of the drug, including the date of the transaction and the names and addresses of all parties to the transaction before each wholesale distribution. Further Section 503 [e] [4] [A] of the Act defines the term "authorized distributors of record" as those distributors with whom a manufacturer has established an "ongoing relationship" to distribute the manufacturer's products. In a 1988 Guidance, FDA indicated that:

"Ongoing relationship" as used in the definition of "authorized distributors of record," may be interpreted to mean a continuing business relationship in which it is intended that the wholesale distributor engage in wholesale distribution of a manufacturer's prescription drug product or products. Evidence of such intent would include, but not be limited to, the existence of a written franchise, license, or other distribution agreement between the manufacturer and wholesale distributor; and the existence of ongoing sales by the manufacturer to the distributor, either directly or through a jointly agreed upon intermediary. The Agency would consider two transactions in any 24 month period to be evidence of a continuing relationship (FDA, 1988).

On December 3, 1999, the Agency published final regulations in 21 CFR Part 203 implementing these and other provisions of the PDMA as amended by the Prescription Drug Amendments of 1992 (64 FR 67720). Section 203.50 of these final regulations requires that, before the completion of any wholesale distribution transaction where the seller is not an authorized distributor of record, the seller must provide the purchaser with a statement identifying each prior sale, purchase, or trade of the drug. The identifying statement, also known as the drug product's pedigree, must include the proprietary and established name of the drug, its dosage, the container size, the number of containers, lot or control numbers of the drug being distributed, the business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer, and the date of each previous transaction. The Agency further refined its definition of "ongoing relationship" in Section 203.3 [u] of the final regulation to mean

". . . an association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to distribute the manufacturer's products

for a period of time or for a number of shipments. If the distributor is not authorized to distribute a manufacturer's entire product line, the agreement must identify the specific drug products that the distributor is authorized to distribute."

Based on concerns expressed by the industry and the Small Business Administration (SBA), FDA decided to delay the effective date for the above and other sections of the final rule (21 CFR Part 203) until October 1, 2001. At present, the prescription drug wholesale industry operates on the basis of its interpretation of the 1988 FDA Guidance regarding drug product pedigrees. Specifically, the wholesale distribution industry has interpreted the last sentence of the "ongoing relationship" definition (see p. 1-2) as indicating that it is sufficient for a wholesaler to have had two transactions within a 24-month period in order to be considered authorized. Figure 1-1 compares the distribution chain and the associated drug pedigrees under current industry practice and the final rule.

1.1.2 State Regulations

All drug wholesalers must be licensed under state licensing systems, which must in turn meet the FDA guidelines under State Licensing of Wholesale Prescription Drug Distributors (21 CFR Part 205). The regulations set forth minimum requirements for prescription drug storage (21 CFR Part 205.50 [a] and [c]) and security (21 CFR Part 205.50 [b]), as well as for the treatment of returned, damaged, and outdated prescription drugs (21 CFR Part 205.50 [e]). Further, under 21 CFR Part 205.50 [f], wholesale drug distributors must establish and maintain inventories and records of all transactions regarding the receipt and distribution of prescription drugs and make these available for inspection and copying by authorized federal, state, or local law enforcement officials.

Figure 1.1



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In most states, wholesale distributor licenses are issued by the State Boards of Pharmacy and require periodic renewal. The majority of states (approximately 80 percent) also require out-of-state wholesalers that distribute drugs within their borders to be licensed as well. Table 1-1 presents the available data on wholesale distributor licensure requirements, license renewal schedules, and the number of in-state and out-of-state licenses issued, by state.

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