

# **The Pharmaceutical Industry**

*A Discussion of Competitive and Antitrust  
Issues in an Environment of Change*

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## Executive Summary

Over the last 15 years, the pricing and other competitive strategies of pharmaceutical companies have been altered by revolutionary developments in information technology, new state drug substitution laws, federal legislation, and the emergence of market institutions that include health maintenance organizations (HMOs) and pharmacy benefit managers (PBMs). The industry has also undergone significant structural changes that include growth of the generic drug segment and substantial horizontal and vertical consolidation (e.g., acquisitions of PBMs by drug companies) by drug companies. This report first examines these institutional and structural changes, and then focuses on the nature of competition in the new environment. The purpose of the report is to identify and discuss both possible antitrust concerns and plausible procompetitive explanations of the emerging pricing and other competitive strategies of pharmaceutical companies in this changing environment. Definitive conclusions on whether particular strategies are anticompetitive, competitively neutral, or procompetitive are likely to involve facts specific to these strategies and must await further study. This report is intended as an initial step in developing a more complete understanding of the competitive dynamics of pharmaceutical markets subject to ongoing informational, institutional, and structural changes.

The report covers four primary areas of analysis. First, the report examines how information technology has altered competition among drug companies. Less than two decades ago, the information flows in the prescription drug industry were relatively simple. A pharmacist would fill each prescription as specified by the doctor, unless the patient was willing to accept a generic substitute. Retail pharmacies would manually order drugs from drug wholesalers, who would deliver the product and replenish their own inventories with drugs ordered from pharmaceutical companies. Physicians obtained drug information from reports on clinical trials published in medical journals and distributed by drug company salesmen, or in their regular practice by observing the success or failure of drugs prescribed for their patients. Competition among drug companies was focused on gaining the allegiance of prescribing physicians.

More recently, as described in the report, the doctor's prescription has become just the starting point in determining what drug the pharmacist dispenses. Today, pharmacies are typically part of PBM networks that administer the drug benefits portion of health insurer plans for employers and others. Computers linking network pharmacies to PBMs enable pharmacists to check which brand name or generic substitutions are required by the patient's health insurer, whether the doctor is prescribing according to health plan policy, what co-payment amount applies, and when drug stocks are low. The same computer technology allows pharmacies to manage their drug inventories. The drug dispensing records of pharmacies are increasingly being used to develop new products and services. Most importantly, prescription drug usage and cost

information can theoretically be merged with the patient care records of doctors and hospitals, conceivably placing significant numbers of patients in large, possibly nationwide clinical trials for existing prescription drugs. Through disease state management (DSM), the firms administering prescription drug insurance plans can learn more than was previously known about how well various drugs work, both relative to other drugs and to non-drug therapies. This information enables insurers and other drug buyers to focus more attention on comparisons of drug alternatives and their prices. While the traditional focus was on gaining the allegiance of prescribing physicians, drug companies now also compete for placement in health plan protocols and for contracts with HMOs.

Second, the report describes how this evolving information technology, coupled with other industry changes, has increasingly prompted drug companies to charge different prices to different groups of buyers. The report also discusses the competitive implications of this differential pricing. In recent years, price discounts offered by pharmaceutical companies have spread beyond large hospitals, the traditional recipients of discounts, to involve other segments of demand, and these price discounts may be linked to ongoing changes in the drug industry. These practices may have evolved partly because certain groups of buyers have adopted cost-containment measures similar to those used historically by hospitals. In addition, information technology has permitted some groups of buyers to substitute more easily among alternative drug treatments.

As described in the report, price differences -- two-tiered pricing (i.e., lower prices to HMOs and PBMs and higher prices to others), special prices to Medicaid recipients, and drug company rebate programs -- may simply reflect unrecognized cost or service differences associated with the sale of pharmaceutical products. Alternatively, these price differences may amount to competitive forms of price discrimination. While such price discrimination may be consistent with competition, the report describes the conditions under which alternative forms of price discrimination may harm competition. In particular, competitive harm is most likely to emerge when doctors and patients have few therapeutic drug alternatives, and when entry into drug markets is difficult. These conditions may apply to a number of drug categories as discussed in the report.

Third, following the discussion of pricing and other strategies of pharmaceutical companies in this new competitive environment, the report discusses different forms of vertical consolidation that have emerged in this changing industry. The focus of attention is on the potential for these vertical strategies to lead to anticompetitive pricing by pharmaceutical companies. The major vertical issues addressed in the report are information exchanges among vertically integrated drug companies, vertical contracting practices, and vertical integration. Possible anticompetitive exchanges of information arise because acquisitions of PBMs by drug companies may permit more effective monitoring of deviations from price coordination arrangements within prescription drug markets. Drug companies could better monitor and detect deviations because ownership of a PBM can provide drug companies with direct information on competitors' bids and transaction

prices. If a drug company learns through its PBM that its rebate offers to PBM customers are higher than rival offers, it could reduce its rebate offers to these PBMs. Other factors necessary for effective coordination are discussed, along with possible efficiency explanations for these exchanges of information.

The report also examines why vertical contracting practices and vertical integration have become more widespread, and focuses attention on how pharmaceutical companies might use these arrangements to increase drug prices. Importantly, the computer-based distribution of drugs at retail and mail-order pharmacies crucially depends on provisions in vertical contracts between drug companies and HMOs or PBMs. The competitive implications of key contract provisions, including most-favored-nation (MFN) and volume-based rebate provisions, are addressed in this report. In addition to efficiency explanations for these provisions, their possible use as devices to raise prices is considered. For example, volume discounts in drug company contracts with HMOs could induce them to maximize their rebates by transacting exclusively with those companies offering the most attractive terms. Exclusive dealing arrangements like this might force competing drug companies to use more costly means of marketing their drugs or could otherwise foreclose competition among them. The report outlines the conditions under which such vertical contract provisions may lead to higher prices. These require an assessment of the marketing alternatives available to rivals and an evaluation of conditions of entry in drug and other downstream markets. Similar foreclosure analyses are applied to examine the competitive implications of PBM acquisitions by pharmaceutical companies.

Fourth, the substantive analysis concludes by addressing some ways in which the changing environment in the drug industry may affect an antitrust analysis of horizontal mergers between and among pharmaceutical companies. Following summaries of public information about both horizontal mergers and Federal Trade Commission (FTC) enforcement actions in this industry, the discussion focuses broadly on possible forms of merger-related anticompetitive conduct. Given the growing importance of bidding competition among drug companies for contracts with buyer agents that include HMOs, the report reviews bidding models to consider the possibility of merger-related price increases to these buyers across multiple product categories.

Overall, among other findings, the report raises several possible antitrust concerns and a number of potential efficiency explanations involving the conduct of pharmaceutical companies.

o Legislative mandates and the application of information technology have transformed this industry in ways that have shifted the focus away from non-price forms of competition (e.g., competition for the allegiance of physicians) toward forms of price competition (e.g., competition for HMO contracts and preferred drug formulary placements). Along with describing these new forms of competition, the report raises the possibility that information technology networks might facilitate price coordination among pharmaceutical companies.

- o Industry transformations raise the possibility of anticompetitive forms of price discrimination in drug markets that are difficult to enter and in situations where doctors and patients have few alternative therapies. Price differences in these markets, however, may also be consistent with competitive forms of price discrimination.
  
- o MFN provisions in vertical contracts between drug companies and PBMs may facilitate price coordination in either upstream prescription drug or downstream PBM service markets by making it costly for firms to engage in selective price cutting, or by raising competitor costs in other ways. These provisions are also the same as those found to produce efficiencies in the supply of other products that include their use as an efficient mechanism for adjusting prices in rapidly changing markets.
  
- o Volume rebate provisions in vertical contracts between drug companies and buyers could amount to exclusive dealing arrangements that could lead to higher drug prices if, for instance, they result in anticompetitive foreclosure. Exclusive dealing agreements could, at the same time, reduce the risks of buyers by guaranteeing them adequate supplies of drugs or by otherwise generating efficiencies in the sale of prescription drugs.
  
- o Vertical acquisitions of PBMs by drug companies could lead to higher drug prices if the transactions result in anticompetitive foreclosure or if they facilitate anticompetitive exchanges of drug price information. These acquisitions can also produce transaction-cost and other efficiencies, even if they lead to the anticompetitive foreclosure explained in the report or otherwise cause higher prices.
  
- o Horizontal mergers in this environment of change may lead to broader forms of anticompetitive conduct that include anticompetitive bidding in a multi-product setting under certain conditions described in the report.

These findings suggest that antitrust authorities need to apply the standard case-by-case approach to antitrust analyses of vertical and horizontal issues that arise in this industry. The report raises the potential for competitive harm in a number of areas, but also highlights the need to evaluate alternative efficiency explanations before challenging any of the pricing or other strategies at issue.

# Chapter I

## Introduction

As recently as a decade or two ago, the information flows in the prescription drug industry were simple.<sup>1</sup> A pharmacist would fill each prescription as specified by the doctor, unless the patient was willing to accept a generic substitute. When pharmacy inventories fell low, or a customer brought in a prescription for an infrequently-sold product, the pharmacy would call in an order to its drug wholesaler, who would deliver the product and replenish its own inventories with orders to pharmaceutical companies. Physicians would learn what drugs to prescribe -- how well they worked and whether they caused side effects -- from reports on clinical trials published in medical journals and distributed by drug company salesmen, or in their regular practice from observing the success or failure of treatments with their own patients.

Today, this major industry, like so many others, has been transformed by information technology. The doctor's prescription is increasingly just the starting point in determining what drug the pharmacist dispenses: the pharmacist first checks which brand name or generic substitutions are required by the patient's health insurer (and the health insurer may in turn

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<sup>1</sup> Prescription drugs account for approximately 80 percent of the sales of the pharmaceutical industry. OTC (over-the-counter) medications account for some 20 percent of dollar sales. For a discussion of the historical shift from OTC to prescription drug consumption in the U.S. see Temin (1979). For a discussion of the increase in switching prescription drugs to OTC status, see "Strong Medicine." (1996).

companies.<sup>3</sup> For example, brand-name pharmaceutical companies face ever-increasing competition from generic drug companies, stemming partly from the Drug Price Competition and Patent Term Restoration Act of 1984.<sup>4</sup> Since the Act was passed, the Pharmaceutical Research and Manufacturers Association reports that the unit share of prescription drugs accounted for by generic forms has risen from 18.6 percent in 1984 to 44.3 percent in 1997. Moreover, the growth of cost-containment institutions has altered the nature of price competition in prescription drug markets. The number of health maintenance organizations (HMOs) in the U.S. increased from 235 in 1980 to 749 in 1996, and enrollment in these cost-containment organizations expanded from 9,100,000 to 77,300,000 over the same period.<sup>5</sup> Pharmacy benefit managers (PBMs), which administer prescription drug delivery under health insurance plans, managed the drug benefits of some 161 million people according to a 1998 report, up from 60 million in 1989.<sup>6</sup> Both HMOs and PBMs utilize a variety of techniques

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<sup>3</sup> For descriptive treatments of the pharmaceutical industry and its ongoing transformation, see Baatz (1995), Boston Consulting Group (1993), Breindel (1994), and Congressional Budget Office (1998). For an examination of competitive issues in the pharmaceutical industry, ranging from the measurement of price changes to analyses of the returns to pharmaceutical research and development, see the discussions in Helms (1996) and Office of Technology Assessment (1993).

<sup>4</sup> This legislation, which we discuss further in Chapter II, provides for extensions in the patent life of name brand prescription drugs, and eases the regulatory requirements governing the introduction of generic drugs. (See, *Drug Price Competition and Patent Term Restoration Act of 1984*, Pub. L. No. 98-417, 98 Stat. 1585 (1984)).

<sup>5</sup> These data were taken from *Statistical Abstract of the United States* (1997) and from "HMO Enrollment Doubles Since 1990." (1998).

<sup>6</sup> See Larsen (1998) and *Pharmacy Benefit Managers - Early Results on Ventures With Drug Manufacturers* (1995) for additional data on the growth of PBMs. See Rosoff (1998) for a discussion of the functions and competitive implications of PBMs, including an assessment of their impact on the quality of care.

confirm the doctor is prescribing according to health plan policy). This allows drugs to compete in new ways -- not merely for the allegiance of prescribing physicians who may be required to use drug formularies, but also for placement in health plan protocols and at point-of-sale in pharmacies. The pharmacy increasingly manages its inventories with computerized systems that automatically order more when stocks are low. And the drug dispensing records of pharmacies are increasingly being used to develop new products and services. Most importantly, drug usage and cost information can theoretically be merged with the patient care records of doctors and hospitals -- conceivably placing significant numbers of patients in large, possibly nationwide clinical trials for existing prescription drugs. Through disease state management (DSM),<sup>2</sup> the firms administering prescription drug insurance plans can learn more than ever before about how well various drugs work, both relative to other drugs and to non-drug therapies. Most of these computerized information systems were developed during the past decade.

At the same time information technology was altering the way the key players in the prescription drug industry interact, regulatory changes were inducing wide-ranging shifts in the structure of prescription drug markets and the competitive behavior of pharmaceutical

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<sup>2</sup> Chapter III contains more detailed discussions of the role of information technology in the pharmaceutical industry, and of innovations stemming from the application of this technology. One of these innovations, DSM, was described as "a system of viewing health care disease by disease and examining the interrelated elements in the treatment process with outcomes research to improve quality and lower costs..." of treatment of these diseases (See, Castagnoli (1995)). In other words, DSM utilizes data on the outcomes of alternative treatments at different stages of a given disease state, including drug and non-drug therapies, to evaluate both the cost and effectiveness of these alternative treatments. The goal of DSM is to improve the overall quality of health care and lower the total treatment costs over the course of the disease state.

made possible by the advances in information technology to contain the costs of prescription drugs, including drug formularies, generic substitution, and therapeutic interchange programs.<sup>7</sup>

These institutional changes have been accompanied by dramatic structural changes in the prescription drug industry. Some consolidation has been vertical, particularly the acquisition of large PBM organizations by brand-name drug companies.<sup>8</sup> These include Merck & Co.'s \$6.6 billion acquisition of Medco Containment Services, and Eli Lilly & Co.'s \$4 billion purchase of PCS Health Systems.<sup>9</sup> The prescription drug industry has also seen substantial horizontal consolidation, including mergers between large brand-name drug companies, acquisitions of generic drug companies by brand-name drug makers, and consolidations of generic drug companies. Both vertical and horizontal consolidation has resulted in antitrust enforcement activity, particularly by the Federal Trade Commission (FTC). The FTC, for example, challenged aspects of the vertical acquisition of PCS Health Systems by Eli Lilly & Co. and the

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<sup>7</sup> For example, a 1994 survey found that 87.3 percent of HMOs instituted some form of generic substitution and 33.8 percent operated therapeutic substitution programs (See, *CibaGeneva Pharmacy Benefit Report - 1995 Facts & Figures* (1995)). A more recent report estimated that 91.3 percent of HMOs operated generic substitution programs in 1998 and 71.7 percent used therapeutic interchange initiatives in the same year to control drug costs (See, *Novartis Pharmacy Benefit Report - Trends & Forecasts* (1997)). Chapter II contains a more detailed discussion of these and other cost-containment techniques utilized by PBMs and HMOs.

<sup>8</sup> Transactions between firms and their suppliers or customers are termed "vertical;" transactions between firms and their direct competitors are termed "horizontal."

<sup>9</sup> Some data from the 1994-96 period indicate that PBM organizations, either owned by or affiliated with drug companies, serve 53.4 percent of all covered lives in the U.S. and process 70.8 percent of all domestic drug prescriptions (See, Table II.7). Others estimate that PBMs owned by drug companies account for as much as 80 percent of the pharmacy benefit management market, but it is not clear how these commentators measure market concentration (See, for example, Hoffmann and Garrett (1995) and Gray (1995)).



horizontal acquisition of American Cyanamid by American Home Products Corporation, but otherwise permitted these transactions to take place.<sup>10</sup>

This study describes how changes in demand and supply conditions, vertical and horizontal consolidations, and the application of information technology have altered the competitive environment in prescription drug markets. It represents a first step in developing a fuller understanding of the competitive dynamics of pharmaceutical markets following these changes. The report highlights the possibility that vertical and horizontal mergers and other industry changes may raise antitrust problems by increasing the risk of unilateral or cooperative anticompetitive conduct that could harm consumers, particularly through price coordination or price discrimination. The study also looks at ways that the transformation of the pharmaceutical industry has promoted competition.

The introductory discussion in this chapter is followed by Chapter II's overview of the pharmaceutical industry and review of the public policy, institutional, and structural changes affecting the prescription drug industry during the last 15 years. This includes a review of federal and state legislation affecting generic drugs and Medicaid program recipients, cost-containment institutions and their use of information technology, and vertical and horizontal consolidation. Chapter III describes in greater detail the role of information technology, focusing attention on the computerization of drug delivery and its implications for price competition and product innovation. Chapter IV examines price competition among brand-

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<sup>10</sup> See, Federal Trade Commission. "FTC Gives Final Approval to Lilly Order, Pledges Continued Monitoring for Anticompetitive Practices." Press Release, (July 31, 1995) and Federal Trade Commission. "American Home Products Settles FTC Charges in American Cyanamid Acquisition." Press Release, (November 10, 1994).

name drug companies in light of the various industry changes, and focuses particular attention on the differential pricing practices of these companies. Chapter V centers on the antitrust implications of the application of information technology, and discusses the competitive effects of information exchange among drug companies. This chapter also considers the competitive and antitrust implications of ongoing vertical and horizontal consolidation in the prescription drug industry. Chapter VI contains some summary remarks about drug industry changes and their implications.

## Chapter II

# An Environment of Change in the Pharmaceutical Industry

### A. Historical Background

The U.S. pharmaceutical industry has a history of substantial growth. For example, current dollar sales of prescription drugs in the U.S. increased by over 500 percent between 1980 and 1997, rising from \$11.8 billion to approximately \$71.8 billion during this time period.<sup>11</sup> Throughout most of the post-World War II period, firms in the prescription drug industry competed primarily on factors other than price.<sup>12</sup> As discussed in more detail in Appendix A, price competition was limited for reasons related to both the demand and supply of drugs. On the supply side, the development of new drugs typically depended on significant investment in risky research and development projects, on the ability of drug companies to obtain intellectual property rights, and on the regulatory requirements of the Food and Drug Administration. In fact, real research and development expenditures (per new drug approval) rose from \$135 million to \$250 million between 1985 and 1995, while the time necessary to clinically evaluate

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<sup>11</sup> For a summary of these and other sales data, see *Industry Profile 1998*.

<sup>12</sup> Industry commentators, while they acknowledge the presence of drug trade as early as 550 B.C. in Egypt, trace the evolution of the contemporary pharmaceutical industry to World War II demand for large quantities of then-existing drugs, and to the postwar distribution of innovative drugs such as penicillin. For discussions of the historical evolution of the prescription drug industry, see, for example, Edwards (1983), Helms (1980), Measday (1977), Statman (1983), and Temin (1980).

and secure marketing approval for new brand-name drugs rose from an average of about 5 years in the 1960s to almost 9 years in the 1990s.<sup>13</sup> These factors combined to discourage research and development aimed at creating “me-too” drugs.<sup>14</sup> In consequence, while the research and development process does lead to competing drugs, some drugs on the market have few close rivals, limiting price competition in existing products, and competition is often directed into innovation aimed at developing new pharmaceuticals that leapfrog existing therapies.

On the demand side, consumers of prescription drugs lacked complete information about drug alternatives and their prices, and, because of third-party insurance, also often lacked the incentives necessary to directly control their expenditures on drugs. Although intermediaries such as physicians and third-party health care plans served as representatives for consumers, these representatives likely exacerbated the incentive and information problems in traditional prescription drug markets. As discussed in Appendix A, these factors may have led to higher drug prices, lower output levels, and poorer quality outcomes for consumers.

These supply and demand characteristics traditionally channeled competition among brand-name drug companies into several non-price dimensions, including research and development, new product introduction, and advertising.<sup>15</sup> Indeed, until recently, aggressive

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<sup>13</sup> Pre-clinical drug development adds to the time necessary to bring a new brand-name drug to market, but the starting and ending points of this stage are often unclear. For additional information on pre-clinical development and other aspects of brand-name drug introduction, see Tables A.4 and A.6 in Appendix A.

<sup>14</sup> However, these changes have not discouraged growth of the generic drug segment as discussed below.

<sup>15</sup> For discussions of non-price competition by pharmaceutical companies, see Comanor (1986), Edwards (1983), Helms (1996), Scherer (1996), and Statman (1983).

price competition among drug companies typically was found only in certain segments of the industry, primarily in sales to hospitals. As noted in Appendix A, hospitals typically negotiated lower prices than others, partly because the change from a cost-plus to the "prospective payment" system encouraged hospitals to minimize their prescription drug expenditures. Hospitals were also among the first buyers to apply cost-containment measures to their drug purchases. Yet, the importance of this additional price competition among pharmaceutical companies can be overstated. Even though drug companies competed for sales to hospitals, they usually enjoyed relatively high accounting rates of return. Stock market evidence, as discussed in Appendix A, also indicates that investors earn above-average returns by investing in pharmaceutical companies. On the other hand, the accounting profitability of pharmaceutical companies may overstate the economic rate of return because it does not account for the cost of intangible capital and does not adjust for the substantial risks associated with R & D.<sup>16</sup> Other factors equal, prospects for higher profits in the future may be negatively affected by the competition-enhancing industry changes that are discussed in the remainder of this chapter.

## **B. Federal and State Public Policy Changes**

A number of public, as well as private initiatives, have altered two institutional features of the pharmaceutical industry. First, the combination of federal and state legislation reduced

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<sup>16</sup> For a seminal discussion of these accounting problems, see Stauffer (1971). For more recent empirical research on these issues, see the discussions by Clarkson, Grabowski and Vernon, and Meyers and Shyam-Sunder in Helms (1996). In another study, the Congressional Budget Office noted that accounting profits ignore significant forms of investment made by drug companies, including investments in R & D and marketing (See, *How Health Care Reform Affects Pharmaceutical Research and Development* (1994)). Appendix A discusses these and other studies analyzing the profitability of drug companies.

the dominance of brand-name drugs by facilitating significant growth in the generic drug segment of the industry. Second, this legislation, coupled with private initiatives, enhanced interbrand competition in both product development and price dimensions.

**1. Waxman-Hatch Act of 1984**

The Waxman-Hatch Act addressed two fundamental problems stemming from the 1962 Kefauver-Harris Amendments to the Federal Food, Drug, and Cosmetic Act of 1938.<sup>17</sup> First, it removed substantial entry impediments facing suppliers of generic versions of post-1962 brand-name drugs. Second, it extended intellectual property rights protection on brand-name prescription drugs by as much as 5 years.<sup>18</sup>

**a. The Waxman-Hatch Act of 1984 and Generic Entry**

Prior to the passage of the Waxman-Hatch Act of 1984, FDA generic drug policy differed for drugs approved before and after 1962. For prescription drugs approved before 1962, FDA maintained an abbreviated new drug application (ANDA) process that typically imposed only manufacturing and labeling requirements on generic versions of brand-name drugs already approved as safe and effective.<sup>19</sup> In other words, potential suppliers of generic versions of pre-

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<sup>17</sup> For early discussions of the Waxman-Hatch Act of 1984, see Flannery and Hutt (1985), Grabowski and Vernon (1986), and Mattison (1986). For an early analysis of the economic effects of state drug product substitution laws, see Masson and Steiner (1985).

<sup>18</sup> In addition to the Waxman-Hatch Act of 1984, the Uruguay Round Agreements Act (P.L. 103-465) provided for the possible extension of all U.S. unexpired patents, including patents on prescription drugs for up to three years (See, Conlan (March 1995) for a discussion of this statute). The economic implications of this patent extension legislation are qualitatively the same as the extensions that are discussed in the context of the Waxman-Hatch Act below.

<sup>19</sup> See, "Abbreviated New Drug Applications." (September 1, 1978) in the *Federal Register* at 39126 for a discussion of these ANDA requirements.

1962 brand-name drugs could rely on safety and efficacy data previously submitted by brand-name drug companies. For drugs approved after 1962, however, generic entrants could not rely on data submitted by brand-name companies. Generic entrants faced the same FDA safety and efficacy requirements faced by the original producers of the name-brand drug.<sup>20</sup> This requirement limited the entry of generic competitors. Research indicated that, for drugs with expired patents in 1983, 90 percent of drugs approved before 1962 faced generic competitors, while only 35 percent of drugs approved after 1962 faced generic rivals.<sup>21</sup>

The Waxman-Hatch Act of 1984 established an ANDA process for prescription drugs approved after 1962. Under this new ANDA process, entry with a therapeutically equivalent generic form requires:<sup>22</sup> (1) developing a generic formulation for possible clinical evaluation; (2) meeting FDA bioequivalence requirements for ANDA approval; (3) following FDA's Good Manufacturing Practice regulations; (4) meeting FDA labeling requirements; and (5) marketing the generic drug. The chief regulatory requirement, establishing bioequivalence, typically

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<sup>20</sup> If adequate public data existed, approval of generic drugs required only the submission of a "paper NDA" (New Drug Application) at an estimated cost of 91 percent less than the NDA process for new drugs (For discussions of FDA policy before Waxman-Hatch, see Flannery and Hutt (1985) and Mattison (1986)).

<sup>21</sup> See Grabowski and Vernon (1986) for an early discussion of the impacts of the Waxman-Hatch Act on generic drug competition.

<sup>22</sup> FDA uses a two-letter system of codes to group drugs into "A" and "B" product groups. Drug groups beginning with the letter A are therapeutically equivalent to other products, while drug groups beginning with the letter B are not. The second letter provides additional information for further classifying drugs. For example, AB-rated generic drugs are therapeutically equivalent to corresponding brand names, while BD-rated drugs possess bioequivalence problems (For more detailed information on this rating system, see Bentley and Summers (1994)).

requires clinical studies with a group of 18 to 36 individuals to establish that the rate and extent of absorption of the generic form does not significantly differ from that of the brand-name drug.<sup>23</sup> Overall, the replacement of lengthy and costly safety and efficacy testing with this ANDA process reduced the time and cost of FDA approval for generic companies.<sup>24</sup> Further, since the Waxman-Hatch Act of 1984 expressly permits the preliminary production and testing of generic drugs prior to the expiration of any relevant patents on corresponding brand-name drugs, generic entrants routinely receive ANDA approval as soon as these patents expire.

Following enactment of The Waxman-Hatch Act, the generic drug segment changed in several important ways. First, this legislation gave rise to substantial entry by generic drug companies. According to reports, FDA had received some 800 ANDAs for generic drugs within just 7 months after the passage of this act.<sup>25</sup> A subsequent backlog of ANDAs was reduced as FDA successfully increased the number of generic drugs approved for sale in the U.S. For instance, FDA had a continuous backlog of hundreds of pending ANDAs during the late 1980s and early 1990s.<sup>26</sup> FDA has reduced this backlog, and has increased the number of ANDAs

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<sup>23</sup> For a broader discussion of the ANDA requirements for FDA approval of generic drugs, see Bentley and Summers (1994).

<sup>24</sup> The cost and elapsed times for formulating generic test drugs and meeting FDA bioequivalence test requirements depend on several factors, including the complexity of the brand-name drug, profit expectations of the potential generic entrants, and FDA review times.

<sup>25</sup> See, Boston Consulting Group (1993).

<sup>26</sup> It should be noted that part of this backlog was created by the so-called generic drug scandal of the late 1980s which involved the submission of fraudulent clinical data by several generic drug companies. Discussions of the scandal and this backlog of generic drug applications can be found in "Generics, The View Ahead." in Drug Topics Supplement (1993).



approved each year.<sup>27</sup> Further, in light of the fact that patents on dozens of popular brand-name drugs will expire before the year 2000, it is likely that significant generic entry will take place in the near future.

Second, since the passage of the Waxman-Hatch Act, the generic share of prescription drug volume increased by almost 150 percent (Table II.1). In fact, some estimate that generic drugs could account for as much as 70 percent of prescriptions by the year 2000.<sup>28</sup>

Third, empirical research indicates that the relaxation of entry impediments after passage of the Waxman-Hatch Act gave rise to significant entry and price competition in drug markets. For example, in an early study, Grabowski and Vernon found that patent expirations in the case of two leading brand-name drugs, Valium and Inderal, led to 25 percent losses in the volume shares of these drugs to generic substitutes. They also found that the generic forms were priced 20 percent or more below the prices of the name brands.<sup>29</sup> In a 1992 study of 18 drug categories, the same authors found that two years after patents expired on brand-name drugs: (1) an average of 25 generic drug suppliers entered each of these drug categories; (2) average generic drug prices fell to 65 percent of the price set at time initial entry took place; and (3) brand-name

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<sup>27</sup> According to information supplied by FDA, FDA reduced the number of ANDAs pending more than 180 days from over 600 during 1990 to less than 100 during 1996. FDA also increased the number of ANDAs approved from 80 in 1990 to 351 in 1996. The number of ANDA approvals declined to 254 in 1997, and averaged about 15 approvals per month during the first half of 1998.

<sup>28</sup> See Salmo (1994) and Goldberg (1994) for other growth projections as they relate to the penetration and use of generic drugs.

<sup>29</sup> See, Grabowski and Vernon (1986).

**Table II.1**  
**Generic Share of Prescription Drug Volume**  
**(1984 to 1997)**

Year	Generic Volume Share
1984	18.6%
1985	21.5%
1986	22.9%
1987	27.0%
1988	29.9%
1989	32.0%
1990	32.9%
1991	34.9%
1992	34.8%
1993	39.7%
1994	41.6%
1995	43.3%
1996	43.1%
1997	44.3%

Source: PhRMA. *Industry Profile* (1996-98).

prescription drugs lost approximately 50 percent of their share of prescription drug volume.<sup>30</sup>

More recent data indicate that generic entrants now often secure market shares of 70 percent

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<sup>30</sup> For a discussion of these and other findings, see Grabowski and Vernon (1992). Another study of 35 compounds subject to generic competition from 1984 through 1987 found that three years after patent expiration dates brand-names retained an average of 83 percent of sales revenue generated during the year these patents expired, and 68 percent of their sales volumes (See, Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards*. (1993). For related empirical and theoretical literature discussing the competitive effects of generic entry, see Caves, Whinston, and Hurwitz (1991), Frank and Salkever (1992), and Scherer (1993). For an earlier study on the impacts of patent expiration in drug markets, see Statman (1981).

following the expiration of patents on some brand-name drugs.<sup>31</sup> The pattern of generic entry following the passage of the Waxman-Hatch Act of 1984 also created competition among brand-name drug companies as discussed below.

**b. The Waxman-Hatch Act of 1984 and Brand-Name Drugs**

The Waxman-Hatch Act of 1984 also extends patent protection on name-brand drugs for up to 5 years, but the act also limits the period of post-NDA exclusivity to 14 years.<sup>32</sup> Congress added these provisions partly to address declines in the effective periods of patent protection after the 1962 Kefauver-Harris Amendments.<sup>33</sup>

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<sup>31</sup> See, for example, Goldberg (1997) and Vaczek (1996).

<sup>32</sup> Under the Act, a drug company must select the particular patent it wants to extend, and, for a given drug, can extend only one patent for each regulatory review period. The extension of other patents is possible if the drug company obtains supplemental FDA approvals for the drug covered by these patents. This means that drug companies might secure additional periods of market exclusivity for drugs covered by multiple patents. Delays in ANDA approval of generic alternatives can also effectively extend periods of exclusivity for brand-name drugs. For a more complete discussion of the provisions of the Act that govern patent term extension, see *Drug Price Competition and Patent Term Restoration Act of 1984*, Pub. L. No. 98-417, 98 Stat. 1585, (1984).

<sup>33</sup> The effective period of patent protection runs from the date of NDA approval for a new drug to the date of patent expiration. Since patents are typically sought and granted before a new drug receives FDA approval, effective periods of protection under these patents are often far short of 17 years. In fact, estimates of these effective periods include: (1) 8.9 years (Grabowski and Vernon (1986)); (2) from 7 to an average of 9 years (Mattison (1986) and Spivey and Trimble (1985)); (3) from 8 to 10 years and 12 to 14 years during different time periods (Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards*. (1993)); and (4) approximately 15 years in 1967 to about 8 years in 1981 (The Boston Consulting Group (1993)).

Generic competition and patent extensions, which vary according to criteria set forth in the Act,<sup>34</sup> alter the incentives of brand-name drug companies to compete in at least two ways.<sup>35</sup> First, while the additional competition from generic entrants reduces short run profits from brand-name drug sales, the prospect of long run profit losses could induce pharmaceutical companies to innovate by developing better drugs.<sup>36</sup> Second, the extension of patent terms may increase returns to R & D, and, therefore, possibly could increase incentives to innovate.<sup>37</sup> Key factors governing the net impact on R & D and innovation in particular drug markets are the length of the extension of the patent term and the extent of the revenue lost because of generic

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<sup>34</sup> For a discussion of the requirements drug firms must meet to extend patents, and the formulae applied to determine these extensions, see Mattison (1986).

<sup>35</sup> This discussion focuses attention on product development competition among brand-name drug companies. For a discussion of the implications of these changes for price competition, see Chapters IV and V.

<sup>36</sup> Although there is not yet an extensive body of empirical literature on impacts of these altered incentives to innovate, a report by the Congressional Budget Office (CBO) concluded "...that since 1984, the expected returns from marketing a new drug have declined by about 12 percent, or \$27 million in 1990 dollars." (See, Congressional Budget Office (1998)).

<sup>37</sup> Although the literature on patents discussed in Appendix A suggests that returns to R & D are positively related to patent length, two notable arguments suggest that longer patent terms, other factors equal, could reduce innovative activity. One argument is that longer duration patents may reduce the incentives of other firms to engage in related research that could lead to successive innovations. This is because the costs incurred by potential innovators to determine if their inventions would infringe existing patents may increase with effective patent life. Market power may also increase as patent duration rises, and may reduce the likelihood that inventors would be able to market successive innovations (See, Gilbert and Shapiro (1990)). A second argument is that longer duration patents might reduce innovative activity by creating monopolies with higher aggregate values. According to this argument, sales of the equity interests in these monopolies by older to younger generations would reflect these higher values. Other factors equal, the younger generation would allocate a higher proportion of its income to purchase these monopolies. Consequently, a lower proportion of the younger generation's income is available for savings and investments, including investments in new product development activities (See, Chou and Shy (1992)).

competition. An early study of this tradeoff found that, with an average increase in patent life of three years, the Act is unlikely to cause any adverse effects on R & D in the pharmaceutical industry.<sup>38</sup>

Numerous product reformulations may have been the result of Waxman-Hatch Act provisions that extend patent protection on brand-name drugs.<sup>39</sup> Such reformulations include sustained-release (SR) versions of several drugs, including Knoll Pharmaceutical's Isoptin SR, Hoechst's Cardizem SR, and G.D. Searle's Calan SR.<sup>40</sup> But other commentators suggest that additional generic competition threatens future R & D spending and the innovations that stem from these expenditures.<sup>41</sup> Again, however, this view is inconsistent with the significant increase in R & D spending by drug companies since the passage of the Waxman-Hatch Act. In fact, inflation-adjusted R & D spending by major pharmaceutical companies rose by more than 100 percent from 1985 to 1995.<sup>42</sup> In addition, it is well-established that vigorous competition between and among firms also leads to innovations that include product improvements. This suggests that the extension of patent rights is not the only way to encourage drug companies to increase their innovative activity in the area of new drug development.

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<sup>38</sup> Grabowski and Vernon (1986).

<sup>39</sup> In fact, the Waxman-Hatch Act grants three-year extensions for some product improvements that require additional research.

<sup>40</sup> For information on these and other sustained-release prescription drugs, see *Physicians' Desk Reference* (1995).

<sup>41</sup> See Blackett (1992) for a discussion of the impact of additional generic competition on R & D spending by pharmaceutical companies.

<sup>42</sup> For additional data on R & D expenditures of major drug companies, see Table A.3 in Appendix A.

## 2. State Drug Substitution Laws and Other Drug Substitution Initiatives

Apart from the Waxman-Hatch Act, still other public and private initiatives sought to facilitate substitution between brand-name and generic prescription drugs. State drug substitution laws were enacted in all states by 1984. These laws, which replaced earlier anti-substitution laws,<sup>43</sup> sought to enhance substitution of lower-priced generic for brand-name drugs, maintain quality of prescription drug care, and lower prescription drug costs for consumers.<sup>44</sup> Notable early research on the economic impacts of these laws found that brand-name prices for 37 prescription drugs exceeded retail prices of generic alternatives by an average of over 30 percent in 1980.<sup>45</sup> Masson and Steiner (1985) also found that generic substitution on eligible prescriptions rose from 7.3 percent in 1980 to approximately 16 percent in 1984, that the share of prescriptions accounted for by generics averaged 18 percent across states in 1980,<sup>46</sup> and that generic substitution reduced consumer expenditures by between \$44 and \$80 million in 1980 and by between \$130 and \$236 million in 1984. Since all but three states passed drug substitution laws by 1980, the study's comparisons of 1980 and 1984 data largely reflected changes in

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<sup>43</sup> A Federal Trade Commission report contains a discussion of the historical evolution of these laws (See, *Drug Product Selection* (1979)). For an analysis of the economic effects of these laws, see Masson and Steiner (1985).

<sup>44</sup> For a summary of major provisions of all the state drug substitution laws, see "The Rules of the Game." in *Drug Topics Supplement*, (1993).

<sup>45</sup> See, Masson and Steiner (1985).

<sup>46</sup> According to Masson and Steiner, approximately four percentage points of this market share were attributable to the drug substitution laws. It should also be noted that generic substitution rates differ from generic shares by definition because generic shares include prescriptions written for both generic forms and prescriptions written for brand-name drugs when generic substitution occurs.

generic drug use over this time period. The relatively modest change in generic substitution early in the history of these drug substitution laws was explained by the novelty of these laws and by a reluctance of pharmacists and consumers to alter the prescription decisions of physicians. Later research suggests that the state drug substitution laws have had a growing impact on generic drug sales, leading to increased use of generic drugs for prescriptions written for brand-name drugs.<sup>47</sup>

Like state drug substitution laws, recent efforts by brand-name drug companies have focused attention on ways to utilize pharmacists to enhance substitution rates among prescription drugs. The drug switch programs of brand-name drug companies, however, involve therapeutic substitution, and not the substitution of generic for brand-name drugs. Miles Inc., for example, paid pharmacists \$35 for each patient switched from a competing antihypertension drug to its Adalat CC.<sup>48</sup> Upjohn Co. offered financial incentives to pharmacists who provided information about its diabetes drug to consumers of competing brand names. Merck & Co. established several incentive programs encouraging substitution of its brand names for those of competing drug companies, including its rebate programs for the brand-name antihypertensive drugs, Prinivil and Prinzide.<sup>49</sup> Prescription drug switch programs faced challenges, largely on

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<sup>47</sup> For example, for a specified category of prescriptions written for brand-name drugs, the number of these prescriptions that were filled using generic drugs increased from 5 percent in 1980 to 29 percent in 1989 (See, Caves, Whinston, and Hurwitz (1991)).

<sup>48</sup> For additional information on these switch programs, see Ukens (April 1994) and Ukens (July 1994).

<sup>49</sup> See, Tanouye (1994) and Ukens (May 1994).

consumer protection grounds, from state attorneys general, state legislatures, and the FDA.<sup>50</sup> Arguably, these switch programs raise potential agency problems that could cause competitive harm. In particular, pharmacists' incentives to act as otherwise good representatives for consumers could change under the drug switch programs.<sup>51</sup> At the same time, however, pharmacists may lack the necessary incentives and the ability to provide consumers with the highest quality and lowest-priced drugs even without these switch programs. Physicians, who would also have to approve any drug substitutions under these switch programs, may also lack the necessary information to make optimal decisions for consumers. In such cases, should these switch programs encourage pharmacists to substitute among drug alternatives without regard to the impact on consumers, this could lead to reductions in the quality of drug care or otherwise harm competition in prescription drug markets.

In addition to the brand-name switch programs of pharmaceutical companies, managed care organizations offer similar programs for generic drug use. Survey evidence indicates that HMOs are expanding their use of incentive payments and programs to increase the use of

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<sup>50</sup> For example, Miles Inc. reached settlement agreements with several state attorneys general, who questioned whether its rebate program for Adalat CC violated consumer protection laws. The settlements barred Miles from offering similar rebate programs. Upjohn Co. ended its program of disseminating information about diabetes drugs after the FDA warned the company that its program failed to provide information to consumers about the risks of switching brand-name drugs. For additional information about these switch programs, see Tanouye (1994) and Ukens (May 1994).

<sup>51</sup> Pharmacists who receive rebates on a selective set of brand-name drugs could steer patients toward these drugs even though consumers might otherwise receive higher quality or lower-priced alternatives, including generic substitutes for prescribed name-brands. This could occur if pharmacists are not good agents for consumers. For a further discussion of agency issues in the retail dispensing of prescription drugs, see Masson and Steiner (1985).



generic alternatives to brand-name drugs.<sup>52</sup> Data from Muirhead (July 1995) indicates that in 1994, for example, between 18 and 25 percent of HMOs offered incentive programs to retail pharmacies, and between 8 and 12 percent of them paid extra fees to pharmacies for dispensing generic drugs (Table II.2).<sup>53</sup> The pharmacy incentive programs are one of several cost-containment techniques HMOs use to control health care costs as discussed in greater detail below.<sup>54</sup>

### **3. Medicaid Program Initiatives**

The joint federal-state Medicaid program currently provides prescription drug coverage in all 50 states to 38.7 million consumers, and expects to spend approximately \$12.9 billion dollars on prescription drugs in 1998 (i.e., over 15% of projected U.S. sales in 1998).<sup>55</sup> This program was established in 1966 to provide health care coverage to low-income groups,<sup>56</sup> and has utilized several mechanisms over the last 10 to 15 years to contain prescription drug

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<sup>52</sup> For a detailed discussion of HMO pharmacy incentives programs, see *CibaGeneva Pharmacy Benefit Report - 1995 Facts & Figures* (1995).

<sup>53</sup> The payment of extra fees for dispensing generic instead of brand-name drugs is one of several incentive programs used by HMOs. HMOs also offer extra fees to retail pharmacies that enforce drug formulary restrictions and consult with physicians about therapeutic drug alternatives.

<sup>54</sup> Another important way HMOs control costs is to obtain price discounts from drug companies. HMOs often receive these discounts for their efforts to shift market share away from other drugs to those drugs subject to the discount pricing. Chapter IV contains a more detailed discussion of issues surrounding discount pricing to HMOs and others.

<sup>55</sup> See *Industry Profile 1998* for this and other information about the Medicaid Program.

<sup>56</sup> Outpatient prescription drug coverage is optional under the Medicaid program, but all states and the District of Columbia provide this coverage. For a discussion of Medicaid program benefits, see the National Pharmaceutical Council's *Pharmaceutical Benefits under State Medical Assistance Programs* (Various Years).

**Table II.2**  
**HMO Pharmacy Incentive Programs**  
**for Dispensing Generics (1994 to 1996)**

Item	1994	1995	1996
Staff/Group HMOs Offering Extra Fees	11.8%	11.8%	17.6%
IPA/Network HMOs Offering Extra Fees	8.3%	13.9%	19.4%
Staff/Group HMOs With Incentive Programs	17.6%	N/A	29.0%
IPA/Network HMOs With Incentive Programs	25.0%	N/A	33.0%

Notes: These data are based on a survey of 53 HMO pharmacy directors, and contain estimates concerning the use of the different HMO incentives in 1996 relative to 1994. N/A means data are not available.

Source: Muirhead (July 1995).

costs.<sup>57</sup> These mechanisms were adopted by states in response to the increases in prescription drug costs and reductions in federal support for the Medicaid program. The mechanisms include the implementation of coverage limits, the use of copayments, and the use of restrictive drug formularies.<sup>58</sup> A large body of empirical research has focused on these changes, and has raised questions about their overall welfare effects. In particular, studies indicate that, although coverage limitations may lower Medicaid expenditures on drugs, they also cause substitution

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<sup>57</sup> Estimates indicate that federal and state governments are the largest consumer of prescription drugs, accounting for 10 to 15 percent of sales (See, Office of Technology Assessment, *Pharmaceutical R & D: Costs, Risks, and Rewards*. (1993).

<sup>58</sup> A coverage limit would apply if, for example, a Medicaid plan imposes a maximum of three prescriptions per month on plan recipients. A copayment would apply if recipients directly pay a specified amount for each prescription purchased under the Medicaid plan. Drug formularies are also used as a cost-containment measure by state Medicaid plans (For a description of the different types of drug formularies, see the discussion below on cost-containment mechanisms used by HMOs to control their drug expenditures).

into higher-cost, health care services.<sup>59</sup> The same research has found that copayments and coverage limits have reduced drug expenditures by state Medicaid plans by comparable amounts. Analyses of the impacts of restrictive formularies generally indicate that they do lower Medicaid expenditures on prescription drugs. Nonetheless, the quality of drug care could fall and substitution to other services such as hospital visits and physician services could rise as a result.<sup>60</sup> Another study of restrictive formularies has found some evidence indicating that restrictive formularies reduce overall welfare.<sup>61</sup> Others, however, are critical of the view that formulary usage causes substitution to higher-priced medical services or otherwise increases health care costs.<sup>62</sup> In fact, some commentators suggest that drug formulary usage can reduce costs, and, at the same time, enhance the overall quality of health care.<sup>63</sup>

More recent efforts at controlling Medicaid prescription drug expenditures involve two noteworthy initiatives. First, through passage of the Omnibus Budget Reconciliation Act of 1990 (OBRA), Congress attempted to control Medicaid costs by influencing prescription drug prices. In effect, OBRA requires drug companies to treat Medicaid recipients as a "most-

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<sup>59</sup> Researchers, in a series of papers, found that coverage limits reduced the consumption of drugs, but increased the consumption of other health care services and otherwise produced overall increases in health care expenditures (See, for example, Soumerai, et al. (1987)). For a summary of other studies of coverage limits by these authors, see the discussion in *Industry Profile 1996* (1996).

<sup>60</sup> For reviews of the extensive literature on the impacts of formulary restrictions, see Jang (1988) and Reede and Lingle (1988).

<sup>61</sup> See, Moore and Newman (1993).

<sup>62</sup> See, for example, Jones (1996).

<sup>63</sup> See Nash, Shulkin, Owerbach, and Owerbach (1992), Pearce and Begg (1992), and Shepherd and Saltzman (1994).

favored-nation" (MFN) class by compelling companies to provide state Medicaid programs with rebates that are based on the lowest prices available to other customers.<sup>64</sup> More recently, Congress passed the Veterans Health Care Act, and extended similar rebates to the Department of Veterans Affairs and to public health clinics.<sup>65</sup>

Second, as part of an effort to control overall Medicaid expenditures, states continue to increase their reliance on managed care organizations (Table II.3). Almost all state programs have used HMOs and enrollment in HMOs has increased to 15.3 million Medicaid recipients in 1997. In addition to receiving rebates under the best price provisions, Medicaid programs control drug expenditures by enrolling recipients in HMO plans that offer capitated drug benefits to enrollees. Under some of these plans, the drug benefits are integrated into the per-person rate that the state pays to the HMO.<sup>66</sup> The use of these and other cost containment measures by HMOs is consistent with their overall growth as described below

### **C. The Rise of Cost-Containment Institutions**

Managed health care organizations, including health maintenance organizations (HMOs), preferred provider organizations (PPOs), and hybrid plans,<sup>67</sup> continue to expand in competition

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<sup>64</sup> This discounted price is referred to as the "best price". The rebate could exceed the discount to the lowest price customer since it depends on the higher of (1) a fixed percentage of average price, or (2) highest discount off of average price. For a discussion of this issue, see United States General Accounting Office, *MEDICAID - Changes in Drug Prices Paid by HMOs and Hospitals Since Enactment of Rebate Provisions*. (1993).

<sup>65</sup> See, Boston Consulting Group (1993).

<sup>66</sup> For a discussion of the use of capitated drug benefits and other cost containment devices by Medicaid programs, see *Industry Profile* (1998).

<sup>67</sup> The role of pharmacy benefit managers (PBMs) as prescription drug cost-containment institutions is discussed in Chapter III.

**Table II.3**  
**State Medicaid Plans and Their Use of HMOs**

Item	1981	1997
Medicaid Recipients Enrolled in HMOs	280,000	15,300,000
Percent of Medicaid Recipients in HMOs	1.0%	48.0%
State Medicaid Programs with HMO Experiments	4 States	Almost All States

Source: PhRMA. *Industry Profile* (1998).

with other third-party health insurance suppliers.<sup>68</sup> These institutions possess incentives to control drug and other health care costs, and utilize several strategies to accomplish this.

#### 1. Growth of Managed Care Organizations

The rise of managed care organizations, particularly HMOs, is often traced to the Health Maintenance Organization Act of 1973, which provided funds to encourage the entry of HMOs into health care markets.<sup>69</sup> Table II.4 reveals that enrollment in these institutions grew significantly during the 1980s and 1990s. In fact from 1980 through 1996 enrollment in all HMOs increased from 9.1 to approximately 77 million enrollees. It is also noteworthy that enrollment in these institutions expanded relative to enrollment in traditional fee-for-service plans, increasing from approximately 5 percent of all consumers with private health care

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<sup>68</sup> For discussions of the evolution of managed care organizations in drug and other health care markets, see Ito (1992) and Baker and Corts (1996). For discussions of competition between managed care organizations and traditional insurance providers in health insurance and other markets, see Baker and Corts (1996) and Goldman (1995).

<sup>69</sup> For a discussion of the evolution of HMOs, see Ross (1996).

**Table II.4**  
**HMOs and HMO Enrollment**  
**(1980 to 1997)**

Year	Number of HMOs	HMO Enrollment (1000s)
1980	236	9,100
1985	393	18,894
1988	659	33,715
1990	610	37,538
1992	562	44,373
1996	749	77,300
1997	N/A	87,300

Note: N/A means not available.

Sources: *Statistical Abstract of the United States* (Various Years), "HMOs: An Industry Snapshot." (1995), "HMO Enrollment Doubles Since 1990." (1998), and Findley (1997).

insurance in 1980 to some 27 percent in 1994.<sup>70</sup> Further, Table II.5 reveals that the 10 largest HMOs account for 47.9 percent of the total enrollment in these institutions, while the top 4 account for 30.7 percent of enrollment. This makes HMOs, both as a group and individually, large consumers of health care services and prescription drugs.<sup>71</sup>

At the end of 1993, approximately 90 percent of all HMO enrollees received prescription drug benefits, and some 99 percent of HMOs offered prescription drug coverage benefits.<sup>72</sup> Data

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<sup>70</sup> These percentages derive from data in U.S. Department of Commerce, *Statistical Abstract of the United States*. (Various Years).

<sup>71</sup> The four major types of HMOs are: (1) the group-model HMO which enters contracts with identifiable groups of health care providers; (2) the IPA-model HMO which contracts with individual providers; (3) the network-model HMO which enters contracts with networks of health care providers; and (4) the staff-model HMO which operates clinics for the provision of outpatient services.

<sup>72</sup> See, Muirhead (November 1994).

**Table II.5**  
**The 10 Largest HMOs (1997)**

HMO	Enrollees (Millions)	Segment Share
Blue Cross and Blue Shield	11.0	12.6%
Kaiser Foundation Health Plans	7.8	8.9%
Aetna/U.S. Healthcare	4.0	4.6%
PacifiCare/FHP International	4.0	4.6%
United HealthCare	3.7	4.2%
Health Systems International	3.4	3.9%
Prudential Health Care Plans	2.4	2.7%
Cigna Health Plans	2.3	2.6%
Humana	1.8	2.1%
Oxford Health Plans	1.5	1.7%
All Others	16.8	52.1%

Note: Segment share refers to share of total HMO enrollment, and uses 1997 enrollment of 87.3 million people as a basis for computing these shares (See, Table II.4).

Source: *Market Share Reporter* (1999) and Findlay (1997).

from 1994 indicate that managed care organizations account for a majority of all drug prescriptions. For example, during the first half of 1994, managed care institutions accounted for 544 million out of a total of 999 million prescriptions, or more than 54 percent of all prescriptions dispensed during this time period.<sup>73</sup> Containing the costs of these prescriptions is an important function of managed care organizations.

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<sup>73</sup> For these and other data, see "An Exclusive Quarterly Report on the Rx Market from IMS America." (1994).

## 2. Managed Care Cost-Containment Initiatives

Managed care organizations apply two broad strategies to control the costs of prescription drugs.<sup>74</sup> They attempt to control the prices that they pay for prescription drugs and they attempt to place limits on the drugs that are used to treat specific conditions.<sup>75</sup>

### a. Exercising Control over Price

HMOs use several measures to control either directly or indirectly their expenditures on prescription drugs. They negotiate price discounts with drug companies and reimbursement rates with retail pharmacies; and they also use prescription drug capitation programs.<sup>76</sup> In addition to bargaining for discounts from drug companies, HMOs also control drug costs by negotiating discounts on reimbursements to retail pharmacies. A survey of HMOs found that they paid 12.7 percent less than the average wholesale price paid by chain pharmacies and 12.1 percent less than the price paid by independent pharmacies.<sup>77</sup> The same survey found that over half of the HMOs offered mail-order pharmacy services, controlling prescription drug costs by vertically integrating into the provision of retail distribution services.

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<sup>74</sup> The literature on the economic impacts of managed care organizations in prescription drug markets contains several descriptive treatments focusing some attention on how these organizations enhance competition among pharmaceutical companies (See, for example, Cohen (1996), Pathak and Escovitz (1996), and Shah (1996)).

<sup>75</sup> For a discussion of the influence of HMOs on prescription drug prices and on drug usage patterns, see Keating (1997).

<sup>76</sup> Drug discounts to HMOs and prescription drug capitation programs, while summarized in this section, are topics discussed in greater detail in Chapters IV and III, respectively.

<sup>77</sup> See, *CibaGeneva Pharmacy Benefit Report - 1995 Facts & Figures* (1995).



HMOs also apply prescription drug capitation models to control costs. Unlike coverage under the traditional fee-for-service reimbursement programs, capitation programs for prescription drugs attempt to distribute the risks inherent in drug usage among payers and providers, while, at the same time, providing these organizations with incentives to control drug costs. For payers, drug capitation contracts reduce the uncertainty associated with their reimbursement obligations for prescription drugs since reimbursement levels are determined by the capitated rate structure of the contracts. By agreeing to particular capitated rates, pharmaceutical companies assume some of the financial risk of providing prescription drugs to consumers. Pharmaceutical companies could suffer losses if prescription drug consumption exceeds expectations and capitated payments by payers are not sufficient to cover the costs incurred by these drug companies. By sharing this risk of excessive drug consumption through the risk-sharing contracts described below, payers and drug companies both have incentives to control prescription drug usage and costs, even though drug companies do not themselves apply the cost-containment initiatives used by HMOs and others to directly control drug consumption. This is accomplished by applying any of several capitation models to drug benefits design,<sup>78</sup> including: (1) fixed-price capitation models under which payers reimburse providers for all drug usage on a per person, per month or per prescription basis; (2) percentage-based capitation programs under which payers and providers negotiate reimbursement limits on the basis of some percentage of health insurance premiums; and (3) several hybrid models, including capitation contracts with cost-sharing provisions.<sup>79</sup>

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<sup>78</sup> For discussions of various capitation models, see Cave (Winter 1996), Coyne and Simon (1996), and Fromberg (1996).

<sup>79</sup> Under this model, payers reimburse for prescription drug usage up to a negotiated level, but the contracts contain provisions for sharing the costs of drug usage beyond specified levels.

With some form of fixed payment and other risk sharing provisions, capitation contracts provide incentives for payers and drug companies to control the costs of utilizing prescription drugs, and require risk sharing between these groups.<sup>80</sup> Negotiation of capitated rates, performance requirements, and other risk sharing provisions requires substantial information in a number of areas. Information on drug utilization and effectiveness is needed to evaluate the risks, costs and benefits of alternative drug and non-drug treatments. Data on the demographic characteristics of the patient population and actuarial risk are needed to assess drug demand characteristics. Access to suppliers of broad lines of drugs is necessary to meet the diverse needs of a given patient population. HMOs need the capability to manage complex bases of information to minimize both over and under-utilization of drug treatments and to otherwise control drug costs.<sup>81</sup>

In light of the foregoing considerations, it is not surprising that capitated rates vary across HMOs, and that the use of capitated contracts varies across regions of the country. For example, in a survey of HMOs, capitated rates for pharmacy services ranged from 6 to 9 percent of premiums for percentage-based contracts and from \$8 to \$12 per person, per month for fixed-price contracts.<sup>82</sup> Further, while 61.4 percent of specified HMO services in California and

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<sup>80</sup> For example, with fixed-price capitation, payers have incentives to control drug utilization rates and costs in order to negotiate favorable capitated rates, while providers have incentives to control costs since they no longer are compensated on a fee-for-service basis. Further, under these models, providers assume much of the risks, including risks of excessive drug usage by a disease prone subset of the population. For different discussions of the various risk and incentive issues arising from the use of capitated contracts, see Cave, Noel, and Munson (1996), Fromberg (1996), Sulger (1996), and Terrill and Munz (1996).

<sup>81</sup> The rise of information technology, as discussed in Chapter III, facilitates the collection and processing of these data.

<sup>82</sup> See, Coyne and Simon (1996).

Pacific Northwest were subject to capitated rates, only 24 percent were governed by capitation arrangements in the East South Central Region.<sup>83</sup>

**b. Exercising Control over the Use of Drugs**

As a complement to controlling the cost of specific drugs, HMOs utilize several strategies to exercise control over which drugs are used to treat specific conditions. The strategies include the use of:

- (1) Drug Formularies, which are lists of prescription drugs covered under benefits plans;<sup>84</sup>
- (2) Generic Substitution Programs, which are programs that require substitution of generic for name-brand drugs;
- (3) Therapeutic Substitution Programs, which are programs that require substitution among drugs within a particular therapeutic class, where those drugs differ in their chemical compositions;
- (4) Drug Utilization Review (DUR), which is an initiative intended to monitor a physician's prescribing behavior in an effort to insure that the lowest cost/highest quality prescription drugs are made available to plan enrollees; and
- (5) Step-Care Programs, which are programs that require physicians to provide drug treatment in a systematic fashion, beginning with low-cost therapies first.

Some of the details of the strategies are noteworthy. To encourage substitution to lower-priced generic drugs, HMOs use differential dispensing fees and copayments. For example, in a survey of 71 HMOs, information indicated that these managed care institutions paid an average

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<sup>83</sup> Arguably, the more prevalent use of capitation arrangements in the Western U.S. occurs because the first HMOs were formed there (For a further discussion of regional differences in the use of capitation arrangements by HMOs, see Kazel (1996)).

<sup>84</sup> These range from "open" to "closed" formularies. Open formularies apply to drug benefit plans that cover drugs both on and off the formulary. Closed formularies apply to drug benefit plans that cover only formulary drugs.

1994 retail pharmacy dispensing fee of \$2.62 for brand-name prescriptions and \$2.67 for generic drugs.<sup>85</sup> These HMOs also set the prescription drug copayments at an average of \$6.67 for name-brand drugs and \$4.91 for generic drugs during the same year. A more recent survey of HMOs estimated that 71.7 percent of them used variable copayment programs in 1998 to control prescription drug costs.<sup>86</sup> Further, in addition to utilization review programs for controlling drug use, prior authorization programs for drugs are also popular cost-containment devices at HMOs. These programs mandate advance approval before using certain prescription drugs as treatment options.<sup>87</sup>

Although different HMOs may emphasize different cost-containment measures, most of the measures were being used by the majority of the HMOs participating in a 1994 survey (Table II.6). Generic substitution, DUR, and prior authorization were the most popular cost-containment strategies in 1994. In all cases these strategies were used by more than 80 percent of the HMOs. Therapeutic substitution programs were used by only 33.8 percent of these HMOs and ranked as the least popular cost-containment strategy among these HMOs in 1994. Although it is not obvious why HMOs utilized therapeutic substitution programs to a lesser degree than other cost-containment mechanisms in the recent past, it is possible that these

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<sup>85</sup> See, *CibaGeneva Pharmacy Benefit Report - 1995 Facts & Figures* (1995).

<sup>86</sup> See, *Novartis Pharmacy Benefit Report - Trends & Forecasts* (1997).

<sup>87</sup> A variety of prior authorization programs are used to control drug costs. For example, a program might require advance approval before a prescription could be filled with a brand-name version of a particular drug (For a further discussion of prior authorization programs for prescription drugs, see Conlan (July 1995)).

**Table II.6**  
**Cost-Containment Programs by HMO Type**  
**(1994)**

Strategy	Staff HMOs	Group HMOs	IPA Model	Network HMOs	All HMOs
No. Drugs on the Formulary	1133	743	682	1138	857
Closed Formulary Use	66.7%	53.8%	38.7%	40.0%	47.8%
Generic Substitution	87.5%	85.7%	87.1%	90.0%	87.3%
Therapeutic Substitution	56.3%	42.9%	22.6%	20.0%	33.8%
DUR	81.3%	71.4%	83.9%	100.0%	83.1%
Step-Care Programs	62.5%	57.1%	41.9%	50.0%	50.7%
Prior Authorization	68.8%	85.7%	80.6%	100.0%	81.7%

Notes: Data derive from a sample of 71 HMOs. Data on the number of formulary drugs are averages of all sample HMOs of a given type. All percentages refer to the percentage of HMOs using a given cost-containment technique.

Source: *CibaGeneva Pharmacy Benefit Report - 1995 Facts & Figures* (1995).

programs are more costly to administer than others.<sup>88</sup>

More recent data indicate that the adoption of cost control measures by HMOs is increasing. A survey of HMOs sponsored by Novartis Pharmaceuticals Corporation estimated that in 1998: (1) 91.3 percent of these HMOs used generic substitution programs; (2) 87 percent

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<sup>88</sup> For example, unlike generic substitution programs, therapeutic substitution programs require physician approval before changing a prescription from one therapeutic alternative to another. HMOs incur costs in administering programs that obtain physician approval of a therapeutic substitute, but avoid these costs using generic substitution programs. Other factors equal, these additional costs could make therapeutic substitution programs less profitable for some HMOs than other cost-containment mechanisms, including generic substitution initiatives. Staff model HMOs, however, may be able to avoid many of these costs by requiring physicians to agree in advance that particular therapeutic substitutions will apply unless they demonstrate particular needs for specific prescription drugs.

of them applied prior authorization programs; and (3) 71.7 percent employed therapeutic interchange programs to control drug costs.<sup>89</sup> All of these data indicate that the use of cost-containment strategies by managed care organizations is widespread. Nevertheless, the effectiveness of these strategies depends critically on information technology. As discussed in Chapter III, the computerization of drug delivery and mechanisms for the electronic interchange of prescription drug data facilitate the real-time substitution required by the generic and therapeutic substitution programs used by HMOs.

#### **D. Vertical and Horizontal Consolidation in the Prescription Drug Industry**

Faced with excess capacity in sales forces, marketing, and possibly product development,<sup>90</sup> pharmaceutical companies have been consolidating assets by merging with rival brand-name and generic suppliers, and by integrating vertically, particularly into the provision of pharmacy benefit management (PBM) services. During the last 10 years, according to PhRMA, "... the industry has been characterized by larger and more frequent acquisitions and mergers."<sup>91</sup>

##### **1. Vertical Integration into PBM Markets**

Markets for PBM services contain a large number of suppliers, but the largest PBMs in the U.S. account for significant portions of all of the lives covered by these organizations. For example, a 1996 study identified 107 PBM organizations in the U.S., and provided information

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<sup>89</sup> See, *Novartis Pharmacy Benefit Report - Trends & Forecasts* (1997).

<sup>90</sup> In light of increases in R & D expenditures (See Table A.3 in Appendix A), it might be difficult to establish that pharmaceutical companies have excess product development capacity. Plans to rationalize this capacity, however, could motivate some of the horizontal consolidation in the drug industry.

<sup>91</sup> See, *Industry Profile* (1996). For another discussion of ongoing merger and acquisition activity in the drug industry, see Breindel (1994).

to calculate 4, 8 and 20 firm concentration ratios of 44.4, 62.9, and 87.5 percent, respectively.<sup>92</sup> More significantly, vertical integration by drug companies into markets for PBM services has transformed the structure of these markets,<sup>93</sup> especially since drug companies now own or have some affiliation with PBMs that collectively account for a majority of PBM activity. In fact, data on vertical integration in Table II.7 indicate that drug companies owned or had affiliations with PBMs that account for some 53.4 percent of all covered lives in the U.S. and 70.8 percent of drug prescriptions dispensed domestically during the fourth quarter of 1994.<sup>94</sup> These acquisitions of PBM operations required significant investments by drug companies. To illustrate the financial investments involved in these transactions, the Merck/Medco, SmithKline/Diversified, and Lilly/PCS combinations were priced at \$6.6, \$2.3, and \$4 billion, respectively.<sup>95</sup> Commentators suggest a number of motivations for these transactions, including: (1) a desire by drug companies to increase prescription drug market shares; (2) efforts by drug companies to consolidate the resources necessary to provide new services that include disease state management and capitated drug programs; and (3) a desire by drug suppliers to diversify

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<sup>92</sup> See, Gondek (1996). The concentration ratios are based on lives covered by these PBMs.

<sup>93</sup> For a discussion of vertical integration in the drug industry, see Dodd (1995).

<sup>94</sup> In other words, in the U.S., independent PBMs account for 46.6 percent of covered lives and 29.2 percent of prescriptions. Of course, the extent of PBM ownership by drug companies has declined with the recent sale of Lilly's PCS unit to Rite Aid Corporation.

<sup>95</sup> See United State General Accounting Office, *Pharmacy Benefit Managers, Early Results on Ventures With Drug Manufacturers* (1995) for a more detailed discussion of the acquisition of PBMs by pharmaceutical companies.

**Table II.7**  
**Drug Company Acquisitions/Alliances with PBMs**

Drug Company	PBM	Date of PBM Acquisition	PBM Share of Covered Lives	PBM Share of Prescriptions
Merck & Co.	Medco Containment	1993	14.7%	16.2%
SmithKline Beecham	Diversified Pharmaceutical	1994	8.1%	9.4%
Eli Lilly & Co.	PCS Health Systems	1994	17.5%	37.8%
Pfizer, Inc.	Caremark International	1994(A)	4.7%	4.6%
Pfizer, Inc.	Value Rx	1994(A)	8.4%	2.8%
Bristol-Myers Squibb	Caremark International	1994(A)	4.7%	4.6%

Notes: Data on covered lives are for 1996, while data on prescriptions are for the fourth quarter of 1994. Prescription data exclude Medicaid prescriptions. A refers to an alliance between a drug company and a PBM.

Sources: Gondek (1996) and *Market Share Reporter* (1996).

product and service offerings in an evolving cost-containment environment.<sup>96</sup> These motivations, as well as the antitrust implications and impacts of vertical integration in the drug industry, are the subjects of additional discussion in Chapter V.

## 2. Horizontal Acquisitions and Mergers in the Drug Industry

The data in Table II.8 reveal that the pharmaceutical industry has experienced significant horizontal consolidation in the form of acquisitions and mergers of drug companies, particularly

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<sup>96</sup> See, "Doubts Emerge About Drug Industry Mergers." (1994), Gondek (1996), Hoffman and Garrett (1995), Keating (1997), and United States General Accounting Office, *Pharmacy Benefit Managers, Early Results on Ventures With Drug Manufacturers*. (1995).



**Table II.8**  
**Selected Acquisitions and Mergers**  
**of Major Brand-Name Drug Companies (1994 to 1997)**

<b>Transaction Date</b>	<b>Drug Company #1</b>	<b>Drug Company #2</b>	<b>Combined Entity</b>	<b>Transaction Value</b>
1997	Hoffmann-La Roche	Boehringer Mannheim	Hoffmann-La Roche	\$11.0 Billion
1997	Nycomed	Amersham	Nycomed Amersham plc	\$1.06 Billion
1996	Ciba-Geigy Ltd.	Sandoz Ltd.	Novartis AG	\$63.0 Billion
1995	Glaxo plc	Wellcome plc	Glaxo-Wellcome Inc.	\$14.1 Billion
1995	Pharmacia AB	UpJohn Co.	Pharmacia & UpJohn, Inc.	\$13.0 Billion
1995	Hoechst, A.G.	Marion Merrill Dow, Inc.	Hoechst Marion Rousell	\$7.0 Billion
1995	Rhone-Poulenc Rorer	Fisons	Rhone-Poulenc Rorer	\$2.9 Billion
1995	BASF	Boots Pharma	BASF	\$1.3 Billion
1995	Bristol-Myers Squibb Co.	Calgon Vestal Laboratories	Bristol-Meyers Squibb Co.	\$261 Million
1994	American Home Products	American Cyanamid	American Home Products	\$9.7 Billion
1994	Pfizer	SmithKline Beechman (Animal)	Pfizer Animal Health	\$1.4 Billion
1994	Roche Holdings Ltd.	Syntex Corporation	Roche Holdings Ltd.	\$5.3 Billion

Note: The value of the Ciba-Geigy/Sandoz merger was based on the value of the stock involved in the transaction. The value of Pharmacia AB and UpJohn Co. combination was estimated at \$13 billion. Some of the other values are approximations.

Sources: Breindel (1994), PhRMA. *Industry Profile* (1996 and 1998), Seiden (1996), Weber (1994), and *The Merger Yearbook U.S./International Edition* (1994-98).

since 1994.<sup>97</sup> The more recent acquisitions and mergers followed a similar consolidation trend in the late 1980s and early 1990s that involved several combinations, including SmithKline and Beecham, Roche Holdings Ltd. and Genentech, Inc., Bristol-Myers and Squibb, Boots Pharmaceutical and Flint and American Home Products and A.H. Robbins.<sup>98</sup>

Horizontal consolidation in the drug industry also involves generic drug suppliers. Generic drug companies have been acquired by brand-name drug companies, and there have been consolidations within the generic segment itself. Transactions involving generic companies included: (1) Marion Merrell Dow Inc.'s acquisition of The Rugby Darby Group, Inc. for some \$300 million in 1993; (2) the combination of IVAX Corporation and Zenith Laboratories, Inc. in 1994 for approximately \$593 million; (3) Hoechst Celanese Corp.'s acquisition of Copley Pharmaceutical Inc. for \$546 million in 1993; (4) Watson Pharmaceuticals Inc.'s acquisition of Circa Pharmaceuticals Inc. for over \$600 million in 1995; and (5) the 1995 merger of Marsam Pharmaceuticals Inc. and Schein Pharmaceutical Inc. valued at \$244 million.<sup>99</sup>

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<sup>97</sup> Strategic alliances in the pharmaceutical industry also increased, rising from 120 in 1986 to an average of over 370 alliances during the 1992 through 1995 period (See PhRMA's *"Corporate Welfare" And The Pharmaceutical Industry* (1996) for additional information on these alliances). Examples of these alliances are: (1) drug development joint ventures like that between American Home Products and Oncogene Science, Inc. to develop gene transcription based drugs; (2) marketing joint ventures like that between Astra and Merck & Co to market an anti-ulcer drug in the U.S.; (3) joint promotion ventures like the SmithKline Beechman/Adria Laboratories agreement to co-promote Mycobutin for the treatment of a bacterial infection in HIV patients; and (4) license agreements that include the Hoffman-LaRoche/Hybridon, Inc. agreement to develop hepatitis and other viral treatments. (For a discussion of these and other alliances, see Breindel (1994)).

<sup>98</sup> For descriptive discussions of this merger activity, see Pursche (1995) and Watanabe (1995).

<sup>99</sup> See, *The Merger Yearbook, U.S./International Edition* (Various Years).

As suggested earlier, commentators point to a number of motivating factors underlying ongoing horizontal merger activity, including the desire of major brand-name drug companies to establish a significant presence in the growing generic segment of the drug industry.

Pharmaceutical firms may also want to reduce excess sales and marketing capacity brought about by the shift from traditional detail sales promotion to contract sales to HMOs and other institutions. In addition, firms may wish to reduce possible excess drug development capacity in an environment where drug formulary usage limits the total number of drugs available to consumers subject to formulary restrictions.<sup>100</sup> In contrast to these efficiency rationales, other commentators raise anticompetitive concerns about horizontal mergers in the drug industry. Chapter V discusses possible anticompetitive motivations for these mergers. Regardless of underlying motivations, horizontal mergers and other transactions continue to alter the supply-side structure of prescription drug markets.<sup>101</sup>

#### **E. Summary of Industry Changes**

The pharmaceutical industry faces ongoing evolutionary changes that are altering the structure of prescription drug markets. Table II.9 summarizes the major public policy, institutional, and private market changes at issue in this evolutionary environment. These changes and other considerations, including the application of information technology to the computerization of prescription drug delivery and the substantial R & D and market risks within

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<sup>100</sup> For discussions of these and other motives for horizontal drug industry mergers, see Quickel (1995), Pursche (1995), and Seiden (1996).

<sup>101</sup> For descriptive and other information on these and other mergers in the pharmaceutical industry, see *The Merger Yearbook, U.S./International Edition* (Various Years).

**Table II.9  
Summary of Major Changes  
in the Drug Industry**

<b>Public Policy/Market Change</b>	<b>Prior Industry State</b>	<b>New Industry State</b>
Real R&D Expenditures Per NCE	\$135 million in 1985	\$250 million in 1995
FDA Approval Times For NCEs	14.2 years in the 1980s	14.8 years in the 1990s
Overall Four-Firm Concentration Ratio	26% in 1982	30% in 1995
Generic Prescription Drug Volume Share	18.6% in 1984	44.3% in 1997
Patent Terms with Waxman-Hatch and Uruguay Round	17 years prior to Waxman-Hatch	Up to 22 years after Waxman-Hatch
Medicaid Enrollees in HMOs	280,000 in 1981	15.3 million in 1997
States with HMO Experiments	4 in 1981	Almost all in 1997
Number of HMOs	236 in 1980	749 in 1996
HMO Enrollment	9.1 million in 1980	87.3 million in 1997
Drug Company Control of PBMs - Covered Lives Basis	0% prior to vertical integration	53.4% in 1996
Drug Company Control of PBMs - Prescription Basis	0% prior to vertical integration	70.8% in 1994
Strategic Alliances Between and Among Drug Companies	120 in 1986	635 in 1997
Transaction Value of Horizontal Consolidation in the Drug Industry	N/A	Over \$100 billion in 1995 and 1996.

Notes: NCE represents new chemical entities, while PBM refers to pharmacy benefit managers. The FDA approval times include the time devoted to the pre-clinical and clinical stages of drug development. Table A.3 in Appendix A demonstrates that most of the increase in FDA approval times reported above involves pre-clinical and clinical drug development. FDA review of drug applications took an average of approximately 2 ½ years in both the 1960s and the 1990s. N/A means no data are readily available. Information in this table relies on data and data tables in Chapter II and Appendix A.

the drug industry,<sup>102</sup> give rise to several competitive and antitrust implications that are discussed in greater detail in Chapters IV and V.<sup>103</sup>

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<sup>102</sup> Appendix A contains a discussion of the R & D and market risks associated with the drug development process.

<sup>103</sup> Chapters IV and V focus attention on the competitive and antitrust implications of these major industry changes. Drug companies, however, face other changes that include: (1) an increase in FDA approvals of prescription drugs for over-the-counter (OTC) usage; (2) an increase in direct-to-consumer advertising; and (3) consolidation at the retail distribution level. These changes also raise consumer protection and antitrust issues, but they are beyond the scope of the present study.



## Chapter III

### Information Technology and Its Application to Prescription Drug Markets

#### A. Introduction

This chapter focuses on three aspects of the emerging role of information technology in the changing drug industry.<sup>104</sup> The first aspect is the dramatic computerization of prescription drug distribution and delivery. The discussion highlights the critical role of pharmacy benefit managers (PBMs) in encouraging this trend.

Second, this chapter explains how information technology has combined with other industry changes to generate efficiencies and enhance competition in drug markets.<sup>105</sup> In

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<sup>104</sup> For a discussion of the importance of computer technology in the distribution of prescription drugs, particularly the development of on-line data exchange networks in the retail distribution segment of this industry, see Kathleen Gondek (1996). For other discussions of the use of information technology in the pharmaceutical industry, see Appleby (1995), *CibaGeneva Pharmacy Benefit Report - 1995 Facts and Figures* (1995), *Novartis Pharmacy Benefit Report - Trends & Forecasts* (1997), and "Study Advocates Integrated Care for Improved Outcomes." (1996).

<sup>105</sup> Information technology in prescription drug markets can create additional opportunities for drug manufacturers to share information. A well-developed literature suggests that information sharing among oligopolists, under certain conditions, could enhance competition among firms by lowering costs and could increase consumer and/or social welfare (See, Kirby (1988), Lee (1985), Shapiro (1986), and Vives (1984)). For a more recent discussion of conditions under which information sharing raises social welfare, see Malueg and Tsutsui (1996). Models of anticompetitive information exchanges also appear in the literature, but, as discussed in Chapter V, are likely to apply to prescription drug markets only under restrictive conditions.

particular, the use of information technology, especially by PBMs, could help counteract potential market failures that may arise when physicians fail to act in the best interests of their patients or third-party payers. In addition, information technology also helps reduce transactions and entry costs for market participants, thus potentially increasing competition among drug suppliers. Further, the marriage of industry changes and information technology could result in a more efficient allocation of drug treatments for disease states in the short run, without reducing the quality of health care.

Finally, this chapter explains how information technology advances the development of innovations that lead to the cost-effective substitution of prescription drug treatments for other health care services over the long run.<sup>106</sup> Substitution of drug for non-drug treatments may reduce costs without compromising the overall quality of health care. A number of other institutions, including standard setting and promoting organizations like the National Council for Prescription Drug Programs, Inc. (NCPDP) and the American Society for Automation in Pharmacy (ASAP) may also foster efficiencies in the use of information technology to distribute prescription drugs, and so contribute to more efficient drug distribution. NCPDP develops standards for processing and exchanging prescription drug data in the pharmacy service segment of the industry, while ASAP promotes the use of standards for the electronic exchange of prescription data. Standardization, like the other innovations discussed below, may reduce the cost of distributing prescription drugs at retail pharmacies.

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<sup>106</sup> For example, HMOs, PBMs, and drug companies use information technology to offer a range of disease state management programs, and to evaluate the cost and effectiveness of alternative treatments for a variety of illnesses.



## **B. Information Technology in the Pharmaceutical Industry**

The computerization of prescription drug distribution at points of purchase in retail or mail-order pharmacies<sup>107</sup> takes place in several stages of the industry and requires the participation of a number of different economic agents. The applicable technology permits real-time substitution among competing drug treatments in the short run and enhances long term competition between drug companies and competing health care providers as discussed below.

### **1. The Computerization of Drug Distribution**

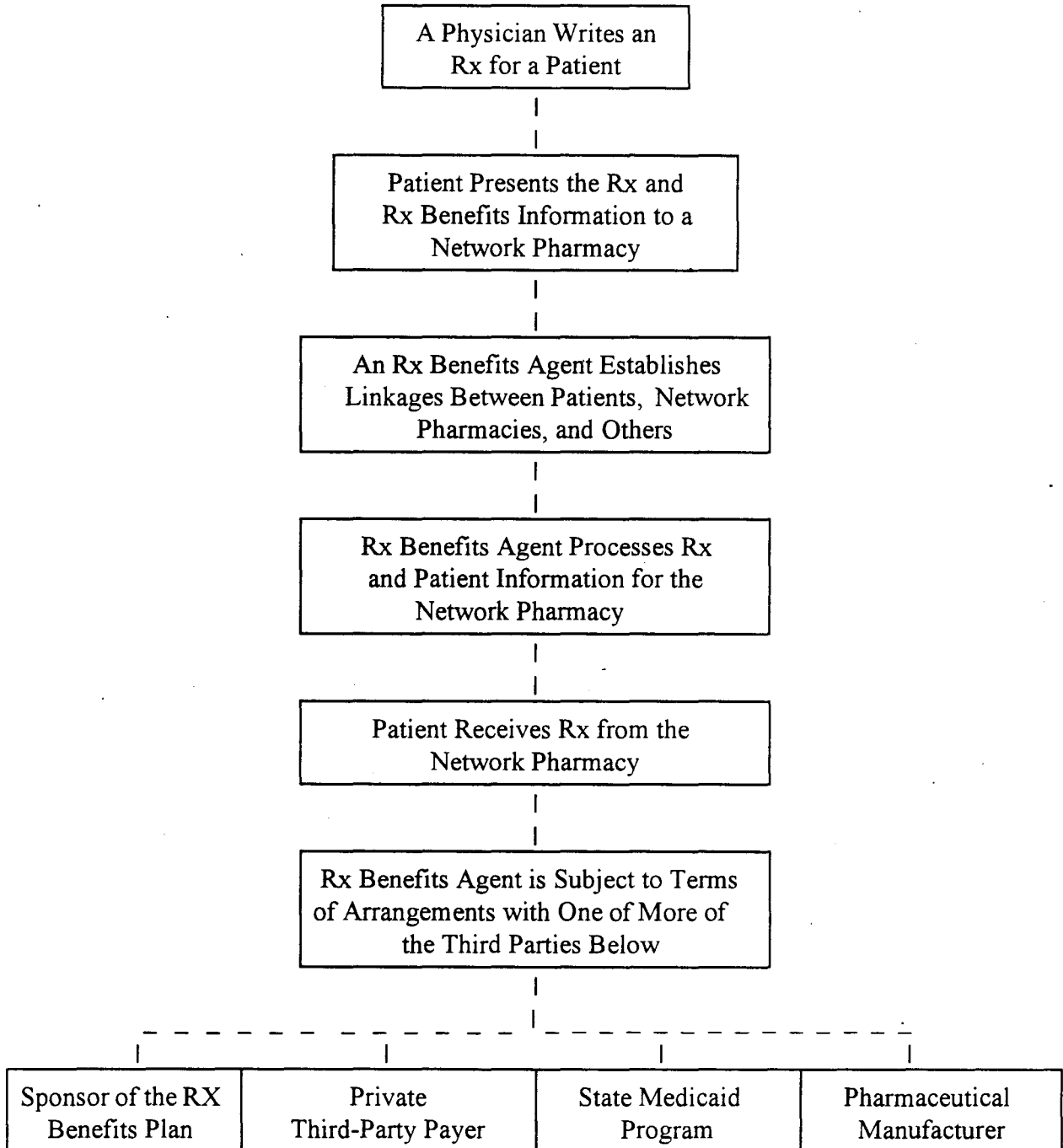
The model depicted in Figure III.1 identifies the various stages of the application of information technology to the retail distribution of prescription drugs.<sup>108</sup> Although the process begins when a physician writes a prescription for a patient, Figure III.1 makes clear that several critical arrangements must already exist to process patient prescriptions at the retail level. These arrangements are established by a central prescription drug benefits agent, commonly referred to

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<sup>107</sup> Mail order pharmacies, particularly the pharmacies under the control of PBMs, continue to expand in competition with chain and independent retail pharmacies. According to one account, some 80 percent of PBMs now offer mail order pharmacy services (See, Gemignani (1996)). Mail order distribution, however, still accounts for a relatively small share of prescription drug distribution, amounting to about 6.4 percent in 1995 compared to 45 percent for retail pharmacies in the same year (See, *IMS America Business Watch* (1996)). Other outlets for prescription drugs include HMOs, hospitals, and home health care companies.

<sup>108</sup> This model stems from discussions of automation of retail drug delivery in numerous trade publications and from annual reports from a number of PBMs, including: (1) Express Scripts, Inc.; (2) Merck-Medco Managed Care, Inc.; and (3) PCS Health Systems. It should be noted that this model does not apply to the distribution of all prescription drugs. Not all consumers receive prescription drug benefits, and not all prescriptions are processed through central benefits agents. For a detailed discussion of the scope of PBM activity, see Gondek (1996).

**Figure III.1  
A Model of Retail Pharmacy  
Prescription Drug Distribution**



as a PBM. The arrangements may be made with any of the third parties enumerated in Figure III.1.<sup>109</sup>

Once all PBM/third-party arrangements are in place, the process of computerized drug delivery involves several steps. First, a network pharmacist transmits patient and prescription benefits information to a central PBM computer. The PBM computer then records patient-specific information about the current transaction and compiles information from third-party contracts that then impacts on the processing of the prescription. PBM computers then transmit all relevant information back to the network pharmacist prior to dispensing the prescription drug.<sup>110</sup> These stages allow the pharmacist to dispense the prescription in accordance with the contractual arrangements between the PBM and third parties. The process usually takes a matter of seconds and typically involves interaction only between network pharmacy and central PBM computers.<sup>111</sup> A broader discussion of the critical role of PBMs follows.

## **2. Information Technology, PBMs and Their Contractual Relationships with Third Parties**

The structure of PBMs and their contractual relationships with retail pharmacies, plan sponsors, HMOs, and pharmaceutical companies highlight their use of information processing technology, and illustrate their cost-containment functions in prescription drug markets.

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<sup>109</sup> Obviously, this model does not establish all linkages, as patients and physicians also enter into contracts with third-party payers that govern Rx benefits coverage and physician conduct, respectively.

<sup>110</sup> In addition, the PBM processes reimbursement claims and submits rebate requests to drug companies for its clients, including HMOs who receive prescription drug rebates from drug companies.

<sup>111</sup> For discussions of the crucial role of PBMs in this process, and of the information and services PBMs provide to network pharmacies and others, see Jones (February 1996) and Gondek (1996).

a. **The Emergence and Functions of PBM Organizations**

PBMs developed in the 1970s and 1980s along with the emergence of prescription drug benefits in health care plans. PBMs evolved from a variety of different origins, including pharmacy claims processors, mail order pharmacies, and HMOs.<sup>112</sup> To perform their functions, PBMs had to form networks of retail pharmacies to dispense prescription drugs. Retail pharmacies had to make investments in computer technology. Such investments not only facilitated pharmacies' participation in PBM pharmacy networks, in some cases they paved the way for pharmacy chains to enter into the provision of PBM services.<sup>113</sup>

Figure III.2 outlines the major management and cost-control functions performed by PBMs.<sup>114</sup> With respect to management functions, PBMs provide pharmacists information on a variety of issues before drugs are dispensed to the patients. The information includes: (1) data on applicable copayments, coinsurance, or deductibles; (2) details relevant to any online claims adjudication; (3) concurrent drug utilization review (DUR) data on basic eligibility requirements, drug interactions, and adverse drug reactions; (4) details about any formulary restrictions; (5) data about any generic substitution requirements; and (6) information on brand-name and generic drug dispensing fees.<sup>115</sup>

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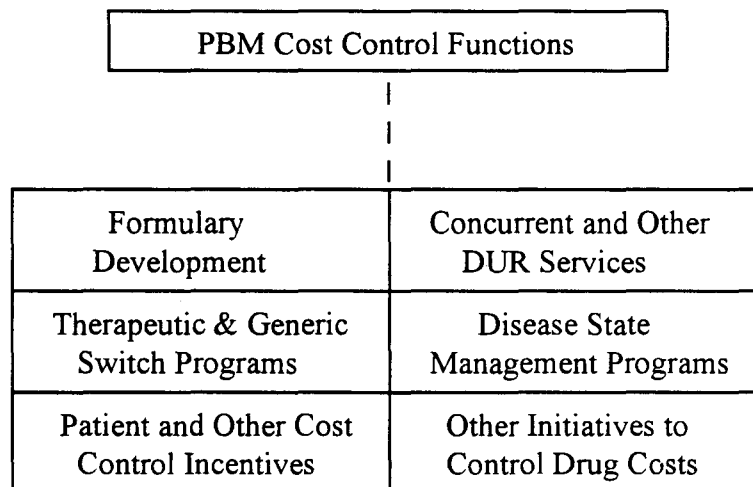
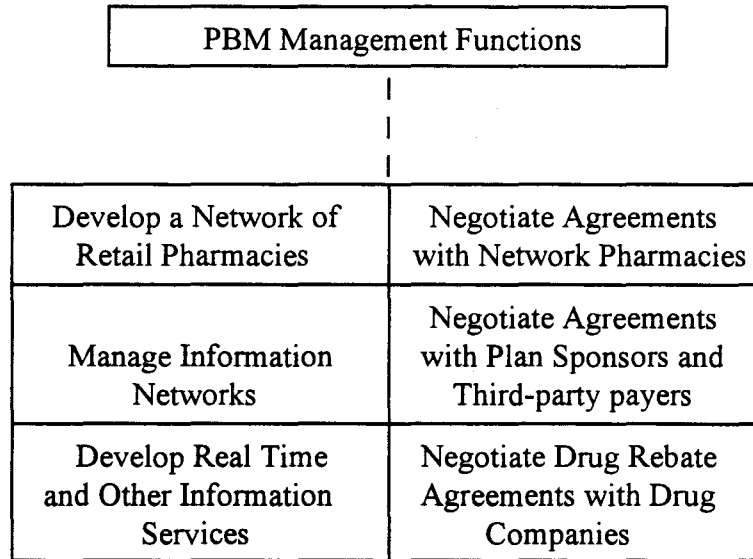
<sup>112</sup> Again, see Jones (February 1996) and Gondek (1996) for additional information on the historical evolution of PBMs.

<sup>113</sup> For example, in the first half of 1996, Genovese Drug Stores, Thrifty PayLess and Walgreen Co. entered the market with their own PBMs, adding to the eight or more PBMs operated by chain drug stores (Muirhead (July 1996)).

<sup>114</sup> Figure III.2 was adapted from information in a 1996 study of PBMs. For a more detailed discussion of the activities of PBMs, including those outlined in Figure III.2, see Gondek (1996).

<sup>115</sup> See the Express Scripts News Release "Pharmacy Benefit Program Features" (1996) and Gondek (1996) for additional information on the data that PBMs provide to pharmacists.

**Figure III.2  
PBM Management and Cost  
Control Functions**



With respect to cost control functions, PBMs supply a variety of services. For example, Express Scripts, Inc., a PBM that provided pharmacy benefits management services to approximately 8.6 million members in 1996,<sup>116</sup> offers both formulary management and mail-order pharmacy services. Among other services, the firm also provides prospective drug utilization review (PDUR) to control drug use before physicians write prescriptions, retrospective drug utilization review (RDUR) to improve drug treatments through analysis of prescription and usage patterns, and summary and analytical reports to clients to permit them to evaluate overall drug costs and usage.<sup>117</sup> More generally, data from a 1996 survey indicate that approximately 95 percent of the PBMs offer PDUR and RDUR services to their clients, but little information is available on the overall value of these services.<sup>118</sup>

Drug substitution and disease state management programs are two other key cost control initiatives used by PBMs. Many PBMs offer patients incentives to select generic instead of brand-name drugs, and they also operate mail order pharmacies to help facilitate therapeutic substitution programs and to monitor formulary compliance. PBMs also offer disease state management programs and provide other services as a means of controlling health care costs over the long term. For example, in 1995 Merck-Medco Managed Care, Inc. offered disease

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<sup>116</sup> See, Gondek (1996).

<sup>117</sup> See the Express Scripts News Release "Pharmacy Benefit Management" (1996) and the Express Scripts News Release "Pharmacy Benefit Program Features" (1996).

<sup>118</sup> See, Gondek (1996). This report also summarizes the cost savings attributable to PDUR and RDUR programs in 42 state Medicaid plans in 1994. The summary indicates that only 3 states reported annual cost savings from their PDUR programs in 1994 (e.g., Maryland reported cost savings of \$8.9 million), and that cost savings from RDUR programs ranged from \$6.5 thousand in Arkansas to approximately \$4.4 million in Louisiana during the same year.

management programs for a number of illnesses, including asthma, diabetes, high cholesterol, and ulcers.<sup>119</sup> In addition, according to 1996 information, Caremark's PBM then offered disease management programs for several disorders, including cystic fibrosis, hemophilia, and multiple sclerosis.<sup>120</sup> In part, these programs attempt to control long term costs by facilitating substitution of prescription drugs for other health care treatments when outcomes research indicates that such substitution is appropriate.<sup>121</sup> PBMs also undertake more direct initiatives to control drug costs, including the negotiation of drug price rebates as discussed below.

#### **b. Key Characteristics of PBM and Other Contracts**

The computerization of drug delivery depends critically on underlying contracts between cost-containment institutions like PBMs and HMOs and pharmaceutical companies. Since PBM and HMO contracts with drug companies have a direct impact on competition in drug markets, it is useful to focus on key provisions of these contracts. The discussion also distinguishes non-capitated from capitated contracts for prescription drugs.<sup>122</sup>

##### **i. Non-capitated Contracts**

Table III.1 lists some provisions commonly found in PBM/HMO contracts with drug companies. These contracts typically cover multiple brand-name prescription drugs and dosage

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<sup>119</sup> See, Merck & Co., *1995 Annual Report - Achieving the Full Potential of Managed Pharmaceutical Care* (1996).

<sup>120</sup> See, "Caremark at a Glance - Disease Management" (1996). At that time, Caremark's PBM also offered disease management programs for genetic emphysema, growth disorders, and ulcers.

<sup>121</sup> See, Muirhead (August 1995).

<sup>122</sup> The glossary at the end of this report describes these different types of contracts. Since the use of capitated contracts is a relatively new phenomenon, there does not appear to be any systematic information on the extent to which they are used as an alternative to non-capitated contracts.

**Table III.1**  
**Key Features of PBM/HMO**  
**Contracts with Drug Companies**

Item	Description
Product Coverage	Contracts often cover a number of specified prescription drugs and dosage forms.
Base Prices	Pricing metric that does not necessarily account for any discounts and rebates.
Formulary Rebates	Manufacturer rebates provided to PBMs for formulary management services undertaken by PBMs.
Cost Effectiveness Rebate	Manufacturer rebates provided to PBMs should PBMs meet some minimum volume requirements.
Retail Conversion Rebates	Manufacturer rebates provided to PBMs in support of some therapeutic substitution program.
Growth Rebates	Manufacturer rebates provided to PBMs who meet specified volume growth targets.
Maximum Rebates	Maximum total manufacturer's rebate.
MFN Provision	Contractual provision under which companies agree to grant most-favored-nation status to PBMs.
Usage Reports	Provisions requiring PBMs to maintain data on drug prices and usage for reporting purposes.

Notes: The items listed are for illustrative purposes. Terminology for the concepts underlying these items may vary across contracts.

forms, and many of their provisions are specific to particular drug products.<sup>123</sup> The price and rebate provisions often use "wholesale acquisition cost" (WAC) as a metric for determining the transaction prices for the prescription drugs subject to the contract.<sup>124</sup> A 1996 study found that

<sup>123</sup> For instance, some of the rebates discussed below could vary by drug product, depending on the nature and extent of therapeutic and generic competition, and by customer class (e.g., HMO v. non-HMO member).

<sup>124</sup> WAC refers to the wholesale list price of the prescription drugs, and often differs from actual transaction prices. Transaction prices would equal WAC if no rebates, discounts or any other credits or allowances apply to transactions involving a particular prescription drug.



rebates typically range from \$1.00 to \$1.50 per claim, averaging about 6 percent of sales.<sup>125</sup>

Although many rebates are expressed as a percentage of dollar sales for particular drug products, some manufacturer rebates might take a per unit form.<sup>126</sup> A formulary rebate is an example of a rebate expressed as a percentage of dollar sales in which companies pay PBMs to place their drugs in preferred positions on the various PBM formularies. The rebate could amount to 5 percent or more of dollar sales of the subject drug.<sup>127</sup> Similarly, cost effectiveness and growth rebates, which are rebates to PBMs that achieve particular volume targets, are often some percentage of dollar sales above some base volume or market share. These volume-based rebates may effectively amount to exclusive dealing agreements that could raise competitive concerns.<sup>128</sup>

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<sup>125</sup> Gondek (1996) also reports findings from comparative studies of Medicaid rebates, indicating that state Medicaid programs receive larger rebates from manufacturers than PBM organizations.

<sup>126</sup> For example, conversion rebates are sometimes expressed on a per unit basis. A drug manufacturer might agree to rebate a PBM \$X for each prescription the PBM undertakes to switch from another brand-name drug to the brand-name of the subject manufacturer. PBMs share these various rebates with plan sponsors or other clients to encourage them to comply with the formulary and other requirements in the PBM/drug manufacturer contracts (See, Jones (February, 1996)).

<sup>127</sup> The contracts also contain provisions that require PBMs to undertake efforts to encourage their clients to place a subject manufacturer's drug(s) on their formularies.

<sup>128</sup> The competitive implications of volume-based rebates are discussed further in Chapter V.

Manufacturer contracts also contain maximum rebate provisions and MFN clauses.<sup>129</sup> Maximum rebates are sometimes expressed as fixed percentages of sales, and, when deducted from WAC, determine the transaction prices for drugs covered by the contract. Maximum rebates could also be governed by MFN provisions, should drug companies offer larger rebates to competing PBMs as a result of competitive bidding. To make the various rebates operational, PBMs and drug companies must negotiate contract provisions governing the creation of databases and the exchange of information. This is done to enable the parties to monitor drug usage and resolve any rebate claim disputes. These, along with other contract provisions,<sup>130</sup> characterize the substantive features of drug manufacturer contracts with cost-containment institutions.

## ii. Capitated Contracts

Drug companies and PBMs are beginning to negotiate capitated contracts to provide prescription drugs to consumers. Similar to the capitated contracts between drug firms and

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<sup>129</sup> The competitive effects of MFN provisions are also discussed further in Chapter V. It is noteworthy that potential antitrust concerns over MFN provisions in drug manufacturer contracts are not new. In fact, as part of the famous Salk polio vaccine case of the 1950s in which the Department of Justice alleged that defendant drug companies conspired to fix prices, the court held that MFN provisions in drug company contracts with government agencies provided them with independent incentives to avoid price cuts. In short, the court found an alternative explanation for the pricing behavior of vaccine suppliers and dismissed the case. For a further discussion of this case, see Scherer (1980).

<sup>130</sup> Other substantive provisions found in some of these contracts include: (1) an agreement on conditions giving rise to the possible renegotiation of price and rebate provisions, such as the entry of either new drugs or generic forms of existing brand-name drugs; and (2) some agreement on the possible matching of competitive price changes.

HMOs,<sup>131</sup> drug companies and PBMs are using these contracts to manage usage risk and prescription drug costs. Capitated contracts contain two key provisions. First, the contracts must provide for some capitated rate. Second, the parties must agree on some risk sharing arrangement. A related provision that may also require considerable negotiation is the degree of exclusivity that companies receive in exchange for agreeing to a specified capitated rate.

Capitated agreements can be advantageous to both drug companies and PBMs.<sup>132</sup> Such contracts may benefit PBMs by establishing fixed rates of payment for their clients, and by permitting them to share both the risk and cost of unanticipated drug usage with drug companies. Drug companies could also benefit from these agreements partly because they secure exclusive

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<sup>131</sup> Chapter II contains a discussion of capitated contracts involving HMOs.

<sup>132</sup> An example of a capitated arrangement can be used to clarify the benefits of these contracts. PBM A establishes a capitated rate of  $\$C$  per member per month, and Firm X and Firm Y, two manufacturers of therapeutically similar drugs, agree to participate in the risk sharing arrangement. The PBM agrees to place both companies' drugs on its formulary to the exclusion of other therapeutic substitutes whose manufacturers choose not to participate in the capitated agreement. Firms X and Y expect incremental profit of  $\pi_x$  and  $\pi_y$  because of their preferred formulary status relative to others. PBM A agrees to bear 30 percent of the upside usage risk. Firms X and Y share the remaining risk in proportion to their shares of incremental profit,  $S_x$  and  $S_y$  ( $S_x = \pi_x / (\pi_x + \pi_y)$  and  $S_y = \pi_y / (\pi_x + \pi_y)$ ). If  $\$D$  is the market value of drug spending per member per month for the products of Firms X and Y and  $N$  is the number of consumers, then the net benefits to all parties, assuming zero transaction and contracting costs, are

- (1) Net Benefit A =  $.3[\$C - \$D]N$ ,
- (2) Net Benefit X =  $\pi_x + .7S_x[\$C - \$D]N$ , and
- (3) Net Benefit Y =  $\pi_y + .7S_y[\$C - \$D]N$ .

Clearly,  $\$C > \$D$  means that all parties to the capitated arrangement realize positive net benefits, partly at the expense of other drug companies. However,  $\$C < \$D$  implies that the PBM faces usage losses, amounting to its share of the unanticipated upside usage. Companies could still benefit from capitation in this case, providing their incremental profits exceed their shares of unanticipated usage.

or semi-exclusive distribution rights for their prescription drugs. These distribution rights may take the form of preferred placements on PBM formularies. Since contracting with PBMs and HMOs has become more prevalent in the drug industry, the discussion in Chapter V explores the competitive implications of key contract provisions, particularly the MFN and volume-based rebate provisions negotiated by PBMs.

### **C. Some Competitive Implications**

The rise of generic drug availability, the growth of cost-containment institutions, and the computerization of prescription drug delivery could lead to several economic efficiencies in markets for prescription drugs. Short-run efficiencies include reductions in claims processing and other transaction costs,<sup>133</sup> while long-run efficiencies stem from information technology-based innovations that could reduce long run costs of treating disease states. These and other efficiencies are discussed below.

#### **1. Industry Changes, Information Technology, and Short-Run Economic Efficiencies**

The growth of HMOs and PBMs had the effect of aggregating buyers on the demand side of prescription drug markets. Cost-containment mechanisms and information technology facilitate consumer substitution among available therapeutic and generic drug alternatives. These changes increase demand elasticities facing drug companies and encourage competition

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<sup>133</sup> Available evidence on the short run cost savings generated by cost-containment organizations is summarized below. Although no systematic study of these cost savings has been undertaken, some anecdotal evidence has emerged in the literature. For instance, a 1997 report estimated that 90 percent of claims adjudicated by PBMs and 95 percent of claims settled by HMOs were successfully completed online (See, *Novartis Pharmacy Benefit Report - Trends & Forecasts* (1997)). The widespread use of online claims adjudication suggests that it is less costly than other means of settling prescription drug claims.

between and among generic and brand-name drug suppliers. Unlike the historical focus on detailing and advertising activities, this competition takes place along the price dimension. The sections below focus upon whether this price competition stems from the elimination of incentive and information problems in prescription drug markets,<sup>134</sup> and whether cost-containment institutions and the application of information technology generate real short-run economic efficiencies without compromising overall quality of care.

**a. Industry Changes, Information, and Agency Issues**

The economic literature suggests that physicians do not necessarily act in the best interest of consumers when making cost effective drug choices.<sup>135</sup> Physicians face information processing limitations that impede their ability to choose efficiently among available treatment options. Further, as discussed in Appendix A, third-party insurance without adequate cost controls makes consumers and others less likely to contain their prescription drug expenditures. These economic problems could lead to inefficiencies in drug markets, including the excessive use of ineffective drug treatments from both a cost and quality perspective. The various changes in the drug industry address these problems in several ways. By investing in computer

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<sup>134</sup> Incentive problems arise in prescription drug markets when the incentives of third parties, including physicians and HMOs, differ from those of consumers. Economists refer to these problems as agency problems. For discussions of agency and information problems in prescription drug markets, see Dranove (1989), Hellerstein (1994), Newhouse (1993), Scherer (1996), and Temin (1980).

<sup>135</sup> The cost effective treatment option may not be optimal if the patient suffers serious side effects, or if alternative treatments result in superior outcomes. However, the cost-effectiveness criterion does take into account patient outcomes. This suggests that the application of this criterion may enhance overall efficiency in the distribution and use of prescription drugs, without necessarily reducing the quality of care.

technology capable of processing significant quantities of data, cost-containment institutions serve to overcome the information imperfections in prescription drug markets discussed above. This technology allows PBMs, HMOs, drug companies, and others to: (1) compile and process vast amounts of information on the costs and quality of alternative drug treatments for various disease states; (2) monitor prescription drug usage and its cost effectiveness on a patient-by-patient basis in the form of the various DUR programs discussed earlier; (3) apply prior authorization and real-time substitution programs to encourage cost-effective substitution among alternative drug treatments; and (4) develop databases on the usage and effectiveness of prescription drugs that, along with available information on non-drug treatments, facilitates outcomes research. These capabilities could reduce the overall costs of drug treatments and, at the same time, improve treatment outcomes.<sup>136</sup>

Moreover, PBMs and HMOs also appear capable of addressing the incentive and cost control problems in prescription drug markets. In particular, in addition to the passage of state drug substitution laws and their impact on generic substitution, cost-containment institutions are able to influence the prescribing behavior of physicians and to apply various mechanisms to facilitate both generic and brand-name switching to control costs. In addition to the generic and therapeutic switching programs, drug formularies, both open and closed, are an important mechanism for controlling both physician behavior and drug costs. More specifically, some data

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<sup>136</sup> Research on particular cost-containment mechanisms such as DUR and prior authorization programs offer at least some evidence indicating that both prior authorization and DUR reduce drug expenditures, but little information is available to evaluate the quality of care implications of these programs. For reviews of empirical research on the effects of these cost-containment devices, see Gondek (1996).

indicate that more and more cost-containment institutions are substituting the use of closed for open drug formularies to control drug costs. For example, a recent survey reported that the percentage of HMOs that have operated closed formularies increased from 23.9 percent in 1995 to an estimated 39.1 percent in 1998. The same survey reported that the use of open formularies by HMOs declined from 93.8 percent in 1995 to an estimated 60 percent in 1998.<sup>137</sup> It is also worth noting that the Omnibus Budget Reconciliation Act of 1993 authorized states to use drug formularies for state Medicaid programs. This initiative adds to drug formulary usage in the pharmaceutical industry.

Some commentators wonder whether the use of formularies, particularly closed formularies, saves costs without benefitting consumers, that is by reducing the overall quality of drug health care. One discussion of this issue reads, in relevant part, "... in a managed-competition environment where health care providers will have to compete for patients, the pressure to keep prices low by buying the cheapest but not necessarily the best drug will be high."<sup>138</sup> On the other hand, competition among HMOs could instead force them to use the best drug treatments to avoid any later need for more expensive drug or non-drug treatments that may arise from using less expensive, lower quality prescription drugs. This competition could also lead to higher quality HMOs that promote higher quality drugs by placing them on their drug formularies. It is too early to tell which alternative is the better story, as empirical research to

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<sup>137</sup> See, *Novartis Pharmacy Benefit Report - Trends & Forecasts* (1997).

<sup>138</sup> Morrison (1993). This report also raises questions about whether formulary committee members might accept inducements to favor particular drugs, and whether sufficient data are available to conduct comparative drug studies for safety and efficacy determinations.

date on the competitive effects of drug formulary use provides mixed evidence on the possible tradeoff between low cost and high quality prescription drug treatments.<sup>139</sup> Thus, while some evidence of formulary-related cost savings exists, research remains inconclusive about the impacts of formularies on the quality of drug treatments.

#### **b. Industry Changes and Other Short-Run Efficiencies**

The application of information technology to the changing drug industry may also have generated other short-run efficiencies. First, transactions costs are reduced for drug companies, HMOs and other third-party payers, and consumers. For example, by applying information technology to their retail and mail order pharmacy networks and by maintaining computer linkages to drug companies and others, PBMs can accomplish several goals at the same time. They can: (1) receive and process prescription information; (2) conduct concurrent DUR; (3) ensure compliance with formulary and other cost-containment requirements; (4) process claims; (5) administer rebates from drug companies, payments to network pharmacies, and other credits for their clients; and (6) update databases for future use.

Transaction efficiencies arise from the various resource savings associated with the computerization of drug delivery. Although systematic data on transaction cost savings are

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<sup>139</sup> A 1996 review, summarizing this literature states, that some "... contend that formularies achieve cost-savings because more cost-effective drug products are used instead of newer, unproven, and more expensive products. The counter argument is that failure to cover selected drugs can lead to unintended reductions in the quality of care and increased costs due to the use of sub-optimal products, the exacerbation of disease or symptoms, ..." (See, Gondek (1996)). As discussed in more detail in this literature review, some of these studies found that: (1) Medicaid formulary use does not generate cost savings and could reduce quality of drug care (Jang (1988)); (2) formulary substitution involving generic drugs reduces prescription costs without any compelling evidence of reductions in quality of care (Dowell (1995)); (3) adherence to formularies in a nursing home setting reduces drug expenditures (Yakabowich et al. (1994)); and (4) restrictive Medicaid formularies may reduce drug expenditures by 13 percent, but these savings are offset by service substitution (Moore and Newman (1993)).



unavailable, a 1996 study of PBMs noted that "PBMs may be better equipped to achieve efficiencies and lower claims processing costs (charges). Current amounts paid by state Medicaid programs may be considerably above those engaged on the PBM side. ..." <sup>140</sup>

Referring to state Medicaid programs, the same study notes, "States reported that PBMs potentially could reduce administrative costs (e.g., claims processing, formulary administration, network contracting) to the agency."

Second, industry changes facilitated by the application of information technology, particularly cost-containment initiatives by HMOs and PBMs, may make it easier for drug companies to enter new markets. The formularies maintained by PBMs and HMOs and the generic and therapeutic switch programs may allow brand-name drug companies to reduce the costly advertising and detailing activities that give rise to significant sunk costs of entry. <sup>141</sup> In fact, commentators observed that brand-name drug companies have placed less emphasis on detail sales personnel because of the growing importance of managed care institutions and drug formularies, <sup>142</sup> but that, in the last few years, sales personnel have played an increasingly important role in detailing prescription drugs to physicians and others inside and outside of managed care organizations. Further, it is plausible that the rapid growth of generic drugs that

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<sup>140</sup> See, Gondek (1996).

<sup>141</sup> However, drug companies do pay cost-containment institutions fees for drug formulary placement services. An example of these services would be efforts by a PBM to market a particular manufacturer's brand-name drugs to plan sponsors, HMOs, and others, charging the manufacturer fees should the PBM secure formulary placements (e.g., a preferred placement on an HMO drug formulary) for these drugs. Drug company payments to PBMs for formulary placement services are often in the form of rebates on drug purchases by these PBMs.

<sup>142</sup> See, Breindel (1994).

resulted in part from the substitution programs mandated by cost-containment institutions,<sup>143</sup> is consistent with the relaxation of impediments facing generic entrants. Easing entry impediments may help make prescription drug markets more competitive.

Third, with the growth of new institutions fostered by the application of information technology, complex contractual provisions related to price have become more common in contracts between HMOs/PBMs and brand-name drug companies. These include: (1) formulary rebate provisions linking rebates to formulary placement; (2) provisions for the renegotiation of prices in the face of generic entry; (3) similar provisions making contract prices an inverse function of the availability of therapeutic alternatives; (4) manufacturer rebate provisions that reduce prices to PBMs that facilitate therapeutic substitution; and (5) manufacturer growth rebate provisions making prices inverse functions of contract drug sales shares.

Although contractual provisions such as these could in principle promote or reduce price competition,<sup>144</sup> some observers think that in practice they have tended to lower prescription drug

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<sup>143</sup> According to PhRMA, while some 63 percent of HMOs required generic substitution of name-brand drugs in 1990, some 87 percent required it in 1994 (See, *Industry Profile* (1996)).

<sup>144</sup> Procompetitive and anticompetitive theories for these and other contract provisions appear in the literature. First, formulary placement fees like "slotting allowances" would be procompetitive if they insure PBMs against the risk that a drug that receives favorable formulary status is inferior to other drugs that would be more profitable, but receive either less favorable formulary status or are not on the PBM's drug formulary. These fees could be anticompetitive if they allow suppliers that have preferential formulary status to strategically exclude rivals' new drugs by raising the formulary fee they are willing to pay for their existing prescription drugs (For a more detailed discussion of these and other theories of these formulary placement fees, see Shaffer's testimony in Federal Trade Commission. *Hearings On Global and Innovation-Based Competition*. Transcript, (November 8, 1995)). Second, contract provisions that reduce prices as the availability of alternatives rises would be procompetitive if they simply serve as efficient mechanisms for price adjustments in rapidly changing markets. These provisions could be anticompetitive if they serve as commitments by existing companies to strategically deter entry by rivals with competitive alternatives. Finally, with regard to other PBM/drug company contract provisions (e.g., MFN provisions), alternative theories are discussed in Chapter V.

prices. In a discussion of manufacturer rebates, for example, a survey of PBMs notes "...that change in market share is now the focus of most rebates, rather than volume. ... increased market share within a therapeutic class or drug category reflects changes in the use of competing products relative to each other."<sup>145</sup> The same study found that total manufacturer rebates to PBMs range from 7 to 17 percent on some brand-name drugs. The survey also found that although these rebates generally fall short of the 18 to 21 percent rebates negotiated by state Medicaid programs under the so called "best price" provisions of the Omnibus Budget Reconciliation Act of 1990, they apparently exceed rebates to other classes of trade, like retail pharmacies. Alternative explanations for differential rebates in prescription drug markets are discussed below.<sup>146</sup>

## **2. Industry Changes, Information Technology, and Long-Run Competitive Innovations**

Information technology in the prescription drug industry also facilitates product innovations capable of reducing health care costs over the long run. Disease state management (DSM) is a notable example of one of these innovations. In what follows, attention is focused on DSM, and on other information-based innovations capable of reducing the costs and/or increasing the quality of drug care.

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<sup>145</sup> See, Breindel (1994).

<sup>146</sup> For example, in Chapter IV, we discuss whether or not differential rebates reflect discriminatory prices, differences in measurement, or variations in the levels of PBM services to drug companies.

**a. DSM and the Pharmaceutical Industry**

One commentator on the pharmaceutical industry described DSM as "... a system of viewing healthcare disease by disease and examining the interrelated elements in the treatment process with outcomes research to improve quality and lower costs ..." <sup>147</sup> Inputs into DSM include not only prescription drug and non-drug treatments, but also: (1) PBMs, with their drug usage and outcomes data and the information technology to process these data; (2) drug companies, with scientific databases and personnel with clinical and other information measuring the outcomes of alternative drug treatments; (3) HMOs, which possess incentives to develop DSM programs as a means of lowering overall health care costs, and are capable of integrating health care providers and medical records data on alternative health care treatments and their costs; and (4) public and private health care research organizations, which also possess clinical and other relevant data on the effectiveness of health care treatment alternatives.

DSM seeks to integrate the various inputs into health care to efficiently manage the different treatments for disease states, reducing overall health care costs as a result. According to one discussion of DSM, "Each disease has a distinct pattern of cost elements ... and a unique range of therapies and interventions. Only by focusing on the cost drivers and their interactions over the course of each disease across all elements of the system can the health care delivery system make rational choices between therapeutic alternatives and best balance clinical and economic needs." <sup>148</sup>

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<sup>147</sup> See, Castagnoli (1995). For other discussions of DSM, see *Disease Management - Background* (1995), Boston Consulting Group (1993), and Breindel (1994).

<sup>148</sup> See, Boston Consulting Group (1993).

However, DSM may effectively amount to large clinical trials for prescription drugs under evaluation, producing only one time benefits for those drugs found to be cost effective treatments.<sup>149</sup> Further, for disease states with established treatments, experimentation using novel drug and non-drug alternatives may be limited because innovators may have less incentive to do so. Reduced incentives would emerge if DSM programs lead to established drug treatments that make the use of novel alternatives less likely to occur. If the adoption of novel drug and non-drug treatments is less likely because of DSM, this could reduce returns to innovation and innovative activity itself.

At the same time, DSM could lead to an ongoing search for the most efficient way of managing a disease. This, coupled with the information technology capable of rapidly spreading information on novel drug treatments, could quickly lead to the widespread use of new prescription drugs. Returns to innovation could increase as a result. Arguably, the potential for DSM programs to generate health care cost savings and stimulate innovative activity is significant, but integration of the various inputs into these programs is a necessary prerequisite to achieving these efficiencies. Further, although outpatient drug sales currently account for less than six percent of national health care expenditures, pharmaceutical companies could dramatically increase the demand for prescription drugs using DSM programs that demonstrate

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<sup>149</sup> Drug evaluations across DSM programs may demonstrate that a given drug is the most cost effective treatment for multiple disease states. For these drugs, DSM leads to cost savings in the treatment of several illnesses.

their cost-effectiveness relative to other treatments.<sup>150</sup> A few comparisons of the costs of prescription drug and non-drug treatments highlight the significant potential for cost savings.<sup>151</sup>

(1) Ulcer treatments - The treatment of ulcers during the 1990s with H2 antagonists cost some \$900 per patient each year. Surgical treatments averaged approximately \$28,000.

(2) Congestive heart failure - A study of patients taking ACE inhibitors for congestive heart failure suggests that these prescription drugs permitted them to avoid \$9,000 in hospitalization expenditures over a three-year period.

(3) Schizophrenia - A 1990 study of a schizophrenia drug finds that annual drug costs of \$4,500 compare to \$73,000 of annual expenditures in state mental institutions.

(4) Transplant rejection - A drug for the treatment of kidney transplant rejection was found to reduce hospital stays, and save some \$10,000 per patient in hospitalization costs.

Although these examples suggest DSM has the potential for significant cost savings,<sup>152</sup> comparing alternative treatments on a cost-effectiveness basis gives rise to any number of problems. For example, comparison of the outcomes of alternative treatments is complicated by the difficulty of measuring outcomes. Although commentators point to efforts by PBMs and

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<sup>150</sup> Pharmaceutical industry executives have also expressed the view that prescription drugs offer a cost-effective way of treating different disease states, and that drug companies play an important role in providing disease state management services to their customers (See, for example, Nader (1997)).

<sup>151</sup> These examples are taken from several studies that are summarized in PhRMA's *Industry Profile* (1996).

<sup>152</sup> PhRMA estimates that the use of ACE inhibitors, instead of hospital care, to treat heart disorders could generate savings of \$2 billion each year in the U.S. alone (See, PhRMA's *Industry Profile* (1996)).

others to conduct outcomes research and to measure the outcomes of DSM programs,<sup>153</sup> comprehensive standards of comparison are unavailable. Efforts are underway, however, to establish some standards of comparison. For example, the National Committee for Quality Assurance (NCQA), a not-for-profit organization, has focused attention on accreditation and performance management in the managed care environment.<sup>154</sup> Despite these efforts, the difficulty in comparing outcomes raises questions about the usefulness of cost-effectiveness analyses of prescription drug treatments.<sup>155</sup>

DSM programs also need to integrate a variety of healthcare resources. For example, while pharmaceutical companies own extensive clinical data on drug treatments, they lack access

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<sup>153</sup> For example, PBMs conduct "quality-of-life" surveys, patient satisfaction surveys, and physician surveys to evaluate DSM programs (See, Gondek (1996)).

<sup>154</sup> See, NCQA's Press Release, "NCQA Launches QUALITY COMPASS; REPORTS PROVIDE A WEALTH OF DATA ON HEALTH PLAN QUALITY." (1996). It should be noted that NCQA administers the HEDIS (Health Plan Employer Data Information Set) formats. HEDIS is a reporting format used by health plans to describe, among other aspects of their businesses, the quality of their services. HEDIS software is intended to provide information on medical outcomes and other measures of performance across health plans. For a further discussion of HEDIS, see "Heading into New Version of HEDIS" (1996) and *Novartis Pharmacy Benefit Report - Trends and Forecasts* (1997).

<sup>155</sup> Although beyond the scope of this study, many other issues surround cost-effectiveness research, including: (1) whether or not FDA should regulate cost-effectiveness claims; (2) how HMOs and others would use cost-effectiveness information; and (3) what standards are relevant for comparative cost-effectiveness claims. These issues were the subjects of discussion at a recent conference on cost-effectiveness research (American Enterprise Institute for Public Policy Research, *Policy Issues in Pharmaceutical Cost-Effectiveness Research*. (1996)). Also, see Comments of the Staffs of the Bureaus of Economics and Consumer Protection of the Federal Trade Commission, Department of Health and Human Services, Food and Drug Administration, *In the Matter of Pharmaceutical Marketing and Information Exchange in Managed Care Environments; Public Hearings*. (1996), and Neumann, Zinner, and Paltiel (1996). For other discussions on cost-effectiveness, see Garber and Phelps (1997) and Claxton and Posnett (1996).

to the usage and outcome data as well as the data processing capability of PBM organizations. Drug companies also lack the medical record data available to HMOs. According to one commentator, "...our component structured [health care] delivery system is uncoordinated in its disease focus. Organizational barriers obstruct the disease management perspective on treatment."<sup>156</sup> However, ongoing industry changes, particularly vertical integration by drug companies into the provision of PBM services and the growing use of PBM services by HMOs, could facilitate the development of DSM programs by integrating inputs into these programs. Some suggest that the acquisitions of PBMs by drug companies are motivated by efforts to integrate drug company and PBM data and data processing capabilities to supply DSM programs to HMOs and others more efficiently.<sup>157</sup> Arguably, the objective of the parties to these transactions is to integrate efficiently inputs into DSM, and to prepare for long term competition with other health care providers.

**b. Other Information-Technology Based Innovations**

The application of information technology to the pharmaceutical industry facilitates other innovations as well. A notable example involves services designed to address the compliance problem in the pharmaceutical industry. According to PhRMA, patient non-compliance with physician prescription drug orders results in premature death and costs billions of dollars in

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<sup>156</sup> See, Castagnoli (1995).

<sup>157</sup> A 1995 discussion, referring to drug company/PBM mergers, states, in relevant part, "By gaining access to patient data, pharmaceutical manufacturers hope to demonstrate that greater use of prescription drugs is a more efficient method of controlling diseases. If the mergers encourage the development and utilization of patient information, the potential benefits of lowered overall health costs should be recognized. ..." (See, Hoffman and Garrett (1995)).



additional hospital and nursing home stays. Estimates indicate that some 50 percent of prescription drugs are taken incorrectly, largely because patients either do not take the correct dosage forms, or because they fail to fill or refill prescriptions in a timely manner. Compliance problems may arise, in part, because physicians are too busy to monitor their patients, and because pharmacies and others fail to adequately notify consumers about the need to fill or refill their prescriptions. Some companies have applied information technology in efforts to resolve this problem.<sup>158</sup> Rite Aid's PBM company, Eagle Managed Care (EMC), created a program called Compli-Line which processes data from some 2,800 pharmacies to identify compliance problems with patients filling or refilling prescriptions at Rite Aid pharmacies, and to take steps to remedy these problems. Similarly, PCS Health Systems created a program that uses its computer technology to identify compliance problems, and to inform network pharmacists of these problems so they might follow-up on them.<sup>159</sup> These information technology-based approaches could eliminate some of the costs arising because of patient non-compliance with prescription drug orders of their physicians.

### **3. Some Comments on Standard Setting and Other Organizations**

Professional standard setting and promoting organizations may also foster efficiencies in the use of information technology to distribute prescription drugs. Two such organizations are noteworthy. First, the American Society for Automation in Pharmacy (ASAP) was founded in

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<sup>158</sup> Compliance problems could also arise if patients suffer serious side effects, or if the drug treatments are not effective. In these cases, the application of information technology will not necessarily solve the compliance problem.

<sup>159</sup> For discussions of the Rite Aid and PCS programs, see Sheetz (1996) and Muirhead (September 1996).

1989. While not a standards organization, ASAP acts to encourage the efficient use of computer technology in community pharmacies and to promote the use of standards for the electronic interchange of prescription data. This association consists of several hundred members, including drug wholesalers, PBMs, and hospital and retail pharmacies.

Second, founded in 1977, the National Council for Prescription Drug Programs (NCPDP) consists of over 1,000 members, including drug companies, PBMs, and independent and chain pharmacies. NCPDP is a standards development organization, and it exists to develop and promote prescription drug processing and data interchange standards for use in the pharmacy service segment of the health care industry. Among its other standards, NCPDP develops standards for manufacturer rebate communications, including the possible use of on-line communications to support rebate claims.<sup>160</sup> Standards for electronic communication may produce transaction efficiencies, including efficiencies relating to the processing of rebate claims.<sup>161</sup>

#### **D. Summary**

The application of information technology, especially by PBMs, gives rise to increases in short and long-run demand elasticities, and may ease entry impediments in prescription drug markets. The various cost-containment mechanisms -- drug formularies, prior authorization, generic and therapeutic substitution programs, drug utilization review, and disease state management -- facilitate the real-time substitution opportunities that lead to these more elastic

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<sup>160</sup> See, Muirhead (March 1996).

<sup>161</sup> As previously mentioned, PBMs negotiate with drug companies to obtain discounts off the list prices of prescription drugs in the form of manufacturer rebates.

demands for prescription drugs. In addition, many of these techniques may effectively serve as marketing measures that provide brand-name and generic drug companies ready access to large groups of customers, reducing their impediments to entry. These developments have likely intensified price competition among drug suppliers. Price competition may take the form of direct price reductions in the face of therapeutic or generic alternatives, and manufacturer rebates that depend on formulary placement, market share growth, and the rebate offers of other drug suppliers, though these types of contractual provisions may under some circumstances reduce price competition. Direct price competition, along with other efficiencies that range from reductions in transactions costs to savings from information technology-based innovations, could lower overall expenditures on prescription drugs without compromising the quality of drug care.



## Chapter IV

### Differential Pricing and Generic Entry Strategies in the Changing Pharmaceutical Industry

#### A. Introduction

The powerful economic forces buffeting the prescription drug industry -- particularly the new uses of information technology and changing legislative mandates -- have led many firms to change their business strategies. The industry has in consequence witnessed a number of high profile mergers, and the firms that remain interact and contract in new ways. The new industry structure and conduct raise several key antitrust issues, addressed in this chapter and the next.<sup>162</sup> This chapter focuses attention on two potentially anticompetitive strategies used by brand-name drug companies partly in response to aggressive competition from generic drug companies. The

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<sup>162</sup> In addition to the competition issues discussed in Chapters IV and V, drug industry changes also raise a number of consumer protection issues. These include: (1) the competitive effects of direct-to-consumer advertising of prescription drugs; (2) the economic implications of possible FDA regulation of cost-effectiveness claims for prescription drugs; and (3) the welfare effects of requiring disclosures to inform consumers about therapeutic switch programs at retail pharmacies. Although these and other consumer protection issues are beyond the scope of this study, staff of the Federal Trade Commission filed comments with the FDA addressing some of these issues (See, Comments of the Staffs of the Bureaus of Economics and Consumer Protection of the Federal Trade Commission, Department of Health and Human Services, Food and Drug Administration, *In the Matter of Pharmaceutical Marketing and Information Exchange in Managed Care Environments; Public Hearings*, Docket No. 95N-0228, (January 16, 1996) and Comments of the Staffs of the Bureaus of Economics and Consumer Protection of the Federal Trade Commission, Department of Health and Human Services, Food and Drug Administration, *In the Matter of Direct-to-Consumer Promotion; Public Hearing*, Docket No. 95N-0227, (January 11, 1996)).

discussion first addresses the differential pricing practices of pharmaceutical companies by examining several competing explanations for observed price differences. Differential pricing may be the result of increased opportunities for price discrimination or may reflect the presence of quality or cost variations in different segments of prescription drug markets.<sup>163</sup> The discussion then considers the likely competitive effects of decisions by brand-name drug companies to introduce their own generic versions of brand-name drugs prior to the expiration of patents for these prescription drugs.

## **B. Industry Changes and Differential Pricing in Prescription Drug Markets**

Pharmaceutical companies have set different prices within different therapeutic drug categories for many years. As discussed in Appendix A, differences in elasticities of demand and degrees of product differentiation have partly explained these price differences. Drug companies have also offered larger discounts to hospitals and other managed care providers.

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<sup>163</sup> The issue of price discrimination in the pharmaceutical industry has been addressed by several authors. See, for example, Frank and Salkever (1992), Scherer (1996), and Scherer (1993). The issue of price discrimination in the drug industry was also addressed by several state legislatures who passed anti-price discrimination laws. For a discussion of the provisions of a number of these state laws, see *Drug Price Discrimination Laws and the Robinson-Patman Act* (1996). It is also noteworthy that, while the discussion below focuses some attention on the price discrimination allegations in the recent litigation involving brand-name drug companies (See, for example, *In re Brand Name Prescription Drugs Antitrust Litigation*, 1996-2 Trade Cas. (CCH) ¶ 71,449 (N.D. Ill. June 21, 1996)), other aspects of this case were examined in a 1997 symposia. These include: (1) the role of drug wholesalers in the alleged efforts by drug companies to price discriminate against retail pharmacies, as well as a discussion of settlements between some of the drug companies and retail pharmacies (Scherer (1997)); (2) a discussion of evidence relating to allegations of collusion (Weinstein and Culbertson (1997)); (3) an analysis of the consumer welfare implications of requiring drug companies to charge uniform prices (Elzinga and Mills (1997)); (4) a discussion of differential pricing in the EU, along with an assessment of the welfare implications of the settlement agreement in the U.S. brand-name drug litigation (Danzon (1997)); and (5) a cross-country examination of the nature of retail pharmacy distribution of prescription drugs (Reekie (1997)).

More recent price discounts have involved other segments of demand, however, and these price discounts may be linked to ongoing changes in the drug industry. These recent pricing practices may have evolved partly because other groups of buyers (e.g., HMOs, PBMs, and Medicaid programs) have adopted cost-containment measures similar to those used historically by hospitals. In addition, information technology has permitted these groups of buyers to substitute more easily among alternative drug treatments.

A notable example of differential pricing is the so-called “two-tiered pricing structure” under which pharmaceutical companies set lower prices to large buyers like hospitals, HMOs and PBMs, and charge higher prices to other buyers that include the uninsured and independent and chain retail pharmacies.<sup>164</sup> Other examples include prescription drug rebate programs for HMO and PBM organizations, and special prices for Medicaid recipients.<sup>165</sup>

Although drug price differences could reflect economic price discrimination,<sup>166</sup> it is theoretically possible that this does not raise competitive concerns. Economic theory indicates

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<sup>164</sup> In recent years, differential pricing practices resulted in numerous private lawsuits brought by independent and chain retail pharmacies. These led to a class-action lawsuit by some 40,000 pharmacy owners against several major drug companies (See, Cohen and Tanouye (1996)).

<sup>165</sup> In fact, as previously mentioned, the Omnibus Budget and Reconciliation Act of 1990 requires pharmaceutical companies to provide rebates to state Medicaid programs for outpatient prescription drug purchases on the basis of “... the lowest prices available to any purchaser.” For a discussion of these and other aspects of this statute, see United States General Accounting Office’s report *Changes in Drug Prices Paid by HMOs and Hospitals Since Enactment of Rebate Provisions* (1993).

<sup>166</sup> Economic price discrimination occurs when sales of the same product to different segments of demand result in different levels of economic profit. Economic price discrimination is not necessarily a violation of the Robinson-Patman Act.

that economic price discrimination can persist in markets where suppliers of differentiated products are subject to free entry constraints.<sup>167</sup> Price discrimination, under free entry conditions,<sup>168</sup> is only one possible theoretical explanation of the observed price differences in prescription drug markets, and whether or not this theory applies depends on careful consideration of entry conditions in these markets.<sup>169</sup> The discussion that follows reviews recent pricing trends in the pharmaceutical industry, and then turns to alternative theoretical explanations for these differential pricing strategies. Previous economic literature on drug industry pricing is discussed in Appendix A.

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<sup>167</sup> See, Borenstein (1985), Holmes (1989), Katz (1984), Lederer and Hurter (1986), and Salop (1979). For a review of various theories of price discrimination, see Varian's discussion on price discrimination in Schmalensee and Willig (1989). Some of this literature suggests that if prescription drug markets are free entry markets, then positive differential price-cost margins could simply cover fixed costs, and potential entry would serve to constrain incumbent profits at competitive levels.

<sup>168</sup> The use of the terms free entry as part of these economic theories does not mean that markets lack entry barriers. It simply means that the ability of existing firms to set discriminatory prices above marginal costs would be limited by potential entrants that could be induced to enter if the economic profits from these discriminatory prices are sufficiently attractive to cause new entry to take place.

<sup>169</sup> Appendix A discusses the various impediments to entry into prescription drug markets, including the sunk costs, regulatory delays, and development and market risks associated with the development of new drugs.



## 1. Differential Pricing Practices in the Pharmaceutical Industry

Prescription drug prices increased at an annual rate of 9.4 percent between 1980 and 1992,<sup>170</sup> prompting some to assert that prices and profits were higher in the pharmaceutical industry than in other industries.<sup>171</sup> But the data in Appendix A Table A.7 demonstrate that consumer prices for prescription medications have moderated in recent years, particularly during the 1995-97 period. Since 1997, however, these same data indicate that drug prices have increased faster than the overall consumer price index (CPI). In fact, drug prices rose by 4.7 percent in 1998 compared to a 0.5 percent increase in the overall CPI (Table A.7).<sup>172</sup>

A review of the trade literature indicates that the moderation in drug price inflation stems partly from additional price competition among drug companies. This competition involves a variety of pricing practices including differential discounts.<sup>173</sup> One practice entails offering significant discounts to HMOs, hospital chains, PBM organizations, and buying groups, but not

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<sup>170</sup> These price changes, based on Bureau of Labor Statistics (BLS) data, might overstate actual drug price inflation over this time period. A number of studies indicate that BLS data fail to fully account for quality changes that explain some of the drug price inflation measured by BLS data. For a discussion of some of these studies, see, Weidenbaum (1995). For other discussions of price indices, see Baye, Maness, and Wiggins (1995), Brendt, Griliches, and Rosett (1993), and Griliches and Cockburn (1994).

<sup>171</sup> See, for example, Scherer (1993) for a discussion of pharmaceutical industry profits.

<sup>172</sup> These price changes, which are based on Bureau of Labor Statistics data, are consistent with those obtained from other data sources. For example, according to data compiled by the National Association of Chain Drug Stores, prices for the top 500 drugs purchased by retail pharmacies rose an average of 4.1 percent from the fourth quarter of 1996 to the fourth quarter of 1997.

<sup>173</sup> Numerous trade publications have documented this drug company practice of offering differential discounts, resulting in lower prices to HMOs, hospitals and others and higher prices to independent and chain retail pharmacies and uninsured individuals. See, Scott (1995), Sakson (1995), Conlan (1995), and "The Continuing Search for a Level Play Field." (1995).

to other categories of buyers.<sup>174</sup> According to one account, “Drug companies forced to give deep discounts to managed health care plans are making up the difference by raising prices to the elderly, uninsured, and others least able to pay ....”<sup>175</sup> Another notable discussion from the economic literature also explains how drug industry changes, including the introduction of generic drugs, could lead to price increases for some consumers and price reductions for others.<sup>176</sup> Some data on price differences for four prescription drugs highlight the significance of these pricing practices (Table IV.1). Other data on average 1992 discounts from manufacturer list prices, ranging from 30 percent for the mail order pharmacy sales to 5 percent or less for nursing home and retail pharmacies sales, suggest that drug price differences are more widespread.<sup>177</sup> A 1998 Congressional Budget Office report, comparing average prices in 1994 for the top 100 selling brand-name prescription drugs, reported that: (1) hospital paid 91 percent

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<sup>174</sup> In addition to PBM organizations, companies offering prescription drug services to individuals without prescription drug benefits attempt to secure drug discounts for consumers who purchase their services (See, Muirhead (September 1995) and Ukens (February 1994)).

<sup>175</sup> See, Sakson (1995) for an extended discussion of these trends in prices in the pharmaceutical industry. In the section below on price discrimination under free entry conditions, the discussion addresses the competitive effects on different segments of demand of moving from some uniform price equilibrium to a discriminatory price equilibrium in the prescription drug industry.

<sup>176</sup> The basic idea is that market changes could lead to segmentation of demand into price sensitive and price insensitive consumers. Lower-priced generic introductions, for example, would cause price sensitive consumers to switch to generic alternatives, forcing the brand-name drug suppliers to lower their prices in order to compete with the generic entrants. Price insensitive consumers would be less inclined to switch to generics, allowing brand-name drug companies to charge them higher prices. The result is a form of differential pricing in prescription drug markets. For a further discussion of this simple model, see Scherer (1996).

<sup>177</sup> These and other data were reported in a study by the Boston Consulting Group (April 1993).

**Table IV.1**  
**1992 Prices for Select**  
**Prescription Drugs**

Prescription Drug	Quantity	Community Pharmacy Price	Other Price
Transderm Nitro	30 Patches	\$39.89	\$8.40
Ventolin, 4 mg	500 Tablets	\$183.71	\$63.84
Calan, 40 mg	100 Tablets	\$22.91	3.90
Eskalith CR, 450 mg	100 Capsules	\$23.02	\$17.18

Notes: Prices are the average prices paid by community pharmacies and by an other category. Select refers to the four prescription drugs listed in the table. The source of these price differences suggests that the other category includes prices to institutional buyers such as HMOs, but the composition of this category is unclear.

Source: Reproduced from data in Scott (1995).

of average price charged to retail pharmacies; (2) HMOs paid 82 percent of that price; and (3) federal facilities paid 58 percent of the price paid by retail pharmacies.<sup>178</sup> These price variations raise the possibility that not all consumers benefit from the additional price competition in the drug industry.<sup>179</sup>

Differential pricing practices also result in discounts to the various state Medicaid programs. As noted in a report by the U.S. General Accounting Office, "The Omnibus Budget Reconciliation Act of 1990 (OBRA), enacted November 5, 1990, required that pharmaceutical companies give state Medicaid programs rebates for outpatient drugs based on the lowest prices

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<sup>178</sup> See, Congressional Budget Office (1998).

<sup>179</sup> Additional information suggests that certain groups of consumers, including the elderly and the uninsured, often face higher prices than others. For example, although the overall rate of inflation was 3.2 percent in 1996, the National Association of Chain Drug Stores compiled data indicating that the prices of a number of drugs used largely by the elderly increased by as much as 10 percent over the same time period (See, Tanouye (1997)).

available to any purchaser."<sup>180</sup> Commentators have noted that, subsequent to its enactment, Medicaid programs faced lower prices for prescription drugs than other groups of buyers.<sup>181</sup> Consequently, the Medicaid best price rules also suggest the presence of differential pricing in the pharmaceutical industry.

The so-called brand-name "switching programs" discussed in Chapter II also led to price differences for prescription drugs, but this is no longer a prevalent form of differential pricing in this industry.<sup>182</sup> Pharmaceutical companies instituted these programs to encourage pharmacists to substitute their brand-name drugs for the brand-name drugs prescribed by physicians. To encourage switching, drug companies made payments to pharmacists who secured physician approval to substitute an alternative name-brand drug for the one prescribed by the physician. The switch programs led to lower prices for retail pharmacies making the drug switches, while others faced higher prices.

These differential pricing strategies prompted some state legislatures to consider laws banning differential discounts, and resulted in several lawsuits filed by independent and chain retail pharmacies. The pharmacies claim, among other allegations, that pharmaceutical

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<sup>180</sup> For a discussion of this and other issues relating to this statute, see United States General Accounting Office's report entitled *Changes in Drug Prices Paid by HMOs and Hospitals Since Enactment of Rebate Provisions* (1993). Chapter II also discusses this legislative initiative in further detail, and defines the meaning of the so-called "best prices."

<sup>181</sup> For various discussions relating to the Medicaid best price rules, see *Changes in Drug Prices Paid by HMOs and Hospitals Since Enactment of Rebate Provisions* (1993), Congressional Budget Office (1998), Morton (June 1996 and 1997), and Wagner (1993).

<sup>182</sup> As discussed in Chapter II, these incentive payment programs were successfully challenged by a number of states on consumer protection grounds.

companies are engaging in illegal price discrimination.<sup>183</sup> In fact, while only a few states (e.g., Maine, Minnesota, and Wisconsin) have enacted statutes prohibiting drug price discrimination, legislation was introduced in over 30 states aimed at eliminating differential discounts in the sale of prescription drugs.<sup>184</sup> Maine's 1994 law, for example, requires that pharmaceutical companies offer discounts to retail pharmacies on the same terms as others, and the law prohibits class-of-trade discounts.

As mentioned earlier, retail pharmacies have also filed dozens of private lawsuits against drug companies in efforts to challenge these differential pricing practices.<sup>185</sup> In the largest class action lawsuit, thousands of retail pharmacies have alleged that major drug companies operate a conspiracy to fix the prices of prescription drugs in violation of the Sherman Act (15 U.S.C. §1) and set discriminatory prices in violation of the Robinson-Patman Act (15 U.S.C. §§13(a), (d) and (f)) by refusing to grant retail pharmacies discounts available to institutional buyers or

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<sup>183</sup> In addition, a few years ago the Virginia state legislature considered a bill that would ban incentive payments by pharmaceutical companies to retail pharmacists who persuade doctors to change prescription orders from one brand-name drug to another, eliminating this form of differential pricing in Virginia. One commentary on this legislative initiative mentions two notable studies suggesting that therapeutic switching programs raise health care costs because they create the need for additional health care services stemming from side effects caused by the drug switches (See, Baker (1997)).

<sup>184</sup> For descriptive discussions of these legislative initiatives, see Scott (1995) and "The Continuing Search for a Level Playing Field." (1995). For a more detailed discussion of the statutes enacted in Maine, Minnesota, and Wisconsin, see *Drug Price Discrimination Laws and the Robinson-Patman Act* (1996).

<sup>185</sup> For discussions of these lawsuits against drug companies, see Kimball (1994), Cohen and Tanouye (1996), and Gebhart (1994).

managed care organizations.<sup>186</sup> In 1996, a federal judge approved a settlement between some of the drug companies and retail pharmacies that included a \$350 million cash settlement and an agreement by these companies to refrain from setting discriminatory prices against retail pharmacies that demonstrate the same ability as HMOs to alter prescription drug market shares.<sup>187</sup> These private actions, along with other evidence of differential pricing, suggest a number of alternative explanations for this pricing conduct.

## **2. Differential Pricing and Possible Price Discrimination**

### **a. Introduction to Price Discrimination in Drug Markets**

In theory, competitive models of price discrimination might help to explain the differential pricing practices that have emerged in prescription drug markets in recent years. The aggregation of consumers by cost-containment institutions effectively groups cost-conscious buyers together, segmenting them from other consumers of prescription drugs. Arguably, this raises the price elasticities of demand for these groupings of buyers and allows drug companies to distinguish these consumers from others. Further, the growing use of generic and therapeutic drug substitution programs, coupled with a relaxation of entry impediments, means that buyers

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<sup>186</sup> See, *In re Brand Name Prescription Drugs Antitrust Litigation*, No. 94 C 897, MDL 997, slip op. at 2-3, 1996 U.S. Dist. LEXIS 4335 (N.D. Ill. Apr. 4, 1996).

<sup>187</sup> See, *In re Brand Name Prescription Drugs Antitrust Litigation*, 1996-2 Trade Cas. (CCH) ¶ 71,449 (N.D. Ill. June 21, 1996). For discussions of this decision and other aspects of the settlement, see the discussion entitled "Class Action Settlement Approved in Prescription Drug Pricing Case." (1996), Conlan (July 1996), Danzon (1997), an article entitled "Price-Fixing Settlement Gets Final Nod." (1996), and Scherer (1997). Recently, the district court entered judgment in favor of the remaining drug company and drug wholesaler defendants, finding no evidence that they conspired to deny retail pharmacies price discounts on brand-name prescription drugs (See, *In re Brand Name Prescription Drugs Antitrust Litigation*, Slip Op. at 43 (N.D. Ill. Jan. 19, 1999)).

such as HMOs may readily substitute between and among differentiated drug alternatives. Consequently, the cross-price elasticities of demand for drugs for these groups of buyers may be higher than for other groups. These relatively new developments may give rise to competitive forms of price discrimination, as economic theory indicates that persistent price discrimination can occur in heterogeneous product markets that are otherwise subject to competitive conditions.<sup>188</sup>

Even though price discrimination may result in different price-cost margins for different segments of demand, it does not necessarily raise competitive concerns.<sup>189</sup> Price discrimination is not necessarily inconsistent with competition: it might take place in prescription drug markets where buyers have 4 or 5 alternatives, or, in theory, even in monopolistic prescription drug markets so long as entry is easy. Yet, as summarized in Appendix A, there are various

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<sup>188</sup> See Borenstein (1985) and Holmes (1989) for the development of competitive price discrimination models. Borenstein develops a monopolistically competitive model of price discrimination which differs from standard monopoly models because, in addition to differences in willingness to pay, price discrimination could stem from differences in either brand preference or the strength of brand preference. Holmes develops a duopoly model of third-degree price discrimination which differs from standard monopoly models because, in addition to differences in willingness to pay, price discrimination could stem from differences in brand preference. Empirical applications of these models appear in the literature (See, Borenstein and Rose (1994) and Borenstein (1991)). Other competitive models of price discrimination, relying on spatial competition theory, also appear in the literature on price discrimination (See, Katz (1984), Lederer and Hurter (1986), and MacLeod, Norman, and Thisse (1988)).

<sup>189</sup> This discussion does not address the possibility that economic price discrimination may raise concerns under the Robinson-Patman Act.

impediments to entry into prescription drug markets.<sup>190</sup> Accordingly, even when doctors and patients have few therapeutic drug alternatives, an assessment of entry conditions is required in order to determine whether price discrimination in prescription drug markets harms competition.

As a general rule, entry with new brand-name drugs is a costly, lengthy, and risky process.<sup>191</sup> In addition, existing and new therapeutic drug alternatives may have difficulty obtaining formulary placements within the various therapeutic categories.<sup>192</sup> Moreover, strategic commitments by incumbents could further discourage entry. For example, strategic product differentiation initiatives by brand-name drug companies, or efforts to impede generic entry, could increase the marginal costs of entry in a manner consistent with anticompetitive discriminatory prices for prescription drugs.<sup>193</sup> Product differentiation strategies may include the development of extended-release versions of certain brand-name drugs to replace prior brand-

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<sup>190</sup> In theory, competition could prevail in various market structures with free entry and exit conditions (See, Baumol, Panzar and Willig (1988) and Spence's review article on contestable market analysis in Ricketts' *Neoclassical Microeconomics* (1988)). The possibility of competitive price discrimination (in free entry markets) is also well-established, as summarized earlier in this chapter.

<sup>191</sup> Chapter II and Appendix A discuss these and other requirements for developing and marketing new drugs.

<sup>192</sup> In markets where additional drugs are available, but not yet on drug formularies, however, it may be difficult for drug companies to price discriminate against buyers with mechanisms to contain their drug costs. For example, a motion for summary judgment by drug companies in the pharmaceutical pricing litigation was rejected, in part, because of evidence of relatively high margins on prescription drug sales to retail pharmacies (See, *In re Brand Name Prescription Drugs Antitrust Litigation*, No. 94 C 897, MDL 997, slip op. at 1, 1996 U.S. Dist. LEXIS 4335 (N.D. Ill. Apr. 4, 1996)). For a critique of this decision, see Scherer (1997).

<sup>193</sup> For a discussion of how product differentiation and other strategies may establish sufficient conditions for anticompetitive price discrimination, see Baker (Spring 1997) and Neven (1989).



names subject to generic competition.<sup>194</sup> In addition, as discussed in Chapter III, drug companies face fees for drug formulary placement services that may increase the cost of entry (expansion).

On the other hand, while entry with new prescription drugs is difficult, other forms of entry or expansion may take less time to accomplish. For buyers that include hospitals and HMOs, for example, access to alternative drug treatments may simply require that these buyers place available therapeutic alternatives on their drug formularies. More generally, cost-containment institutions are likely to facilitate entry (expansion) by prescription drug companies and distributors since they have a strong incentive to encourage the additional competition likely to emerge from new entrants.<sup>195</sup> For these reasons, the extent to which the prospect of entry or expansion discourages the exercise of market power must be assessed when evaluating allegations that price discrimination harms competition.

**b. Some Price Discrimination Models**

The purpose of this section is to examine how well the theoretical, competitive models of price discrimination might perform in explaining differential pricing in prescription drug

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<sup>194</sup> For a 1995 discussion of conditions under which product differentiation efforts could lead to excessive product variety in free entry markets, see Anderson, Palma, and Nesterov (1995).

<sup>195</sup> For discussions of buyers' incentives to encourage entry, see Coate and Kleit (1993) and Scheffman and Spiller (1992).

markets.<sup>196</sup> Competitive price discrimination models are most likely to apply in the increasingly common circumstances where multiple generic or therapeutic alternatives exist (regardless of whether entry is easy). To illustrate a simple model of competitive price discrimination for the case of the "two-tiered pricing structure" described above, assume that drug consumers fall into brand-loyal and price-sensitive categories, and that these consumers have access to differentiated prescription drug alternatives (i.e., different alternative treatments for the same disease state) of Manufacturer A (Drug A) and Manufacturer B (Drug B).<sup>197</sup> Also, assume that Manufacturers A and B maximize their profits by charging the same equilibrium discriminatory prices between brand-loyal and price-sensitive consumers, and that they face the identical marginal costs and demands for their drugs at given sets of prices. Under these conditions, the price facing each group of consumers for each of the drugs depends on the price elasticity and cross-price elasticity of demand. Price discrimination against brand-loyal consumers arises if their demand for Drugs A and B is less elastic than the demand by the price sensitive consumers, and/or if they are less willing than price sensitive consumers to substitute between Drugs A and B.

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<sup>196</sup> This does not mean that unilateral competitive effects from monopoly price discrimination could not emerge in prescription drug markets. On the contrary, if the other conditions for profitable price discrimination exist (e.g., market segmentation is possible and resale arbitrage is unlikely), monopoly models would apply if: (1) consumers do not have access to even differentiated alternatives for a given prescription drug; or (2) a single supplier produces all available substitutes. These conditions could be met in a variety of circumstances, including cases in which drug companies realize unilateral market power by introducing novel brand-name prescription drugs. For a survey discussion of different models of price discrimination, see Varian's treatment of price discrimination models in Schmalensee and Willig (1989).

<sup>197</sup> One could characterize price sensitive consumers as all members of cost-containment organizations, and brand-loyal consumers as all other consumers. Price sensitive buyers are subject to cost-containment mechanisms that include therapeutic and generic substitution initiatives, while brand-loyal consumers are not subject to these initiatives.

Appendix B more fully specifies this model, and derives the elasticity conditions that determine the prices for both groups of consumers.<sup>198</sup>

With respect to the pharmaceutical industry, several noteworthy features of competitive price discrimination models merit attention. First, unlike the case of monopoly price discrimination, differences in cross-price elasticities as well as price elasticities could underlie competitive price discrimination. For instance, a group of buyers could face lower prices than another group because their demand is more elastic or because they are more willing to substitute between these drugs. Arguably, both of these characteristics apply to prescription drug consumers affiliated with HMOs.

Second, competitive price discrimination can persist if potential entrants find it unprofitable to enter at existing discriminatory prices. Supply conditions in the pharmaceutical industry suggest that there are impediments to entry. The discussion in Appendix A demonstrates that it is likely to take new entrants several years to introduce competing drugs. Pharmaceutical companies may find it profitable to engage in price discrimination during this time period. Further, it is unlikely that generic entry would defeat discriminatory pricing in prescription drug markets since these entrants tend to serve segments of demand with relatively high price and cross-price elasticities. This does not mean that brand-loyal consumers are completely insensitive to the price of generic drugs, but that a cost-containment environment with ongoing generic entry causes these consumers to have lower price and cross-price elasticities of demand than other groups of consumers. In other words, industry changes that include changes in segment demand elasticities could alter pricing from some uniform quality-

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<sup>198</sup> Although competitive price discrimination models exist in theory, their possible application to the pharmaceutical industry has received significantly less attention.

adjusted price equilibrium to a discriminatory price equilibrium.<sup>199</sup> In any event, the availability of generic drugs would not necessarily undermine any price discrimination efforts by brand-name drug companies, and might unintentionally facilitate discriminatory pricing as prescription drug companies attempt to maximize profits.<sup>200</sup>

Third, several conditions must apply before these theoretical, competitive price discrimination models might explain pricing in prescription drug markets.

(1) Brand-name drug preferences must differ across different segments of demand. For instance, consumers affiliated with HMOs might effectively possess weaker brand preferences than others (e.g., uninsured consumers or consumers insured under indemnity health plans) since managed care plans might encourage more drug substitution than other consumer agents.

(2) Drug companies must have access to some means of sorting consumers for the purpose of engaging in profitable price discrimination. This would involve both segmenting demand and preventing arbitrage. Again, in competitive price discrimination models, willingness to pay or brand preference differentials are bases for sorting consumers. In the drug industry, affiliations with different types of health insurance organizations could provide drug companies with useful information pertinent to sorting consumers. HMOs, for example, may be viewed

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<sup>199</sup> This discussion envisions equilibrium pricing before and after changes in a drug industry that is subject to free entry constraints, but does not conclude that there is an absence of entry barriers in prescription drug markets. An illustration of a limiting case might clarify this comparison. Assume State I refers to an equilibrium before changes in the drug industry and State II refers to an equilibrium after these changes. Before the industry changes, assume drug companies cannot sort consumers into brand-loyal and price sensitive categories. This implies that these groups have uniform demand elasticities, and, according to the elasticity conditions in Appendix B, both consumer groups would face the same prices. After the industry changes, assume drug companies can sort consumers on the basis of different demand elasticities. Drug companies may now be able to sort buyers by simply segmenting those consumers affiliated with cost-containment institutions from others. This ability to sort implies that segment demand elasticities have changed relative to one another, and, according to the elasticity conditions in Appendix B, brand-loyal and price sensitive consumers would face different prices. In sum, although drug companies maximize profits in both States I and II, market changes move the industry from a uniform to a discriminatory price equilibrium.

<sup>200</sup> Generic entry could also increase the dispersion of prices since, other factors equal, prices to the price sensitive consumers would decline with generic entry.

as drug buyers that provide health insurance to cost-conscious consumers that possess relatively weak brand-name drug preferences.

(3) Entry by drug companies serving particular groups of consumers must not occur. For example, in the unlikely event that discrimination against uninsured individuals gives rise to entrants who specialize in serving this segment of demand, then price discrimination schemes could break down. Drug companies, however, do not supply their drugs to only particular segments of demand. Significant economies of scale or scope in drug production, marketing, or distribution are likely to prevent specialized entry attempts. Price discrimination is more likely as a result.

The changing pharmaceutical industry may have increased the probability that these conditions apply to prescription drug markets. In particular, the aggregation of buyers by cost-containment institutions may facilitate the segmentation of drug demand. Buyer aggregation also may enable drug companies to distinguish price-sensitive segments of demand from others. In addition, it is unlikely that specialized entrants would emerge within prescription drugs markets. It is also unlikely that new entrants would respond immediately to profit opportunities since new drug development is a lengthy process. Competitive price discrimination is more likely to emerge under these circumstances in those market segments with at least a few pharmaceutical alternatives.

### **3. Other Explanations for Differential Pricing**

In theory, differential pricing of prescription drugs might not reflect any discriminatory pricing conduct by drug companies. Instead, the price differences might simply reflect unrecognized costs or ill-defined services associated with the sale of pharmaceutical products.<sup>201</sup>

It may be difficult to determine which of these theories applies in the case of prescription drugs. A decision on various motions for summary judgment in the drug pricing litigation

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<sup>201</sup> The literature, in addition to price discrimination, points to several alternative explanations for apparent price differences. These differences could stem from unrecognized costs or quality differentials across sales categories (See, Lott and Roberts (1991)).

contains a summary of reasons why drug companies set higher prices for retail pharmacies and lower prices for others.

The defendants [drug manufacturers] maintain that the various pricing and discounting decisions made by the defendants were based on a variety of legitimate business concerns, including the changing posture of the health care industry and the economic emergence of managed care. The granting of discounts to hospitals and managed care organizations was purportedly justified by the manufacturers' desire to avoid being denied access to participating physicians and patients. The denial of comparable discounts to retail pharmacies was similarly justified given the defendants' belief that the retail pharmacies, which did not utilize restrictive formularies, did not possess the same ability to deny manufacturers access to certain groups. ... According to the defendants, discounts were not extended to retail customers because, unlike managed care, retail customers did not have the power to affect market share.<sup>202</sup>

The manufacturers' motion for summary judgment was denied, in part because of some evidence indicating that retail customers could also affect drug market shares. One interpretation is that retail demand is more inelastic than hospital and health maintenance organization demand. If so, different discounts to these different classes of buyers might amount to competitive price discrimination, but it would still be necessary to evaluate conditions of entry in specific instances and determine whether or not drug companies can effectively sort these buyers into identifiable groups before concluding that these price differences represent anticompetitive price discrimination.

But this is not the only possible interpretation of the facts in this matter. It is conceivable that the facts are consistent with cost or service-based justifications for price discrimination that appear in the economic literature. For instance, unlike retail pharmacies, hospitals and HMOs might effectively provide promotional services to drug companies in addition to purchasing their

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<sup>202</sup> See, *In re Brand Name Prescription Drugs Antitrust Litigation*, No. 94 C 897, MDL 997, slip op. at 29-30, 1996 U.S. Dist. LEXIS 4335 (N.D. Ill. Apr. 4, 1996).

prescription drugs.<sup>203</sup> This could take the form of prescription drug trials in hospitals that lead to additional outpatient consumption, and to a variety of formulary services that effectively amount to advertising. Arguably, preferred placements on HMO formularies are examples of this type of formulary service. Discounts on drug purchases for these preferred placements could simply represent payments for a form of semi-exclusive advertising undertaken by HMOs on behalf of drug companies. In addition, if the preferred formulary placements are a more efficient means of marketing prescription drugs than efforts undertaken by others, including retail pharmacies, drug companies may find it less costly to supply drugs to HMOs than to retail pharmacies. If so, charging HMOs lower prices than retail pharmacies would simply reflect the lower costs of supplying drugs to these cost-containment organizations.

Another way HMOs increase drug sales is through their use of therapeutic substitution initiatives. As discussed in Chapters II and III, HMOs receive rebates for facilitating switches among therapeutic drug alternatives. If HMOs are more successful or efficient than retail pharmacies at supplying these services, rebates to only these HMOs are not necessarily discriminatory. Instead, these rebates would simply represent payments by drug companies to HMOs for the efficient provision of marketing services. These, and other explanations of

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<sup>203</sup> Hospitals might lack the incentives to provide promotional services to pharmaceutical companies, particularly if these services lead to drug treatments that are not in the best interests of their patients. However, it is not obvious that the provision of promotional services would amount to a disservice to hospital patients. For example, the promotional services might simply amount to the ongoing use of effective drug treatments by physicians who learn about them in hospital settings. Hospitals benefit from the lower prices, while their patients are given access to drug treatment alternatives and drug information through their physicians.

discriminatory or differential pricing in prescription drug markets,<sup>204</sup> merit further attention before concluding that this conduct is anticompetitive.

### **C. Generic Entry by Brand-Name Drug Companies**

The significant competition brand-name drug companies anticipated from generic competitors motivated these companies to enter the generic segment with generic versions of their own brand-name drugs before others entered the segment. In the early 1990s, this practice began with Merck's formation of West Point Pharma, a division established to market generic versions of Merck's drugs that lost patent protection.<sup>205</sup> This was followed by a variety of production and marketing agreements that allowed brand-name drug suppliers to make generic versions of their drugs before others, and by several acquisitions of generic companies by brand-name companies that included the acquisition of Rugby by then Marion Merrell Dow and Copley Pharmaceutical by then Hoechst Celanese.<sup>206</sup>

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<sup>204</sup> Alternative explanations stemming from cost differentials, including potential differences in production, planning, marketing, and distribution costs, could also explain the price differences in prescription drug markets. For a recent discussion of cost and other defenses to allegations of price discrimination under the Robinson-Patman Act, see Clark (1998).

<sup>205</sup> It is important to mention that this entry strategy of the early 1990s was one of several strategies undertaken by brand-name drug companies to compete more intensely in the price dimension. Aggressive pricing of brand-name drugs, particularly to HMOs and PBMs in competition with generic alternatives was another practice pursued by brand-name drug manufacturers in this evolving competitive environment. For an overview of this changing competitive dynamic, see Scherer (1996).

<sup>206</sup> For an historical discussion of the entry of brand-name drug companies into the generic segment by acquisition or otherwise, see Goldberg (1994). In contrast, for another discussion of the recent trend toward the divestiture of generic drug units by brand-name drug companies, see Congressional Budget Office (1998).



Commentators have suggested that this practice of introducing generic drugs before others may enable patent holders to set anticompetitive prices for their drugs after the patents expire.<sup>207</sup> Two potentially different anticompetitive scenarios are noteworthy. One explanation is that this practice of early generic entry by the firm whose patent is lapsing may either preempt or make it more costly for others to enter the generic market segment once patents expire. The basic idea is that because brand-name companies possess an inherent first-mover advantage in introducing generic forms of their brands before others, they may be able to set prices above the marginal costs of supplying these generic drugs, notwithstanding the possibility that other firms may later enter the generic segment. In particular, since it is likely that retail pharmacy and other buyers face costs of switching suppliers, the first supplier to introduce a generic drug can set a price above the marginal cost of subsequent entrants without necessarily inducing buyers to switch to their generic alternatives. This could allow brand-name suppliers to maintain prices above marginal costs after the expiration dates of applicable patents, and also make entry unprofitable. A second possible anticompetitive concern is that brand-name drug companies may be able to extend their patent monopolies with the earlier introduction of generic drugs by imposing anticompetitive contract prices for these generic forms that extend beyond the patent

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<sup>207</sup> See, Davis (1995) and Liang (1996). For a discussion of alternative marketing strategies brand-name companies might pursue in the face of generic competition, see Mehta and Mehta (1997).

expiration dates.<sup>208</sup> Monopoly extension may occur if contract prices are negotiated before applicable patents expire, but the contract terms extend beyond the patent expiration dates.

Yet, these anticompetitive possibilities are not preordained, for several reasons. First, consumers will benefit from the early introduction of a low-priced generic form of a branded drug, even if the generic price is higher than it would have been had the generic form not been introduced by the brand-name producer. A higher price could emerge if the brand-name drug company prices the generic drug higher than an independent generic drug company would as part of an effort to limit cannibalization of the brand's sales revenue. It is not obvious, however, that generic prices would necessarily be lower with initial entry by an independent generic drug company. In particular, under the two anticompetitive theories discussed above, similarly-timed generic entry by either the brand-name drug company or an independent generic supplier could result in the same prices (i.e., some markup over the marginal cost of follow-on entrants that depends on the extent of the switching costs), unless the expected profitability of follow-on entry depends on whether or not the brand-name drug manufacturer is the first to enter the product category.

This leads to a second point. Anticompetitive outcomes depend crucially on the possibility that early entry by the brand-name producer will deter follow-on entry by other generic producers, even if the first firm is charging a price for generics in excess of the

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<sup>208</sup> If the chief explanation of why brand-name drug companies are able to raise prices above the marginal costs of follow-on entrants is that buyers would incur switching costs (e.g., costs associated with negotiating new contracts and inventorying and distributing the generic drugs of other suppliers) should they decide to purchase generic drugs from subsequent entrants, then these two anticompetitive theories are the same. In both cases, anticompetitive prices arise and could extend beyond the time periods patents expire since the brand-name manufacturer that enters first benefits from a switching cost disadvantage that faces follow-on entrants, and because subsequent entry by others may be deterred.

competitive price. This could occur if such entry reduces the expected profitability of potential follow-on entrants. If, however, entry would not be deterred, the brand-name producer would not be able to use its first-mover advantage to insist on prices above competitive levels in post-patent expiration periods.<sup>209</sup>

Third, it is not necessary to appeal to an anticompetitive theory to explain why some brand-name drug companies use contractual arrangements with at least some buyers when making generics available in advance of patent expiration. Instead, other industry changes that led to the overall growth of the generic drug segment, including the passage of Waxman-Hatch Act and the enactment of state drug substitution laws, could also explain why these brand-name drug companies have entered this segment of the pharmaceutical industry. Other factors equal, entry stimulated by the growth of this segment would be a procompetitive reaction to changes in the marketplace. In addition, these contracts may also reflect the trend toward contract sales in the managed care segment of the pharmaceutical industry, and not represent any evidence of anticompetitive effects.

Fourth, in light of the growth of cost-containment institutions and the availability of information technology, drug purchasers, particularly in the managed care segment, have gained access to additional information on drug alternatives that may make these segments of the market more competitive. Access to and use of information technology may reduce any information disadvantage these buyers have relative to brand-name drug companies, and also may limit the ability of these companies to use any remaining information advantage to secure

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<sup>209</sup> Another way to make the point is to observe that unless entry is deterred, brand-name drug companies would not be able to acquire the additional market power necessary to enable them to negotiate longer term contracts with prices above corresponding marginal costs.

higher prices by entering the generic drug segment before others. To do so, it would be necessary to argue that HMOs, PBMs, and other cost-conscious buyers fail to internalize the cost of prescription drugs, and are not knowledgeable about available substitutes. It is possible that, despite significant incentives to control drug costs and to utilize information technology to obtain and apply information about alternative drug treatments, HMOs are not able to completely control the prescribing behavior of affiliated physicians.<sup>210</sup> It is also plausible that drug companies are effective in their detail activities with regard to physicians either directly employed by HMOs or otherwise affiliated with HMO networks. If these physicians fail to internalize the cost of prescription drugs, higher brand-name drug prices may result. If, however, managed care organizations address this possibility by using effective drug formulary management programs and other cost-containment initiatives, it is difficult to see how brand-name drug companies, by exploiting first-mover advantages to introduce generic drugs before others, would cause higher prices under these circumstances.

Finally, if early entry strategies by brand-name drug producers commonly generate streams of anticompetitive profits, it is not obvious why several prominent brand-name drug companies decided to divest their generic drug assets. Recently, for example, Merck sold its generic drug interests to Endo Pharmaceutical executives, Hoechst Marion Rousell sold its

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<sup>210</sup> If HMOs increase their use of more flexible models, including IPA/network HMO models (i.e., a model in which the HMO forms a network of otherwise independent physicians and other providers), they may become less effective at influencing the prescribing behavior of their affiliated physicians. In fact, IPA/network HMO models accounted for the largest percentage of the HMO enrollment in a recent survey of a sample of HMOs, accounting for over 40 percent of HMO enrollment within this sample (See, *Novartis Pharmacy Benefit Report - Trends & Forecasts* (1997)).

Rugby Laboratories to Watson Pharmaceuticals, and Warner-Lambert sold its generics unit to Elan Corporation.<sup>211</sup> Exit strategies, which would presumably impede entry into the generic segment by brand-name drug companies,<sup>212</sup> seem inconsistent with the view that the early generic entry strategies of these companies are generally anticompetitive, though do not preclude that possibility in any individual case.

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<sup>211</sup> For a discussion of this current trend involving the divestiture of generic subsidiaries of brand-name drug companies, see Freudenheim (1997).

<sup>212</sup> Brand-name pharmaceutical companies that supply generic versions of their own prescription drugs after they divest their affiliated generic drug companies may face impediments if they enter these markets by alternative means (e.g., entry that requires costly contractual arrangements with existing generic drug companies). If so, after divesting their generic drug subsidiaries, brand-name drug companies could face higher costs if they engage in efforts to subsequently enter generic drug markets by contracting with independent generic drug companies. In these cases, the exit strategies could potentially delay or deter brand-name drug companies from entering generic drug categories in the future. Nevertheless, brand-name drug companies could always enter into alliances with generic drug companies to introduce generic prescription drugs. As a result, even if these companies sell their generic drug divisions, they could still supply generic forms of their own brand-name drugs before others by entering agreements with independent generic drug companies that would market these generic forms on behalf of the brand-name drug companies.



## Chapter V

### Antitrust Issues and the Changing Pharmaceutical Industry

#### A. Introduction

In addition to issues surrounding the differential pricing practices of drug companies, the environment of change in the pharmaceutical industry raises several vertical and horizontal antitrust issues surveyed in this chapter. The major vertical issues involve information exchanges among vertically integrated drug companies, vertical contracting practices, and vertical integration. The key horizontal issues involve market definition and market power concerns, the competitive effects of mergers in innovation markets,<sup>213</sup> and the possibility of broader forms of merger-related coordinated or unilateral anticompetitive conduct.

#### B. Vertical Integration and Contracting in the Drug Industry - Some Antitrust and Competition Issues

Vertical acquisitions of prescription benefit management (PBM) companies by drug companies could facilitate anticompetitive information exchanges. The PBM assets acquired by

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<sup>213</sup> For example, as a result of its investigation of the acquisition of American Cyanamid by American Home Products Corporation, the FTC's complaint, among other concerns, raised the possibility that this acquisition could result in anticompetitive effects in research and development markets for Rotavirus vaccines (See, *American Home Products Corporation*, FTC Docket No. C-3557, Complaint, (February 14, 1995)). In addition, in its report on global competition, FTC staff focused some attention on competition in innovation markets and discussed ways to evaluate mergers in research and development markets (See, the Federal Trade Commission's report entitled *Competition Policy in the New High-Tech, Global Marketplace*, Volume I, (May 1996)).

drug companies include the information technology networks that are at the hearts of these organizations. The combination of access to competitor information and information technology might facilitate information exchanges among drug companies that could enhance the likelihood of price coordination.<sup>214</sup> Vertical contracts, particularly most-favored-nations (MFN) and volume-related rebate provisions, could also raise competitive concerns. In addition to raising concerns over vertical foreclosure,<sup>215</sup> vertical integration itself may give rise to other potential anticompetitive effects.<sup>216</sup>

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<sup>214</sup> For discussions of conditions under which information sharing could enhance incentives to engage in some traditional form of coordinated interaction or otherwise reduce consumer welfare, see Baker (1996), Bernheim and Whinston (1985), Clarke (1983), and Freid (1984). For a broad discussion of antitrust issues and cases involving information sharing among suppliers of health care services, see the American Bar Association's *Information Sharing Among Health Care Providers: An Antitrust Analysis and Practical Guide* (1994). Also, see the literature on "cheap talk" for discussions of simple mechanisms oligopolists might use to reach otherwise complex price coordination agreements (Farrell (1987), Farrell and Rabin (1996), Gillespie (1995), and Crawford and Sobel (1982)). Cheap talk generally refers to communications among suppliers that allow them to more easily reach price coordination agreements.

<sup>215</sup> The FTC challenged aspects of the vertical acquisition of PCS Health Systems by Eli Lilly & Co. A chief concern discussed in the complaint was that, as a result of the acquisition of PCS, Lilly would exclude the products of other drug companies from the PCS formulary (See, *Eli Lilly and Company*, FTC Docket No. C-3594, Complaint, (July, 28, 1995)). The FTC subsequently challenged similar aspects of the vertical acquisition of Merck-Medco Managed Care by Merck & Co., Inc. (See, Federal Trade Commission. "Merck Settles FTC Charges that Its Acquisition of Medco Could Cause Higher Prices and Reduced Quality for Prescription Drugs." Press Release, (August 27, 1998)).

<sup>216</sup> For summary discussions of different aspects of the FTC's antitrust policy toward vertical integration in the pharmaceutical industry, see Balto (1997) and Steiger (1996). For an earlier summary discussion of vertical theories of competitive harm, see U.S. Department of Justice, *Merger Guidelines*, 4 Trade Reg. Rep. (CCH) ¶13,103, (1984) (*1984 Horizontal Merger Guidelines*).



## 1. **Vertical Integration, Information Technology and the Exchange of Information**

Along with generating possible efficiencies,<sup>217</sup> information technology and vertical integration could facilitate anticompetitive information exchanges in two major ways.

### a. **Vertical Integration, Information Exchange and Possible Price Coordination**

As discussed in Chapter II, drug companies own or have alliances with pharmacy benefit management firms (PBMs) that account for over 70 percent of the prescriptions processed by all PBMs. This degree of vertical integration raises the potential for problematic information exchanges among vertically integrated drug companies.<sup>218</sup> The FTC addressed this issue specifically in its 1995 consent agreement with Eli Lilly and Company (Lilly), even though its complaint in this matter only dealt with this issue in general terms.<sup>219</sup> The consent order, in relevant part, reads,

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<sup>217</sup> Chapter III discusses possible efficiencies that could arise from the application of information technology to the pharmaceutical industry.

<sup>218</sup> Under the standard theory, drug companies, through their ownership of or affiliation with PBMs, exchange competitive information (e.g., transaction prices, rebates, and bids) that might facilitate the formation and/or monitoring of price coordination agreements in prescription drug markets. If the markets are concentrated and difficult to enter, and should the information exchanges allow drug companies to better anticipate and monitor rival conduct, anticompetitive effects could result. These effects could take the form of direct price increases, reductions in rebates, and/or increases in capitated rates. For a discussion of a collusion model, see Clarke (1983).

<sup>219</sup> The FTC's complaint in this matter does not contain any specific language indicating that vertical integration by drug companies into the provision of PBM services might lead to anticompetitive exchanges of information, but does indicate that this transaction could facilitate price coordination among vertically integrated drug companies (See, *Eli Lilly and Company*, FTC Docket No. C-3594, Complaint, ¶13, (July 28, 1995)).

A. Lilly shall not provide, disclose, or otherwise make available to PCS any Lilly Non-Public Information; and

B. PCS shall not provide, disclose, or otherwise make available to Lilly any PCS Non-Public Information.<sup>220</sup>

In addition to Lilly, public reports indicate that Merck & Co., Inc. and SmithKline Beecham also voluntarily agreed to erect similar so-called "fire walls" in connection with their PBM acquisitions.<sup>221</sup> Critics, including the National Association of Chain Drug Stores, question the enforceability of these consent provisions and suggest that they would not prevent the exchange of sensitive information between drug companies and PBMs.<sup>222</sup>

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<sup>220</sup> See, *Eli Lilly and Company*, FTC Docket No. C-3594, Consent Order, (July 28, 1995). According to this order, "'Lilly Non-Public Information' means information not in the public domain that is provided to Lilly in its capacity as a pharmaceutical manufacturer by a supplier of PBM Services and that concerns bids, proposals, contracts, prices, rebates, discounts, or other terms or conditions of sale of any person other than PCS." Similarly, "'PCS Non-Public Information' means information not in the public domain that is provided to PCS in its capacity as a supplier of PBM Services by a manufacturer or seller of prescription drug products and that concerns bids, proposals, contracts, prices, rebates, discounts, or other terms or conditions of sale of any person other than Lilly."

<sup>221</sup> See, for example, Conlan (June 1996). The FTC also recently entered into a consent agreement with Merck and Co., Inc. to settle allegations that its acquisition of Medco would (1) foreclose the products of other drug companies from Medco's formulary, (2) enhance the likelihood of collusion, and (3) eliminate Medco as an independent buyer of prescription drugs (See, Federal Trade Commission. "Merck Settles FTC Charges that Its Acquisition of Medco Could Cause Higher Prices and Reduced Quality for Prescription Drugs." Press Release, (August 27, 1998)).

<sup>222</sup> For a critical discussion of the consent agreement, see the United States General Accounting Office's report entitled *Pharmacy Benefit Managers - Early Results on Ventures With Drug Manufacturers* (1995). Others also raised questions about the adequacy of this consent decree in preventing exchange of information between Lilly and PCS (See, for example, Schulman, Rubinstein, Abernethy, Seils, and Sulmasy (1996)), and questioned the effectiveness of the consent decree in preventing Lilly from using closed formularies or raising drug prices (See, Letter from the National Association of Chain Drug Stores to the Federal Trade Commission (July 30, 1996) and Letter from the Consumer Federation of America to the Federal Trade Commission (July 31, 1996)).

Alternatively, the marriage of vertical integration, vertical contracting practices and information exchange opportunities might facilitate widespread collusion among vertically integrated drug companies.<sup>223</sup> In particular, the combination of vertical integration and MFN contract provisions could provide drug companies with additional incentives to coordinate the price/rebate provisions of multiproduct contracts with PBMs, and with a more effective means of monitoring deviations from a collusive agreement.<sup>224</sup> Drug companies could better monitor and detect deviations from a price coordination agreement because ownership of a PBM can provide drug companies with direct information on competitors' bids and transaction prices through the owned PBM. If a drug manufacturer learns that its rebate offers to PBM customers are higher than rival offers, it could reduce its rebate offers to these PBMs. In addition, ownership of a PBM can provide drug companies with indirect information on bids and prices available to rival PBMs through MFN provisions in PBM/drug company contracts. In fact, many of these MFN provisions require drug companies to notify PBMs under contract whenever they supply competing PBMs prescription drugs at lower transactions prices. In other words, MFN provisions could facilitate coordination by requiring vertically integrated drug companies to inform one another about certain price reductions to downstream PBM customers. Further, as

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<sup>223</sup> Although the discussion below outlines a standard theory of potential anticompetitive effects, other economic literature suggests that the use of fire walls to remedy possible anticompetitive information exchanges following vertical mergers could itself lead to higher prices for consumers. The basic idea is that fire walls reduce information flows between vertically integrated suppliers and unintegrated suppliers that would otherwise lead to additional price competition between them. (See, Thomas (1997)).

<sup>224</sup> Chapter III contains a more detailed discussion of MFN provisions in drug company contracts with PBMs and HMOs.

discussed in greater detail below, MFN provisions could reduce incentives to deviate from a collusive agreement since the provisions could require price reductions to a broader group of downstream buyers.<sup>225</sup> This, along with direct and indirect price information, could facilitate price coordination among drug companies.

Despite these foregoing considerations, information exchanges among vertically integrated rivals may not raise any competitive concerns. For example, unintegrated rivals or drug companies who do not negotiate MFN provisions may lack the necessary information about rival bids that would enable them to coordinate prices with their integrated rivals. Further, if drug companies attempt to use competitive information to exclude competing drugs from the formularies of their PBM affiliates as one possible means of restricting output, other PBMs that supply these drugs may prefer to take advantage of that competitive opportunity by increasing sales at the expense of the vertically-integrated PBMs, thereby counteracting any potential for price to rise.<sup>226</sup> In addition, ongoing generic entry would impede price coordination, particularly since HMOs and PBMs utilize mandatory generic substitution programs and generic drug companies would lack incentives to participate in a price coordination agreement.

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<sup>225</sup> The antitrust implications of MFN provisions were at issue in a 1998 case involving the drug wholesale segment of the pharmaceutical industry. In the FTC's case against several drug wholesalers, the court described how the use of MFN provisions could facilitate price coordination among prescription drug wholesalers by providing them with incentives to avoid price cutting competition that would otherwise take place (See, *FTC v. Cardinal Health, Inc. et al.*, Civil Action Nos. 98-595, 98-596, Slip Op. (D.D.C. July 31, 1998)).

<sup>226</sup> It is conceivable that neither unintegrated drug companies nor independent PBMS would be able to counteract coordinated price increases by their integrated rivals by expanding sales. Unintegrated rivals may face production or other capacity constraints that would impede their ability to expand in the short run, and may offer differentiated products or services that would be imperfect substitutes for managed care plans and other purchasers of prescription drugs.

Entry into PBM or relevant drug markets could also counteract any attempt to raise prices, provided that entry into these markets is easy.<sup>227</sup> For example, as mentioned earlier, several retail drug chains already entered into the provision of PBM services. Independent PBMs would lack incentives to participate in any upstream collusion that might benefit pharmaceutical companies.<sup>228</sup> These independent PBMs could serve as alternatives to consumers and plan sponsors who benefit from price competition among drug companies. Finally, under some circumstances, knowledge of competitor pricing would be expected to enhance, not reduce, price competition among upstream drug companies. If a drug manufacturer learns that its rebate offers to PBM customers are lower than rival offers, it could raise its rebate offers to these PBMs.

**b. “Cheap Talk” and the Pharmaceutical Industry**

Antitrust cases involving the securities and airline industries suggest how information technology in the pharmaceutical industry could be used to coordinate prices in prescription drug markets. In the case of airlines, for example, the Department of Justice (DOJ) alleged that competing airlines fixed airline fares using a jointly operated computer reservation system

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<sup>227</sup> It is noteworthy that in its complaint against Eli Lilly and Company, the FTC alleged that there are substantial entry barriers into the relevant PBM and prescription drug markets (See, *Eli Lilly and Company*, FTC Docket No. C-3594, Complaint, (July 28, 1995)).

<sup>228</sup> For a broader discussion of the emergence and functions of PBMs, see Balto (1998). With respect to the entry of independent PBMs, if drug companies coordinated higher prices, the existence of independent PBMs would not necessarily prevent this price coordination. However, these PBMs would have incentives to encourage additional price competition by, for example, sponsoring new entrants or facilitating any additional therapeutic competition that may exist among pharmaceutical companies.

known as Airline Tariff Publishing Co. (ATP).<sup>229</sup> Some evidence suggested that airlines used ATP to exchange information about possible future fares without necessarily binding themselves to any particular fare structure.<sup>230</sup> ATP, after receiving actual and planned fare changes from major airlines, distributed these fares to competing airlines. By using various designators on particular fare changes and by exchanging information on when fare changes might go into effect, DOJ alleged that airlines were able to use ATP to sort among the enormous number of fares and fare changes to identify and monitor efforts by competitors to coordinate fares. This computerized exchange of information allegedly enabled major airlines to coordinate higher fares and avoid fare wars that would undermine the price coordination agreement.

Unlike the airlines industry, the pharmaceutical industry does not operate a central information exchange network. Instead, with the possible exception of drug wholesalers,<sup>231</sup> numerous different information technology systems are used to computerize the distribution of prescription drugs. In addition, while drug companies now own many of the large PBMs, their

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<sup>229</sup> For discussions of the airlines case, see Baker (Fall 1996), *Economic Report of the President* (February 1998), and Gillespie (1995). See also, *United States v. Airline Tariff Publishing Co.*, 1994-2 Trade Cas. (CCH) ¶ 70,687, (D.D.C August 10, 1994). For some commentary on DOJ's case involving Nasdaq, see Schroeder (1996).

<sup>230</sup> For a discussion of the merits of this case, see Gillespie (1995).

<sup>231</sup> Prescription drug wholesalers receive price and other information from numerous drug companies, and may facilitate information exchanges that support price coordination attempts by pharmaceutical companies. See, *In re Brand Name Prescription Drugs Antitrust Litigation*, 1996 U.S. Dist. LEXIS 4335 (N.D. Ill. Apr. 4, 1996), *reversed*, 123 F.3d 599 (7th Cir. 1997) (Posner, C.J.). The likelihood of price coordination among drug wholesalers themselves factored into a decision by Judge Stanley Sporkin to issue preliminary injunctions in connection with two proposed mergers involving drug wholesalers (See, *FTC v. Cardinal Health, Inc. et al.*, Civil Action Nos. 98-595, 98-596, Slip Op. (D.D.C. July 31, 1998)). In addition, see *Burlington Drug Co. v. VHA, Inc.*, 898 F. Supp. 257 (D. Vt. 1995) for a discussion of a variety of related antitrust issues in private litigation involving drug wholesalers.

information technology networks generally operate independently of one another, making it unlikely that drug companies can use them to negotiate and maintain complex price coordination agreements. Further, since various contractual commitments on prices, rebate levels, and capitated rates form the basis for the operation of these PBM information networks, it appears more difficult for pharmaceutical companies to exchange information on the types of non-binding price or rebate offers that facilitated price coordination in the airlines case.

While the risk of coordination through information exchange may be less than in the airlines case, it cannot be ignored entirely. Vertical integration likely brings information more quickly and completely to drug companies than before.

## **2. The Competitive Effects of Selected Vertical Contract Provisions**

Two vertical contract provisions merit particular attention: MFN provisions and volume-based rebate provisions.

### **a. Vertical Contracts and MFN Provisions**

PBMs and HMOs often negotiate MFN provisions into their contracts with pharmaceutical companies. These provisions typically require drug companies to supply PBMs or HMOs with prescription drugs at transaction prices that are no greater than the transaction prices available to their direct competitors. The contracts also typically provide mechanisms for drug companies to make any necessary price adjustments. MFN provisions often apply to manufacturer rebate percentages, and could involve one or more prescription drug products.<sup>232</sup>

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<sup>232</sup> For a multiproduct contract between Drug Manufacturer A and PBM B, for example, the MFN provisions could require A to supply several prescription drugs to B subject to an overall percentage rebate from A to B that is no less than the overall percentage rebate A offers to any of B's competitors. MFN provisions could also apply to individual drug products purchased by B should A supply some individual prescription to a competitor of B at a lower price.

Under some circumstances, MFN provisions could generate efficiencies that lower costs and raise output levels. For instance, MFN provisions could serve as an efficient price mechanism in long term contracts for adjusting prices to reflect changes in demand and cost conditions.<sup>233</sup> For example, if supply-side changes reduce the costs facing an industry, MFN provisions would facilitate downward price adjustments to buyers with MFN status without the need for costly contract renegotiations. In addition, MFN provisions could lead to higher output levels as buyers respond to these price reductions by increasing their purchases.

On the other hand, MFN provisions could also lead to higher prices. MFN provisions may facilitate implicit price coordination by making it costly for firms to engage in selective price cutting, and these provisions might allow oligopolists to discourage competition by raising competitor costs.<sup>234</sup> These competitive effects could arise in the pharmaceutical industry.<sup>235</sup> In a coordinated interaction model with two colluding drug companies, the competitive concern can be illustrated by assuming that each drug manufacturer contracts with a distinct group of PBMs. Each of these two groups of PBMs has MFN status, and each collectively represents 25 percent of drug consumers. Because of the MFN provisions between manufacturers and PBMs, these

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<sup>233</sup> For a discussion and test of this efficiency hypothesis, see Crocker and Lyons (1994).

<sup>234</sup> For discussions of MFN provisions in oligopoly settings, see, among other references, Baker (Spring 1996), Cooper (1986), Holt and Scheffman (1987), Neilson and Winter (1992 and 1993), and Schnitzer (1994). MFN provisions could also permit monopolists, in a repeated game framework, to extract additional consumer surplus (See, for example, Neilson and Winter (1994)). For an earlier unilateral theory of competitive effects involving the use of MFN provisions, see Cooper and Fries (1991).

<sup>235</sup> Antitrust enforcement agencies have challenged MFN provisions in several industries including the manufacturing and, more recently, the retail distribution segments of the pharmaceutical industry (For discussions of these matters, see Baker (Spring 1996)).



two drug companies may have less incentive to compete for additional PBM buyers (who represent the remaining 50 percent of consumers) by offering lower prices.<sup>236</sup>

Anticompetitive prices would not arise from this strategy, however, if the drug companies supply their current PBM customers at competitive prices (i.e., these suppliers fail to commit to some form of coordination);<sup>237</sup> if other drug companies (not subject to MFN provisions) compete for other PBM business with products that are close substitutes for those offered by the drug companies who have agreed to MFNs;<sup>238</sup> or if new entry takes place at the manufacturing level sufficient to counteract supracompetitive prices. Moreover, these cooperating suppliers may be unable to discipline their rivals or potential rivals, though vertical integration into PBM markets may solve this difficulty by giving these companies some ability to foreclose rivals or potential entrants from access to much of the market or raise rivals' marginal costs of supplying competing drugs.<sup>239</sup> In sum, while MFN provisions could lead to efficiencies, they also might raise anticompetitive concerns under the conditions discussed above.

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<sup>236</sup> Drug companies that enter into contracts with MFN provisions may, by doing so, commit to a cooperative form of pricing. If so, even though MFN provisions may create unilateral incentives to avoid future price reductions, they can also be used as a device by drug companies to establish these commitments. As a practical matter, however, it may be difficult to determine whether drug companies that negotiate MFN provisions are acting unilaterally or cooperatively.

<sup>237</sup> For discussions on the importance of commitment, see Alexander and Reiffen (1995), Hart and Tirole (1990), Ordober, Saloner, and Salop (1992), and Reiffen (1992).

<sup>238</sup> In light of the Medicaid best price rules, any manufacturer that supplies drugs to Medicaid recipients would face consumers with MFN status. The Medicaid rules, therefore, may make it difficult to satisfy this requirement for anticompetitive effects.

<sup>239</sup> For discussions on whether or not it would be profitable to raise a rivals' marginal cost, see Krattenmaker and Salop (1986) and Salop and Scheffman (1987).

## b. Volume-Based Rebates and Exclusive Dealing Agreements

Vertical contracts with volume-based rebates, including the minimum volume and growth rebates discussed in Chapter III, could amount to exclusive dealing arrangements between drug companies and HMOs (PBMs).<sup>240</sup> This possibility arises because these contracts could induce HMOs and PBMs to maximize their rebates by transacting exclusively with those companies offering the most attractive terms.<sup>241</sup> Hence, these vertical contracts, like exclusive dealing arrangements, could cause competitive harm or could generate efficiencies in prescription drug markets.<sup>242</sup>

On the one hand, contracts with volume discounts might force competing drug companies to use less efficient means of marketing their drugs or could otherwise foreclose competition among them. One model of anticompetitive foreclosure operates quite simply. If one drug manufacturer is able to employ volume-based rebates in contracts with HMOs and PBMs to make it difficult for a rival manufacturer to achieve effective distribution for its

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<sup>240</sup> The economic literature discussing vertical contracts as exclusive dealing agreements often distinguishes between contracts with volume-based prices or quantity discounts and contracts with per unit prices. Vertical contracts with volume-based rebates or quantity discounts could serve as substitutes for exclusive dealing arrangements (See, for example, O'Brien and Shaffer (1994 and 1997)). Vertical agreements with unit price provisions have different competitive implications (See, for example, Aghion and Bolton (1987), Besanko and Perry (1993), Chang (1992), and Gilbert and Shapiro (1997)).

<sup>241</sup> Bork (1978) argues that manufacturers would have to compensate downstream distributors for exclusive distribution of their products in order to induce them to limit their product offerings. Minimum volume and growth rebates may represent forms of compensation to HMOs and PBMs for exclusive distribution rights for prescription drug companies.

<sup>242</sup> For a summary of alternative models developed to analyze the competitive effects of exclusive dealing agreements, see Frasco (1991). For another discussion on the possible anticompetitive effects of exclusivity arrangements, see Balto (October 1998).

competing drugs, the rival's marginal costs of distribution may rise. This may force the rival to reduce output and raise price, allowing the first drug manufacturer to raise price as well.<sup>243</sup> This anticompetitive theory might apply whenever market foreclosure is a concern; it is not limited merely to volume-based rebates. Accordingly, the conditions under which this anticompetitive possibility is plausible are discussed in greater detail in the next section.

Another model of possible anticompetitive market foreclosure requires more explanation. To illustrate this model, assume that upstream suppliers differ along some dimension but that they offer substitute products to a downstream distributor. Any one of these suppliers could potentially secure exclusive distribution rights if it were willing to offer sufficiently low prices so that exclusive distribution would maximize the distributor's profit.<sup>244</sup> Exclusivity would only be profitable to the supplier, however, if it possesses some product or cost advantage that it is able to share with the downstream distributor.<sup>245</sup> Otherwise, no particular supplier can increase both its profits and the distributor's profits using exclusive distribution rights. If exclusive contracts emerge, they are anticompetitive if the welfare gain from the lower prices that pass through to consumers is more than offset by the welfare loss from the reduction in product

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<sup>243</sup> The first drug manufacturer can share the resulting profits from charging an anticompetitive price for drugs with the HMOs and PBMs that it contracts with, perhaps in the form of a lump sum payment, in order to induce them to accept the volume-based rebates.

<sup>244</sup> The focus of this theory is on foreclosure using contracts with unit price provisions, but the authors suggest that foreclosure with quantity discount provisions is feasible (See, Mathewson and Winter (1987)).

<sup>245</sup> For a more formal development of this model, see O'Brien and Shaffer (1994 and 1997). For an earlier discussion of nonlinear contracts, see Shaffer and O'Brien (1992).

offerings.<sup>246</sup> For these contracts to persist, it is likely that any welfare loss would have to be borne by consumers or others that are not parties to these contracts,<sup>247</sup> and not by HMOs or PBMs subject to the exclusive contracts.<sup>248</sup>

On the other hand, vertical contracts with quantity discount provisions may facilitate price competition. This may be particularly true for contracts that award higher discounts to PBMs and HMOs that purchase higher shares of their drug requirements from the contracting drug companies. The highest discounts would apply to situations where PBMs (HMOs) purchase all of their requirements for given drugs exclusively from particular drug companies. In these cases, instead of competing on a continuous basis, competition for exclusive contracts may encourage intensive rivalry for the award of contracts, and may facilitate new entry in anticipation of contract renewals. Further, drug company/PBM contracts with volume-based

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<sup>246</sup> Another potentially anticompetitive foreclosure story involves the exclusion of potential entrants using penalty clauses in contracts between incumbent suppliers and distributors that penalize distributors that market the products of new entrants (See, Aghion and Bolton (1987)). An extension of this model would involve the use of quantity discounts to restrict entry. In such a model, quantity discounts could be used to induce distributors to deal exclusively with incumbent manufacturers, making it unprofitable for competing suppliers to enter the market or expand to achieve an efficient scale of operation.

<sup>247</sup> In addition to consumers, exclusive contracts may produce welfare losses for suppliers and other intermediaries that are not subject to these contracts. Non-contracting suppliers would face welfare losses if existing exclusive contracts force them to use more costly means of distributing their products. Non-contracting HMOs or PBMs would face welfare losses if existing exclusive contracts reduce their product variety or otherwise impose anticompetitive effects on them.

<sup>248</sup> If HMOs or PBMs have more information than consumers they may be able to circumvent any of the welfare loss by switching to available alternative drugs or by avoiding the use of exclusive contracts to purchase prescription drugs. In such cases, exclusive contracts would not persist over the long run.

rebate provisions may prevent free-riding, and could encourage efficient investments in drug marketing.<sup>249</sup> A review of various contracts indicates that drug companies pay PBMs for formulary management services designed to promote the use of their brand-name drugs. Without some degree of exclusivity, PBMs may find it profitable to use these promotional monies to market the drugs of competing companies. Volume-based rebates in drug company/PBM contracts may prevent this free-riding by competing drug companies.<sup>250</sup> Further, unlike vertical contracts with per unit prices, contracts with volume-based prices allow the

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<sup>249</sup> It has been argued that suppliers may under-invest in promotional activities that increase the demands facing competing companies unless contracts with downstream parties contain provisions that address this free-riding problem. This problem may be exacerbated if downstream distributors can influence the demands facing competing companies (See, Marvel (1982)). The pharmaceutical industry, however, ranks high among other industries in its expenditures on advertising and promotion of prescription drugs (e.g., 20 percent of sales by some estimates (See, Scherer (1996))). This suggests that drug companies do not under-invest in promotional activities.

<sup>250</sup> If volume-based rebates lead to exclusive contractual arrangements, PBMs would not be able to use promotional payments by drug companies subject to these arrangements to foster the use of prescription drugs of other suppliers. Further, this type of free rider problem is unlikely to arise if the services provided by PBMs occur after prescription drug sales, and if buyers are aware of alternative drug treatments prior to any advertising or promotional activity by PBMs. If PBMs provide postsale services to drug companies (e.g., the compilation of data on treatment outcomes) they can compensate PBMs for these services and, at the same time, benefit from the sale of their prescription drugs. In addition, if buyers are already aware of available drug treatment alternatives and their prices, promotional activities by PBMs do not necessarily provide useful information to such buyers. Under these circumstance, free riding would not necessarily generate inefficiencies. For a further discussion on the limitations of free rider concerns, see Scherer and Ross (1990).

contracting parties to avoid double markup distortions that constitute inefficiencies.<sup>251</sup> This suggests that the use of these contracts could increase output and lower prices in prescription drug markets.

Without detailed analysis of specific minimum volume and growth rebate contracts between drug companies and HMOs (PBMs), it is hard to assess their likely competitive effects. On the one hand, they could raise competitive concerns; on the other hand, their use could result in efficiencies that benefit consumers of prescription drugs.

### **3. The Competitive Effects of Vertical Integration**

Acquisitions of PBMs by drug companies have been the subject of several research studies that discuss several theories under which they might cause competitive harm.<sup>252</sup> The following discussion develops two of the more prominent anticompetitive theories of these vertical transactions. One involves market foreclosure scenarios, and the other involves the emergence of agency problems.<sup>253</sup>

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<sup>251</sup> The double markup problem arises when an upstream and a downstream firm both possess market power at their respective stages of production. Exercise of this market power could cause each firm to set price above the marginal cost of production, generating the double markup. Vertical contracts could incorporate price provisions that provide the contracting parties with incentives to jointly maximize their profit, and to share that profit without each firm independently setting price above marginal cost. For an additional discussion of these distortions, see O'Brien and Shaffer (1997).

<sup>252</sup> See, "Doubts Emerge About Drug Industry Mergers." (1994), Gondek et al. (1996), Hoffman and Garrett (1995), and the United States General Accounting Office's report entitled *Pharmacy Benefit Managers, Early Results On Ventures With Drug Manufacturers* (1995).

<sup>253</sup> Market foreclosure and other anticompetitive theories are also reviewed in other discussions of the competitive effects of PBM acquisitions by drug companies (See, Dodd (1995) and Balto (1997)).

**a. Vertical Integration and Market Foreclosure**

The significant degree of vertical integration arising from PBM alliances and acquisitions by drug companies raises foreclosure opportunities that could lead to competitive harm.<sup>254</sup>

Vertical foreclosure to both upstream prescription drug markets and downstream PBM service markets is possible. Although there is some mention of unilateral foreclosure theories, the scenarios below focus attention on ways in which foreclosure may facilitate collusion among upstream drug companies and downstream PBMs, respectively.<sup>255</sup> Different collusion theories are discussed to acknowledge the theoretical possibility that vertical integration may facilitate different forms of price coordination, even though all of these alternatives involve some discussion of market power.

**i. Vertical Integration and Foreclosure in Prescription Drug Markets**

PBM acquisitions by drug companies could raise the marginal costs of unintegrated drug companies and lead to higher prices and lower output levels in prescription drug markets.

Figure V.1 depicts a framework for evaluating this possibility. The model assumes that Drug

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<sup>254</sup> A well-established literature describes cost raising models of vertical mergers that could lead to higher prices and lower output levels. See, for example, Krattenmaker and Salop (1986), Nelson (1957), Ordoover, Saloner, and Salop (1990), and Salop and Scheffman (1983 and 1987). For treatments of the issue of commitment in these vertical models, see Alexander and Reiffen (1995), Hart and Tirole (1990), Ordoover, Saloner, and Salop (1992), and Reiffen (1992). For discussions on the evaluation of procompetitive and anticompetitive effects of vertical mergers, see Klass and Salinger (1995), Reiffen and Vita (1995), Salinger (1988), and Salop and Riordan (1995).

<sup>255</sup> In this context, foreclosure refers to the possibility that vertical integration may facilitate coordination among vertically integrated rivals that leads to the exercise of market power in upstream or downstream markets that are difficult to enter without being undermined by price competition from unintegrated competitors.





necessary for third-party payers, consumers, and others to pay anticompetitive prescription drug prices, but C lacks the necessary private incentives to cooperate with A and B. After the acquisition of downstream PBMs, assume that Manufacturers A and B provide C with less desirable placements on the drug formularies of these PBM affiliates, requiring C to use potentially less efficient means of marketing its drugs.

Anticompetitive effects emerge from this exclusionary conduct if: (1) Manufacturers A and B possess incentives to form and maintain a coordinated agreement to limit C's ability to undermine the collusion;<sup>257</sup> and (2) Manufacturer C faces imperfect substitutes for the marketing services of A's and B's downstream PBMs. Three points about this foreclosure theory are noteworthy, assuming vertically integrated companies maintain exclusionary commitments.<sup>258</sup>

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<sup>257</sup> In the case of unilateral conduct, while a monopolist could lack private incentives to raise entry costs because the strategy could reduce its profitability (e.g., profits could decline if there are no barriers to entry), no requirement to maintain some form of collusion would exist. Thus, if Manufacturer A were sufficiently large it could profit from foreclosure without the need for cooperation from Manufacturer B.

<sup>258</sup> It may be possible to obtain some information about the validity of this assumption by undertaking a Merger Guidelines-like analysis of possible price coordination in prescription drug markets (See, U.S. Department of Justice and the Federal Trade Commission, *Horizontal Merger Guidelines*, Section 2, (April 2, 1992, Revised April 8, 1997)) (*1992 Horizontal Merger Guidelines*). For example, the existence of contract terms and the underlying motivations for at least some contract provisions may be contained in internal company documents. Nevertheless, it may be difficult to determine whether competitors have committed to some form of cooperative conduct designed to exclude rivals. It is noteworthy that coordination may be unnecessary if, in the context of this hypothetical example, Manufacturers A and B supply therapeutic substitutes for Manufacturer C's drug. In this case, the vertically integrated PBMs could charge a relatively high price for C's drug and induce substitution to the products of Manufacturers A and B. This strategy would be profitable unless Manufacturer C is able to market its drug through independent PBMs at a lower price. Lower prices for Manufacturer C's drug would induce substitution away from the higher priced products of Manufacturers A and B, unless buyers face switching costs that discourage them from purchasing a single drug from an independent PBM. If so, the pricing of Manufacturer C's drug would have to reflect these switching costs and still remain below the prices set by Manufacturers A and B for substitution to take place. The significance of independent PBMs in this scenario is discussed further below.

First, anticompetitive effects from foreclosure would depend on the availability of alternative ways for unintegrated drug companies to avoid any exclusionary conduct by their vertically integrated rivals. These could include: (1) efforts to encourage the assistance of large buyers like HMOs and institutional buying groups in efforts to avoid the foreclosure;<sup>259</sup> and (2) the adoption of some form of pricing to gain better access to independent downstream PBMs.<sup>260</sup>

This leads to a second point. If unintegrated drug companies lack alternatives to PBMs A and B, this means that these PBMs have some degree of market power.<sup>261</sup> If so, in the context of this hypothetical, it may not be profitable for them to place Manufacturer C's product in less

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<sup>259</sup> HMOs do operate therapeutic substitution programs as part of their efforts to control drug costs. In fact, 18 percent of HMO plans applied therapeutic substitution programs in 1996 to facilitate substitution among competing brand-name drugs (See, *Industry Profile* (1998)). These programs may be viewed as efforts by buyers to encourage competition among brand-name drug suppliers, and may represent a vehicle to facilitate the sale of prescription drugs by unintegrated drug companies that might be subject to vertical foreclosure attempts by vertically integrated rivals. For discussions of buyer strategies intended to encourage new entry, see Coate and Kleit (1993) and Scheffman and Spiller (1992).

<sup>260</sup> For instance, Manufacturer C could make lump sum payments to competing PBMs for preferred placement on their formularies, but would have to outbid its vertically integrated rivals. This could be difficult if the vertically integrated rivals are willing to share anticompetitive profits with those PBMs, or if Manufacturer C is subject to MFN provisions in its contracts with the PBM affiliates of Drug Manufacturers A and B.

<sup>261</sup> It is noteworthy that if market power exists at both the upstream and downstream levels, then vertical integration would generate efficiencies by resolving the double markup problem that would stem from the exercise of this market power. This could result in offsetting cost savings for consumers.

desirable locations on their drug formularies or to otherwise attempt to exclude C from the market. This could undermine any collusion efforts of Manufacturers A and B.<sup>262</sup>

Third, unintegrated drug companies that face PBMs and other customers with MFN status might lack the incentives to engage in direct competition with their vertically integrated rivals to secure better access to drug formularies. This is because efforts by these unintegrated companies to offer discount prices selectively to particular PBMs could trigger MFN provisions in numerous other contracts that could also result in lower prices to these PBMs,<sup>263</sup> rendering these attempts unprofitable. Further, since PBMs seek MFN status, similar incentives could deter new entry as well. This could occur, for example, if profitable new entry requires some access to PBMs owned by drug companies. MFN demands by these PBMs could render entry by unintegrated drug companies unprofitable when that entry triggers MFN provisions.<sup>264</sup> At the same time, since the introduction of new drugs takes several years, MFN provisions currently in force may not affect entry decisions by drug companies.

Nonetheless, although attempts to raise rivals' costs might lead to anticompetitive effects under some conditions, other literature on the efficiencies arising from vertical integration points

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<sup>262</sup> However, if Manufacturer C incurs higher costs than Manufacturers A and B because it faces PBMs that possess market power, the integrated companies could then profitably raise prices without the cooperation of Manufacturer C. Manufacturers A and B would still have to coordinate their conduct in this case, and would be constrained in their ability to raise prices by the higher costs that face Manufacturer C.

<sup>263</sup> It is noteworthy that if PBMs with MFN status are demanding lower prices, then the MFN provisions would have no competitive effect. Buyers without MFN status would have no contractual right to the lower prices, while PBMs with MFN status would not be bound by these contractual provisions.

<sup>264</sup> If entry into prescription drug markets triggers MFN provisions, new entrants may have to reduce their prices below profitable levels. If this is known before new entry takes place, then potential competitors may lack the incentive to enter these drug markets.

to ways that prices could fall even if upstream market power exists.<sup>265</sup> Further, available empirical literature raises questions about the marketplace significance of anticompetitive theories of vertical integration, finding little evidence that anticompetitive theories (price-increasing incentives) dominate the efficiency theories (price-reducing incentives) as the explanation for vertical integration in general.<sup>266</sup> At the same time, this literature has not specifically analyzed the competitive effects of vertical integration in the pharmaceutical industry. In addition, along with efficiency considerations, the anticompetitive theories could be important in individual cases, and antitrust scrutiny of vertical acquisitions should determine whether or not they may facilitate price coordination in upstream markets.

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<sup>265</sup> See, for example, Abiru (1988), Reiffen and Vita (1995), Salinger (1988), Warren-Boulton (1974), Waterson (1982), and Westfield (1981).

<sup>266</sup> See, Levy (1985), Lieberman (1991), MacDonald (1985), Spiller (1985), and Vita (1997).

## ii. Vertical Integration and Foreclosure in PBM Service Markets

Acquisitions of PBMs by drug companies could also raise prices in downstream PBM markets. In addition to possible unilateral anticompetitive effects,<sup>267</sup> these acquisitions could facilitate downstream price coordination by excluding unintegrated PBMs from the market or by raising their costs.<sup>268</sup> For exclusionary conduct to raise prices, integrated drug companies must

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<sup>267</sup> To illustrate a unilateral theory of foreclosure, assume Drug Manufacturer A, who operates in upstream markets that are difficult to enter, supplies prescription drugs to PBMs A and B. These are the only two PBMs competing in downstream service markets that are difficult to enter, and both pay Manufacturer A prices equal to  $P$ . Drug Manufacturer A then buys PBM A, and, after the acquisition, sets a transactions price at  $P_B > P$  for PBM B and an internal transfer price at  $P_A$  for PBM A. This would lead to downstream anticompetitive effects if: (1) the unintegrated PBM B is unable to avoid the higher price set by Manufacturer A; and (2) Drug Manufacturer A sets the transfer price  $P_A$  above  $P$ . The first condition requires that Manufacturer A possesses some degree of market power, while the second requires that it would be profitable for A to raise the transfer price to its PBM affiliate after the acquisition. Raising the transfer price is a sufficient condition for higher downstream prices, but not a necessary one. Anticompetitive effects would emerge even if  $P_A < P$ , provided that the benefits of these lower transfer prices are more than offset by the higher prices to unintegrated PBM B. It is possible that  $P_A < P$ , but the relationship between  $P_A$  and  $P$  partly depends on the competitive impacts of the vertical acquisition. One possibility is that the vertical acquisition eliminates a double markup and Manufacturer A sets  $P_A$  below  $P$ . Another possibility is that the vertical acquisition provides Manufacturer A with incentives to set  $P_A$  above  $P$ . A third possibility is that the vertical acquisition is competitively neutral and Manufacturer A sets  $P_A$  equal to  $P$ . It is noteworthy that the literature suggests that it is not likely to be profitable for an integrated firm to set this transfer price at some value other than upstream marginal cost (See, Klass and Salinger (1995) and Ordovery, Saloner, and Salop (1990)).

<sup>268</sup> Vertical acquisitions could also dampen competition among vertically integrated rivals, causing prices to rise as a result. The basic idea is that these acquisitions may produce conduct which competing drug companies view as some commitment to avoid aggressive competition. For example, by making PBM drug formularies more restrictive following vertical mergers, integrated drug companies may be making commitments to deter new entry. Such commitments could lead to higher drug prices. (See, Baker (Spring 1996) and O'Brien and Shaffer (1993)). At the same time, new entry in the drug industry takes several years, and occurs in response to product development competition among pharmaceutical companies. Arguably, in light of the incentives drug companies have to develop and launch new prescription drugs, commitments to deter new entry are unlikely to emerge in the pharmaceutical industry.

benefit from downstream price coordination and avoid cheating on one another, and they must impose unavoidable costs on unintegrated PBMs. The first condition requires that the benefits of their coordination efforts against unintegrated PBMs exceed the costs of disadvantaging these PBMs, and that integrated PBMs avoid competition that could undermine these efforts. The second condition requires that unintegrated PBMs be unable to avoid the higher costs imposed on them by their integrated rivals.

As a hypothetical illustration of the foregoing anticompetitive story, assume that the two vertically integrated drug companies compete with unintegrated drug companies and PBMs in the market for anti-cholesterol drugs.<sup>269</sup> The first condition for anticompetitive effects, in part, requires that these vertically integrated suppliers find it profitable to cooperate in handicapping unintegrated PBMs.<sup>270</sup> Restricting their distribution of anti-cholesterol drugs may be one way the integrated PBMs impose higher costs on their unintegrated rivals. Higher prices that result could encourage buyers to switch to unintegrated PBMs. This implies that for this cooperative strategy to be profitable, any additional profit from higher prices must offset foregone profit from restricted distribution that would include possible sales losses to unintegrated PBMs. Without restricting their distribution through unintegrated PBMs, these PBMs would be able to arbitrage any price differences between them and their vertically integrated rivals.

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<sup>269</sup> In the standard unilateral competitive effects story discussed above, the cooperation of competing vertically integrated drug companies is not required for anticompetitive effects to occur. However, if prices are to increase, the unintegrated PBMs, as well as new entrants, must be disadvantaged because they are unable to distribute the prescription drugs of the vertically integrated drug company.

<sup>270</sup> If entry into the provision of anti-cholesterol drugs would occur, the integrated suppliers must also handicap new entrants.

Consequently, these vertically integrated suppliers must avoid deviating from this cooperative strategy by, for example, expanding distribution of their anti-cholesterol drugs through unintegrated PBMs.

The second condition requires that unintegrated PBMs be unable to avoid these higher costs by securing distribution alternatives, or by inducing integrated drug companies to provide them with additional drug supplies. As suggested earlier, the vertically integrated drug companies may find it privately profitable to expand sales through unintegrated PBMs.<sup>271</sup> It may also be possible for these PBMs to expand distribution of other anti-cholesterol drugs, including those of unintegrated drug companies or new entrants. Any alternative source for additional low cost distribution of these drugs could undermine the cooperative strategy of the integrated entities. Unintegrated PBMs may also attempt to align themselves with other buyers (e.g., HMOs and retail drug chains) to gain leverage in price negotiations with all drug companies.<sup>272</sup>

**b. Vertical Integration and Agency Issues**

Vertical acquisitions of PBMs by drug companies could create an agency problem by altering the incentives of PBMs to serve as agents for third-party payers, employers, or

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<sup>271</sup> Efficiencies from vertical integration could induce vertically integrated drug companies to make additional sales of their anti-cholesterol drugs. It is by no means certain that they would choose to forego these sales in an effort to limit downstream competition among PBMs. Again, if profit increases from additional sales at the manufacturing level, including sales through unintegrated PBMs, more than offset any profit losses from restricting distribution of their drugs, integrated drug companies would increase sales to unintegrated PBMs.

<sup>272</sup> In fact, evidence of contractual and other alignments exists, although there is no evidence these relationships were developed as a means of counteracting anticompetitive foreclosure strategies adopted by vertically integrated drug companies rather than as a means of achieving efficiencies. Further, in addition to PBM acquisitions by pharmaceutical companies, PBMs have also become business units of retail drug and other chain retailers. CVS, Eckerd, Rite Aid, Kmart, and Wal-Mart have all provided PBM services (See, Muirhead (July 1996)).

consumers. If PBMs fail to act as good agents on the demand side because of vertical integration, they could facilitate coordination among drug companies or otherwise generate higher prices.<sup>273</sup> Under some circumstances, vertically integrated combinations of drug companies and PBMs could exploit this agency problem to raise prices to prescription drug consumers through vertical foreclosure. Figure V.2 outlines a framework for evaluating these foreclosure scenarios. To illustrate one variant of this theory, assume Drug Manufacturer A acquires PBM A, and the combination competes with unintegrated Drug Manufacturer B and PBM B in upstream and downstream markets that are difficult to enter. Under this theory, PBM A can inhibit price competition between Manufacturers A and B after the vertical acquisition by restricting the access of Manufacturer B to its drug formulary or otherwise limiting competition between Manufacturers A and B. The result could be higher prices to downstream consumers.<sup>274</sup> This scenario is similar to the vertical foreclosure argument made earlier, and requires that Manufacturer B is either unable or unwilling to serve as an alternative for Manufacturer A for the downstream buyers, and that the integrated entity possesses the incentives necessary to restrict the supply of Manufacturer B's drugs. For anticompetitive effects to emerge under this theory, it would also be necessary that the vertical transaction not produce offsetting efficiencies.

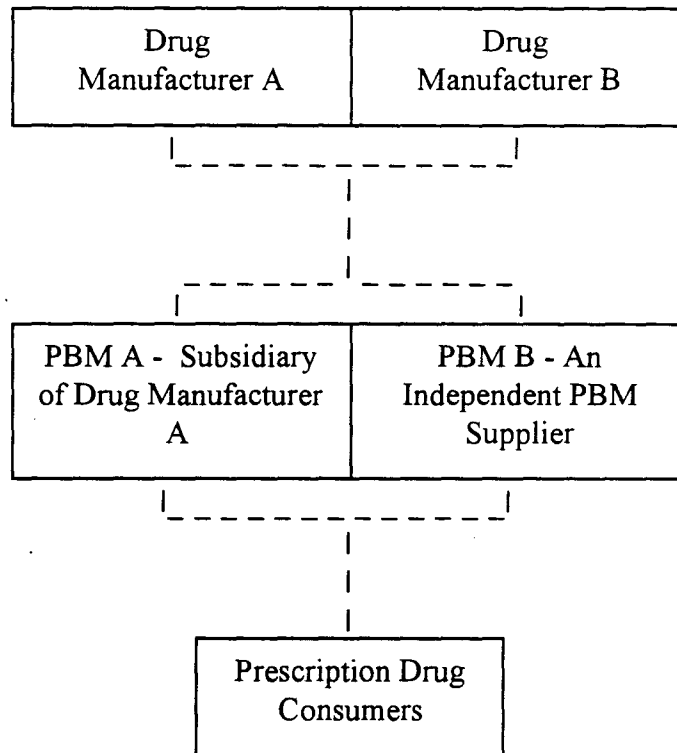
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<sup>273</sup> The 1992 Horizontal Merger Guidelines discuss the role buyers could play in undermining price coordination attempts by their suppliers (See, *1992 Horizontal Merger Guidelines*, §2.12). The 1984 Horizontal Merger Guidelines outline a theory of disruptive buyer behavior (See, *1984 Horizontal Merger Guidelines*, §4.222). For a discussion of a more recent theory of countervailing power, see Snyder (1996).

<sup>274</sup> PBM A might simply avoid shifting buyers from Manufacturer A to Manufacturer B to obtain lower prices after its acquisition by Manufacturer A. PBM A could also move the products of Manufacturer B to less preferred positions on its drug formulary.



**Figure V.2**  
**A Framework for Analyzing Vertical**  
**Foreclosure Scenarios in Prescription**  
**Drug and PBM Markets**



Under another variant of this theory, PBM A reduces competition between Manufacturers A and B by restricting PBM B's access to the product offerings of Manufacturer A. For example, PBM B might be given less favorable rebate terms for A's products. This is similar to the PBM foreclosure argument outlined earlier, and requires that similar conditions be met before any anticompetitive effects stem from vertical integration. In both cases, assessments of these agency theories of competitive harm would parallel those involving either upstream or downstream vertical foreclosure in prescription drug and PBM markets, respectively.

**c. Observations on the Competitive Effects of Vertical Integration**

Some commentators have suggested that vertical mergers of drug companies and PBMs could achieve substantial efficiencies: reducing transaction costs, reducing the risk of opportunistic behavior, and providing for the more efficient marketing and distribution of prescription drugs.<sup>275</sup> One key event, however, calls into question whether one such vertical merger has actually generated significant cost savings for either drug companies or consumers. In particular, Eli Lilly's decision to reduce the book value of its PBM unit, PCS Health Systems, by \$2.4 billion or more than 50 percent of the \$4.1 billion purchase price for PCS, as well as its recent sale of PCS to Rite Aid Corporation, raises the possibility that Lilly overestimated the likely cost-savings from this vertical merger.<sup>276</sup> Press accounts indicate that Eli Lilly, for example, acknowledged that it was mistaken about the ability of PCS to expand its drug sales, and consequently reduced the book value of its PCS unit by \$2.4 billion.<sup>277</sup> These press accounts also suggest that other acquisitions of PBMs by drug companies (e.g., the acquisition of Medco Containment by Merck & Co. and Diversified Pharmaceutical Services by SmithKline Beecham) led to changes in prescription drug sales that fell short of expectations.

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<sup>275</sup> For a summary discussion of efficiency explanations for vertical mergers, see Dodd (1995).

<sup>276</sup> It is also possible that Eli Lilly merely overestimated the value of PCS Health Systems at the time of the acquisition, or that the value of other Eli Lilly assets increased at the same time. In fact, contemporaneous press accounts suggest that Lilly executives believed the company paid too much for PCS (See, for example, Freudenheim (June 1997)). Further, although Lilly paid less per covered member for PCS (\$80 per member) than Merck & Co. paid to acquire Medco Containment Services (\$182 per member) or SmithKline Beecham paid for Diversified Pharmaceutical Services (\$177 per member), PCS cost more on an earnings basis. In particular, Lilly paid 130 times PCS's annual earnings, while Merck paid some 66 times Medco's annual earnings to complete its acquisition (See, Harrison (1994)).

<sup>277</sup> See, Freudenheim (June 1997).

The reduction in Lilly's book value, as well as its recent sale of PCS to Rite Aid Corporation, equally calls into question whether this vertical merger led to higher prices or profits from anticompetitive foreclosure. This may simply reflect the success of regulatory intervention.<sup>278</sup> Alternatively, it may mean that exclusionary practices, such as efforts by vertically integrated drug companies to limit competitor access to the drug formularies of downstream PBM affiliates,<sup>279</sup> were not successful in achieving anticompetitive foreclosure in this case.<sup>280</sup> In short, Lilly's decision to mark down the book value of PCS offers little support for either an efficiency or an anticompetitive interpretation of that transaction.

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<sup>278</sup> The Federal Trade Commission's consent agreement with Lilly is discussed earlier in this chapter.

<sup>279</sup> For a summary of these efforts, see Balto (1997).

<sup>280</sup> It is important to note that anecdotal evidence of efforts by Eli Lilly or Merck & Co. to place certain of their drugs on the formularies of their PBM affiliates to the exclusion of competing drugs is not evidence of anticompetitive effects. Even if this did occur, it may simply be that the vertical transactions produced efficiencies (e.g., the elimination of double markup problems) that produced increases in the representation of the products of upstream companies on the formularies of their PBM affiliates. Available anecdotal evidence, however, is mixed. In a discussion of the acquisition of PCS by Eli Lilly, Balto (1997) notes that Pfizer subsequently brought a suit against PCS, charging it with breach of contract for failing to include several Pfizer drugs on a number of the PCS closed formularies. The court ruled in favor of Pfizer, and ordered PCS to include certain Pfizer drugs on its formularies for a specified period of time. In a review of drug formulary changes following the acquisitions of Diversified Pharmaceutical Services by SmithKline Beecham and Medco Containment by Merck & Co., GAO found that: (1) very little change occurred in Diversified's drug formulary; and (2) Merck drugs tended to be favored on the Medco formulary (See, the United States General Accounting Office's report entitled *Pharmacy Benefit Managers - Early Results On Ventures With Drug Companies* (1995)). Overall, this GAO report concluded that these changes were not the result of anticompetitive behavior by vertically integrated drug companies.

### C. Horizontal Consolidation in the Drug Industry - Some Antitrust and Competition Issues

The significant changes observed in the prescription drug industry may help to explain the significant increase in mergers and alliances between competing pharmaceutical firms. For example, the growth of the generic segment may have created a need for major brand-name drug companies to establish a significant presence in the generic segment by acquiring generic drug companies. Similarly, the shift from traditional detail sales promotion to contract sales to HMOs and PBMs may have caused drug companies to merge in an effort to provide these customers with broad product lines and to consolidate sales and marketing capacity. Finally, since drug formularies may serve to limit the total number of drugs available to consumers, consolidation of new drug development capacity may have become increasingly important.<sup>281</sup>

Horizontal merger enforcement policy in the pharmaceutical industry has focused historically on the potential for transactions among rivals to cause anticompetitive effects in particular product or therapeutic categories common to the merging parties.<sup>282</sup> The FTC has also challenged horizontal pharmaceutical industry mergers that have created the potential for

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<sup>281</sup> The consolidation of R & D capabilities in the pharmaceutical industry has been the focus of some attention by antitrust enforcement agencies. Investigations of several mergers have led to enforcement actions that have addressed competitive concerns in innovation markets (Table V.1). In addition, hearings on global competition by the FTC have also focused some attention on the role of antitrust in innovation markets (See, the Federal Trade Commission's report entitled *Competition Policy in the New High-Tech, Global Marketplace*, Volume I, Chapter VII, (May, 1996)) (*1996 Global Competition Report*).

<sup>282</sup> Anticompetitive effects, following a horizontal transaction, could emerge from either unilateral or coordinated conduct (See, *1992 Horizontal Merger Guidelines*, §2).

competitive harm in innovation markets.<sup>283</sup> The remainder of this section summarizes these enforcement actions, and examines the impacts that pharmaceutical industry changes might have on analyses of the competitive effects of horizontal consolidation in the drug industry.

#### **1. Pharmaceutical Mergers and Antitrust Enforcement Activities**

The FTC has challenged aspects of several horizontal mergers and acquisitions in the pharmaceutical industry. These enforcement actions have addressed the potential for competitive harm in a variety of individual antitrust markets for existing pharmaceutical products, and have also considered the competitive effects of pharmaceutical mergers in innovation markets. Table V.1 contains information on several of the FTC's enforcement actions involving horizontal mergers, and summarizes some of the characteristics of these cases.

The FTC enforcement actions are noteworthy in several ways. First, regardless of whether the anticompetitive theory is unilateral or coordinated, the FTC's complaints and remedies often center on effects in antitrust markets for particular pharmaceutical products. The growing influence of HMOs and PBMs, along with other industry changes, might prompt a reassessment of this product-specific approach to merger analysis in the drug industry.<sup>284</sup> In the context of broader markets, pharmaceutical companies that acquire additional market power as a

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<sup>283</sup> See, *1996 Global Competition Report*, Volume I, Chapter VII. In addition, see U.S. Department of Justice and Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property*, (1995). For several commentaries on innovation market analysis, see Azcuenaga (1996), DeSanti (1996), Pitofsky (1996), and Starek (1996).

<sup>284</sup> For a discussion of the traditional approach to market definition in the antitrust analysis of pharmaceutical industry mergers, see Bloch, Perlman, and Hansen (1997).

**Table V.1**  
**Summary of Horizontal Acquisitions/Mergers**  
**and FTC Enforcement Actions in the Pharmaceutical Industry**

Transaction	Summary of FTC Complaint	Summary of FTC Remedy
Ciba-Geigy Limited (CGL) Merger with Sandoz Ltd. (FTC Docket No. C-3725 - April 8, 1997).	The merger may substantially lessen competition in relevant markets for gene therapy products, corn herbicides, and flea control products (CGL Complaint, ¶VII).	The FTC's order, in addition to provisions relating to other products, requires the licensure of gene therapy technology and patent rights to third parties (CGL Order, ¶I).
American Home Products Corporation (AHP) Acquisition of American Cyanamid Company (FTC Docket No. C-3357 - February 14, 1995).	The acquisition may substantially lessen competition in three relevant product markets and two R & D markets. The product markets are: (1) a combination tetanus and diphtheria vaccine for adults and children at least seven years old, (2) a similar combination vaccine for children from two months to seven years old, and (3) "tetanus toxoid". The R & D markets are (1) a vaccine against Rotavirus infection, and (2) cytokines for white blood cell and platelet restoration (AHP Complaint, ¶V and ¶VIII).	The FTC's order requires: (1) a divestiture of tetanus and diphtheria patents, knowhow, and other intangibles; (2) AHP to contract manufacture the vaccines for a third-party acquirer of AHP's intangible assets; and (3) licensure of intellectual property relating to Rotavirus vaccine research (AHP Order, ¶IV and ¶V).
Glaxo plc Acquisition of Wellcome plc (FTC Docket No. C-3586 - June 14, 1995).	The acquisition may substantially lessen competition in the R & D market for 5HT <sub>1D</sub> agonists for the treatment of migraine attacks (Glaxo Complaint, ¶V and ¶VIII).	The FTC's order requires the divestiture of intellectual property and other intangible assets relating to the development of 5HT <sub>1D</sub> agonists, either under development by Wellcome or Glaxo Order, ¶II).
Hoechst AG (Hoechst) Acquisition of Marion Merrell Dow Inc. (FTC Docket No. C-3629 - December 5, 1995).	The acquisition may substantially lessen competition in three R & D markets. They are: (1) the market for mesalamine for the treatment of colitis and Crohn's disease; (2) the market for rifampin for the treatment of tuberculosis; and (3) drugs for the treatment of leg cramps (Hoechst Complaint, ¶III and ¶VII).	The FTC's order requires divestiture of intellectual property, other intangible, and some physical manufacturing assets relating to the development and manufacture of the relevant products (Hoechst Order, ¶III and ¶IV).
IVAX Corporation Acquisition of Zenith Laboratories, Inc. (FTC Docket C-3565 - March 27, 1995).	The acquisition may substantially lessen competition in the market for generic verapamil (IVAX Complaint, ¶V and ¶VI).	The FTC's order prevents IVAX from obtaining any rights to market or sell generic verapamil pursuant to an agreement with G.D. Searle & Co. (IVAX Order, ¶II).
Marion Merrell Dow Inc. (MMD) Acquisition of Rugby-Darby Group Companies, Inc. (FTC Docket No. C-3533 - September 23, 1994).	The acquisition may substantially lessen competition in the market for dicyclomine (MMD Complaint, ¶V and VIII).	The FTC's order requires that MMD (1) license intangible dicyclomine assets, and (2) contract manufacture dicyclomine for the licensee (MMD Order, ¶II).
Roche Holding Ltd (Roche) Acquisition of Syntex Corporation (FTC Docket No. C-3542 - November 22, 1994).	The acquisition may substantially lessen competition in the market for drugs of abuse reagent products. These test for the presence of illegal drugs in the urine (Roche Complaint, ¶IV and ¶V).	The FTC order requires the divestiture of physical and other assets relating to the relevant product (Roche Order, ¶III).
The Upjohn Company (Upjohn) Acquisition of Pharmacia Aktiebolag (FTC Docket No. C-3638 - February 8, 1996).	The acquisition may substantially lessen competition in the R&D market for topoisomerase I inhibitors. These products are under development for the treatment of colorectal cancer (Upjohn Complaint ¶IV and ¶VII).	The FTC order requires the divestiture of intellectual property and other intangible assets of Pharmacia Aktiebolag relating to the development of the relevant product (Upjohn Order, ¶II).

Notes: Information in this table is taken from FTC complaints and consent orders entered into as a result of investigations of the likely competitive effects of these transactions. The dates in the first column refer to the dates the FTC either issued or finalized the orders in these matters. This table contains only brief summaries of examples of these enforcement actions.

result of acquisitions may be able to raise prices across several of their product lines as discussed later in this chapter.<sup>285</sup>

Second, in addition to assessing the competitive effects of mergers and acquisitions in existing prescription drug markets, the FTC has examined the impacts of these transactions in innovation markets. In the Glaxo/Wellcome matter, for example, both companies had development programs for 5HT<sub>1D</sub> agonists used to treat migraine attacks. The FTC complaint alleged that the acquisition might eliminate R & D competition between Glaxo and Wellcome in the development of these drugs, decrease the number of R & D tracks for their development, and increase Glaxo's ability to reduce R & D in this product area.<sup>286</sup> The FTC required Glaxo to divest Wellcome's R & D assets relating to the development of 5HT<sub>1D</sub> agonists.

The Glaxo/Wellcome matter and the other enforcement actions summarized in Table V.1 raise several issues, including: (1) whether to analyze cases such as this under a potential competition, innovation market or some other analytical framework; (2) whether innovation market structure has predictable implications for economic performance in these markets; and (3) the issue of the appropriate remedy to potentially anticompetitive horizontal mergers in .

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<sup>285</sup> The likelihood of a broad form of anticompetitive pricing arose in connection with Rite Aid's proposed acquisition of Revco (See, Federal Trade Commission. "FTC Will Seek to Block Rite Aid/Revco Merger: Deal Could Lead to Higher Prescription Prices in Numerous Metro Areas Along the East Coast and in the Midwest, Agency Says." Press Release, (April 17, 1996). That matter raised the possibility that, by combining its pharmacy network with Revco's network, Rite Aid would be able to raise retail prices to health plans because, as a result of the acquisition, these plans would lack access to alternative pharmacy networks necessary for the distribution of prescription drugs to consumers. For a more detailed discussion of this analysis, see Baker (1997). For a discussion of the importance of retail pharmacy networks, see Balto (1998).

<sup>286</sup> See, Glaxo Complaint, ¶VIII.

innovation markets.<sup>287</sup> Indeed, fashioning appropriate remedies in these innovation markets could at times be difficult. The costly, risky, and time-consuming characteristics of the prescription drug R & D process may make it hard to restore innovation competition to pre-acquisition levels using the types of divestiture remedies summarized in Table V.1. An initial difficulty is that any acquirer of the divested assets may otherwise lack the capability to compete with the merging parties in the innovation market at issue.<sup>288</sup> Further, these divestitures may threaten any efficiencies that flow from a combination of complementary R & D assets that could characterize some mergers involving innovation markets.<sup>289</sup> But when the assets required for R&D are readily identified, when the foregone scope economies in research are small relative to the benefit to consumers from protecting R&D competition,<sup>290</sup> and when a strong buyer can be identified, divestitures of overlapping innovation assets can reasonably be employed to remedy potentially anticompetitive drug mergers.

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<sup>287</sup> A discussion of these issues is beyond the scope of this report. For an evaluation of these and other aspects of innovation market analysis, see *1996 Global Competition Report*, Volume 1, Chapter VII.

<sup>288</sup> The fact that any such acquirer is not a current competitor raises questions about its ability to compete with the parties to a merger. This may be particularly problematic in the case of innovation market overlaps in which the merging parties have significant expertise from previous R & D programs in the same therapeutic area.

<sup>289</sup> For a discussion of the potential market power/efficiency tradeoff stemming from horizontal mergers in innovation markets, see Gilbert and Sunshine (1995). For another treatment on the analysis of the competitive effects of mergers in innovation markets, see Yao and DeSanti (1993).

<sup>290</sup> It is noteworthy that if the foregone scope economies would be large, and if a divestiture of additional assets would not create any significant inefficiencies, then a broader divestiture of R&D assets (going beyond the assets directed to the competitive problem) may be required to restore competition to pre-merger levels. The information in Table V.1 would suggest that divestitures in pharmaceutical matters brought by the FTC were narrowly tailored to remedy the competitive problems at issue in those cases. For a further discussion of this issue, see Cary and Bruno (1997).



## 2. Drug Industry Changes and the Competitive Effects of Pharmaceutical Mergers and Acquisitions

The growth of cost-containment institutions and generic drugs have several important implications for assessments of the competitive effects of horizontal mergers. First, product-specific antitrust markets might, in some cases, come to include more products than in the past. The mechanisms adopted by HMOs and PBMs to eliminate traditional agency problems have the potential to increase price competition both from generic forms and from alternative brand-name pharmaceuticals within therapeutic drug categories. For example, by marketing prescription drugs through formularies and adopting generic and therapeutic substitution initiatives, cost-containment institutions have the potential to reduce the degree of product differentiation between and among generic and therapeutic drug alternatives. This may lead brand-name drug companies to compete with more alternatives within therapeutic categories than in the past. Yet, even if more firms compete in some antitrust markets, drug company mergers could still eliminate localized competition in specific product areas within those markets. For example, a merger of drug companies supplying the two closest substitute drugs may lead to higher prices even if these drugs are part of a larger antitrust product market.<sup>291</sup>

Second, even though the growth of generic drugs and cost-containment institutions serve to broaden competition among pharmaceutical companies, horizontal consolidation in a changing environment could also lead to broader forms of oligopoly coordination. In particular, by potentially increasing the number of product markets in which drug companies compete,

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<sup>291</sup> For a discussion of localized merger-related anticompetitive effects, see *1992 Horizontal Merger Guidelines*, §2.21.

industry changes could foster oligopoly coordination across multiple markets. Additional competitive overlaps, resulting from mergers or other changes, might permit drug companies to hold each other hostage in more product markets, and, therefore, raise the costs of deviating from the terms of a multimarket agreement to coordinate prices. By raising both the opportunities for disciplining rivals and the costs facing these rivals, anticompetitive coordination is more likely to take place.<sup>292</sup> A useful theoretical examination describes some market and firm characteristics that could lead to price coordination across markets.<sup>293</sup> The research concludes that differences in market shares or firm costs could result in higher prices in some markets and lower prices in others. This suggests that the prospect for merger-related collusion in a multimarket setting is largely an empirical question.<sup>294</sup> Nevertheless, the Justice Department's allegation of tacit collusion in the airline industry suggests that information technology networks can facilitate price coordination in a multimarket setting. The previous

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<sup>292</sup> For an early discussion of this anticompetitive theory of conglomerate mergers, see Corwin's discussion on conglomerates in NBER's *Business Concentration and Price Policy* (1955). The basic problem with this early conglomerate theory is that, while the costs of cheating in multiple markets could increase, the benefits from cheating could increase as well.

<sup>293</sup> See, Bernheim and Whinston (1990). Multimarket contact does not lead to additional coordination if markets and firms are identical and production is subject to constant returns to scale. In this case, rivals who meet in additional markets would proportionally increase the benefits and costs of deviating from a price coordination agreement, but would not otherwise alter their incentives to coordinate prices.

<sup>294</sup> On the one hand, some empirical research provides support for the multimarket price coordination hypothesis (See, Evans and Kessides (1994), Parker and Roller (1994), and Scott (1991)). In addition, antitrust authorities have challenged anticompetitive conduct that emerged in several markets, including the price-fixing case involving the airlines industry which was multimarket in nature. On the other hand, other studies, including studies in experimental economics, raise questions about the multimarket collusion hypothesis (See, Feinberg (1985) and Phillips and Mason (1992)).

discussion on information exchanges suggests that the evolution of information technology in the drug industry may facilitate complex price coordination agreements among merger pharmaceutical companies. This implies that antitrust enforcement agencies should evaluate multimarket collusion hypotheses while investigating mergers among drug companies.

The marriage of horizontal mergers and other aspects of the changing pharmaceutical marketplace could also raise the likelihood for multimarket price coordination. For instance, the combination of horizontal mergers and contracts with MFN provisions could increase incentives for consolidated drug companies to coordinate prices across multiple drug markets. To illustrate, prior to any horizontal consolidation, assume that Drug Manufacturer A competes with Manufacturer B in Market X and Manufacturer C in Market Y, but Manufacturers B and C do not meet one another in either of these markets. Also, assume that the two markets are difficult to enter, and that Manufacturers A, B, and C are subject to contracts with MFN provisions in the markets in which they compete. After a merger of B and C, A competes with BC in Markets X and Y.

The merger could result in anticompetitive effects if: (1) it causes the costs of deviating from a price coordination agreement in Markets X and Y to more than offset any benefits from engaging in such conduct; and (2) this condition would not hold for price coordination efforts between duopolists in either one of these two markets without the merger. The first condition could hold if competition for new contracts and contract renewals triggers MFN provisions in both Markets X and Y, and the profit levels of both incumbents decline as a result. The second condition could hold if, in either Market X or Market Y, profit increases from price competition for new contracts or contract renewals more than offset any losses this competition creates by

triggering MFN provisions in existing contracts. Under these conditions, even though Drug Manufacturers B and C did not directly compete with one another, their merger could lead to price coordination in both Markets X and Y. Of course, any economic efficiency benefits of these consolidations, including the possibility that they would lead to lower prices, higher drugs sales, or additional product innovations, would also deserve consideration.

Third, because of the growing focus on price competition, mergers and acquisitions in the drug industry could cause some broader form of unilateral competitive harm. For example, some unilateral theories of anticompetitive mergers in auction settings, with some modification, may apply to the prescription drug industry.<sup>295</sup> To illustrate, suppose that alternative drug portfolios are imperfect substitutes for certain buyers,<sup>296</sup> and that these buyers make purchases from several, but not all of the suppliers. In addition, assume that new entry or the repositioning of products or portfolios is costly, and that all suppliers face identical marginal costs. If a buyer

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<sup>295</sup> See, Baker's (1997) discussion of a model of unilateral competitive effects. In this model, differentiated suppliers, who face capacity constraints, supply an indivisible homogeneous good to downstream buyers. The suppliers differ in their costs of production, but could collectively supply more than the requirements of particular buyers. Capacity constraints require that buyers purchase the good from multiple suppliers. To illustrate the price-effects of a merger, assume that we order these suppliers from most to least efficient, and that a particular buyer purchases 1 unit from  $N < T$  of these suppliers, where  $T$  equals the total number of suppliers. The buyer purchases  $N$  units, and pays an amount equal to the marginal cost facing supplier  $N+1$ . This is the buyer's opportunity cost if the buyer decides to purchase the good from someone other than the low cost supplier. A merger of any two suppliers from 1 through  $N$  could increase price since the merged entity could now raise the average offering price of two units to just under the marginal cost facing supplier  $N + 2$ . If the buyer rejects the offer, it must purchase the last unit from supplier  $N+1$  and pay the marginal cost facing supplier  $N+2$ . In either case, the result is a higher average price. For other unilateral theories of anticompetitive mergers, see Baker (March 1996) and *1992 Horizontal Merger Guidelines*, §2.2.

<sup>296</sup> In this model, buyers such as retail pharmacies might view different drug portfolios as imperfect substitutes even if consumers cannot substitute among drugs in different portfolios.

requires N out of a total of T portfolios, ranked from most to least preferred, the average prices would correspond to the quality-adjusted marginal costs facing supplier N + 1. A merger of any two product portfolios from 1 through N could raise prices to levels that correspond with the quality-adjusted marginal costs facing supplier N+2. If suppliers have some ability to influence output levels and buyers can alter their purchase amounts in response to price changes, mergers of product portfolios could cause anticompetitive effects.

This anticompetitive theory may or may not apply to pharmaceutical industry mergers. It is not obvious that intermediaries would have different chains of substitutes for given prescription drugs or groups of drugs than consumers. If not, alternative product portfolios (i.e., prescription drug offerings of different pharmaceutical companies) might not be substitutes from the viewpoint of these intermediate buyers. Further, while drug companies may bundle some of their prescription drugs, there is no reason to believe these buyers would necessarily purchase the entire portfolio of drug offerings for a given manufacturer. Although this does not appear to be critical,<sup>297</sup> establishing quality-adjusted prices for individual prescription drugs or subsets of a manufacturer's drug portfolio could prove difficult.

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<sup>297</sup> One could construct subset portfolios under some minimum purchase requirements for buyers, and model potential unilateral anticompetitive effects from combinations of individual prescription drugs or groups of drugs. However, the assumptions of the more general model would apply, subject to some restatement, to these special cases.



## Chapter VI

### Summary Discussion

U.S. pharmaceutical companies have seen new developments in information technology and new legislative mandates in prescription drug markets, particularly during the last 10 to 15 years. Firms have responded to this changing environment by altering their pricing strategies within prescription drug markets, and by pursuing vertical and horizontal consolidation strategies. Chapters II and III of this study discuss three sets of changes that have characterized the ongoing competitive evolution of the pharmaceutical industry. First, a number of demand side changes have led to a more competitive environment in the pharmaceutical industry. In addition to state and federal legislative initiatives such as the Medicaid program reforms, the growth of HMO and PBM organizations has effectively aggregated buyers of prescription drugs and permitted these buyers to overcome some of the traditional agency and information problems that have tended to result in higher prices for drugs.

Second, several important supply side changes have facilitated competition in prescription drug markets and may have led to increased R & D activities by brand-name drug companies. For instance, the Waxman-Hatch Act of 1984 eliminated a variety of impediments to generic drug entry and encouraged additional brand-name drug development by effectively extending patent protection on brand-name pharmaceutical products. In addition, vertical and

horizontal consolidation in the drug industry may have enhanced the efficiency of research and development, production, and distribution of prescription drugs.

Third, the emergence and application of information technology, particularly by PBMs, have complemented these demand and supply changes by facilitating additional competition among drug companies in several important ways. Buyers now have access to real-time substitution opportunities among alternative prescription drug treatments. Drug companies have access to efficient drug marketing organizations that substitute drug formulary management and other services for the traditional detail and promotional activities of pharmaceutical companies. Drug suppliers also have the ability to collect and process the clinical, drug usage, and other data necessary to evaluate the effectiveness of drug and non-drug treatments for disease states. As described in Chapter III, the application of information technology to prescription drug markets encourages price competition by making demand more sensitive to price and may encourage supply-side responses within these markets, particularly if potential generic and therapeutic drug entrants have ready access to efficient prescription drug marketing organizations that would include PBM affiliates.

Although these trends may be making the pharmaceutical industry more efficient and more competitive in general, they may have also led to conduct that may raise antitrust concerns. There has been private antitrust litigation that has focused on price discrimination and price-fixing allegations. Also, the FTC has challenged aspects of both vertical and horizontal mergers involving drug companies. Acquisitions of PBMs by brand-name drug companies could facilitate anticompetitive information exchanges, and raise the possibility of foreclosure in both downstream PBM service and upstream prescription drug markets. Horizontal acquisitions and



mergers could lead to unilateral or coordinated anticompetitive effects both in relevant markets for prescription drugs and in innovation markets for products under development. Horizontal transactions also raise the possibility of broader forms of coordinated and unilateral anticompetitive conduct in the pharmaceutical industry.

Chapters IV and V address the major areas of antitrust concern, including anticompetitive theories of: (1) price discrimination in monopoly and oligopoly markets; (2) generic drug introduction strategies by brand-name drug companies; (3) anticompetitive exchanges of information; (4) the collusive potential of vertical contract provisions involving PBMs and drug companies that include MFN provisions; (5) vertical foreclosure in PBM and/or prescription drug markets; (6) multimarket collusion from horizontal mergers and acquisitions; and (7) unilateral anticompetitive effects in an auction model setting. The conditions necessary for anticompetitive effects under each of these theories are discussed, along with possible efficiency explanations for the same practices. In this evolving industry, as in general, antitrust enforcers are charged with undertaking careful economic analysis to distinguish between procompetitive and anticompetitive explanations for firm conduct.



## Glossary

**Agency Problem** - A breach of the explicit or implicit contract one person or persons (i.e., agent(s)) enter(s) into to take actions on the behalf of some other person or persons (i.e., principal(s)).

**Capitated Contracts** - Agreements that include those between health care providers (e.g., hospitals, pharmaceutical companies, and physicians or physician groups) and third-party payers that are based on a fixed form of payment (e.g., a per person or per diem rate) that is applicable to all enrollees of the health plan.

**Closed Formulary** - A listing of branded and generic prescription drugs, by therapeutic category, that are approved for sale in the U.S. by the Food and Drug Administration which health care professionals (e.g., pharmacists, pharmacologists, and physicians) deem appropriate for inclusion on the formulary, but that may not be included by the sponsor of the formulary.

**Drug Formulary** - A listing of branded and generic prescription drugs, by therapeutic drug category, that are approved for sale in the U.S. by the Food and Drug Administration, and that are used by individuals (e.g., health plan personnel, pharmacists, and physicians) in the health care industry.

**Duopoly** - A market structure that consists of two firms on the supply side, and one that recognizes the interdependence of these firms with respect to price, output, and other decision-making processes.

**Oligopoly** - A market structure that consists of a small number of firms on the supply side, and one that recognizes the interdependence of these firms with respect to price, output, and other decision-making processes.

**Open Formulary** - A listing of branded and generic prescription drugs, by therapeutic category, that are approved for sale in the U.S. by the Food and Drug Administration which health care professionals (e.g., pharmacists, pharmacologists, and physicians) deem appropriate for inclusion on the formulary.

**Pharmacy Benefit Manager** - A supplier of services relating to the distribution and marketing of prescription drugs that include formulary services, claims processing, utilization review, and price negotiations with pharmaceutical companies.

**Plan Sponsor** - A party that offers individuals access to group health insurance plans, typically an employer, and that is fully or partially responsible for the payment of premiums associated with those plans.

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## Appendix A

# Overview of Traditional Prescription Drug Markets

This appendix describes basic supply and demand conditions in prescription drug markets, and summarizes aspects of the structure and performance of the pharmaceutical industry.

### A. Basic Characteristics of Drug Supply

The supply of brand-name prescription drugs depends critically on the research and development (R & D) activities of pharmaceutical companies. R & D activities, in turn, depend on the companies' access to intellectual property rights, and on the entry requirements of the Food and Drug Administration (FDA).

#### 1. Prescription Drug Research and Development

The basic research stages that lead to new prescription drugs begin with an analysis of the infectious agents or gene mutations that cause disease. Basic research also involves the development of animal or *in vitro* models to assist in the testing and discovery phases of drug development, and the process of designing and screening compounds.<sup>1</sup> The development stages include pre-clinical safety studies on laboratory and animal models, animal and *in vitro* tests, and

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<sup>1</sup> Ongoing advances, particularly in computer technology and biotechnology, provide drug companies with alternatives to the traditional process of identifying promising drugs by screening thousands of compounds. For discussions of these new approaches, see Breindel (1994) and Gambardella (1995).

clinical phases of the FDA approval process.<sup>2</sup> Drug development also involves the identification of alternative manufacturing processes, the establishment of pilot production facilities, the development of dosage forms and pharmaceutical preparations, and the assurance of quality control.

Pharmaceutical companies make substantial investments in the various stages of R & D, particularly the clinical stages of drug development (Table A.1). Members of the Pharmaceutical Research and Manufacturers Association (PhRMA) allocated 44 percent of 1994 R & D expenditures to the pre-clinical stages of drug research and development, while the clinical and other stages accounted for 56 percent of expenditures in that year (Table A.1). Further, other data reveal that PhRMA members invested over 5 times more per sales dollar in R & D efforts in 1994 than did companies in a composite of all industries (Table A.2).

**Table A.1**  
**1994 R & D Expenditures and Percentages by R & D Stage**

R&D Stage	R&D Expenditures (Millions)	Percentage
Synthesis/Extraction	\$1338.8	12.1%
Pre-Clinical (Other)	\$3,540.1	31.9%
Clinical Evaluation	\$3,682.8	33.2%
Manufacturing and Other	\$2,539.1	22.8%
<b>Totals</b>	<b>\$11,100.8</b>	<b>100.0%</b>

Note: Data apply only to PhRMA members. Also, since it would appear that PhRMA capitalizes all R & D costs, the category expenditures in this table may not accurately reflect the relevant economic costs for 1994.

Source: PhRMA. *Industry Profile* (1996).

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<sup>2</sup> For a discussion of these stages of the R & D process in the drug industry, see Kaitin and Houben (1995). For other discussions of this process, see DiMasi and Hansen (1991), Toole (1995), and Moore (1996).

**Table A.2**  
**1994 R & D Expenditures by Industry**

<b>Industry</b>	<b>R&amp;D/Sales Ratio</b>	<b>R&amp;D Per Employee</b>
Prescription Drugs	18.6%	\$54,618.50
Electrical and Electronics	5.7%	8,257.60
Automotive	3.8%	9,257.70
Food	0.8%	1,566.00
Housing	1.7%	2,742.30
Telecommunications	3.3%	7,137.30
Chemicals	3.7%	10,289.10
Aerospace & Defense	4.2%	7,106.10
<b>All-Industry Composite</b>	<b>3.5%</b>	<b>7,651.30</b>

Notes: Data for the prescription drug industry apply only to PhRMA members. R & D expenditures for drugs and medicines overall amounted to 11.7 percent of sales in 1994.

Sources: Coy, Billups, and Hansen (1995) and PhRMA. *Industry Profile* (1996).

In part, the high level of R & D reflects the high, and growing cost of drug development. During the FTC hearings on global competition, testimony indicated that the average cost of launching a successful new prescription drug was about \$359 million in the 1980s.<sup>3</sup> Moreover, the relationship between R & D expenditures and the number of new drugs suggests that there has been a decline in the productivity of drug industry R & D. Information in Table A.3 indicates that, while the number of new chemical entities (NCEs) approved by FDA remained relatively constant between 1985 and 1995, R & D expenditures by drug companies rose by

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<sup>3</sup> This average cost of \$359 million was a part of hearing testimony before the Federal Trade Commission, and was not discussed in great detail. Thus, it is difficult to determine how the witness estimated this cost (See, Federal Trade Commission. *Hearings On Global and Innovation-Based Competition*. Prepared Statement of Dr. Allen Bloom and Stephen A. Stack, Jr., p. 4, (October 23, 1995)). Others estimate that this cost averages approximately \$350 million for new prescription drugs (See, Federal Trade Commission. *Hearings On Global and Innovation-Based Competition*. Transcript, p. 652, (October 23, 1995)).

**Table A.3**  
**Domestic R & D Expenditures and New Drug Approvals (1985 to 1995)**

<b>Year</b>	<b>Nominal R&amp;D Expenditures (Millions)</b>	<b>Constant Dollar R&amp;D Expenditures (Millions)</b>	<b>Number of NCEs Approved By FDA</b>
1985	\$3,378.7	\$3,378.7	25
1986	3,875.0	3,542.0	17
1987	4,504.1	3,794.5	17
1988	5,233.9	4,130.9	16
1989	6,021.4	4,421.0	20
1990	6,802.9	4,714.4	23
1991	7,928.6	5,212.8	30
1992	9,312.1	5,875.1	26
1993	10,477.1	6,479.3	25
1994	11,101.6	6,736.4	22
1995	11,845.4	7,009.1	28

Notes: Data on R & D expenditures apply only to PhRMA members. Data on 1995 R & D expenditures are estimates. Constant dollar expenditures equal nominal expenditures divided by the producer price index for pharmaceutical preparations (1985 = 1.00). NCE refers to new chemical entity.

Sources: PhRMA Backgrounder. *Prescription Drug Prices and Profits* (1996) and Toole (1995).

more than 250 percent in nominal dollars and by over 105 percent in constant dollars.<sup>4</sup> R & D expenditures increased on a per approval basis as well. The data in Table A.4 indicate that,

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<sup>4</sup> At the same time, given the complexities associated with R & D and its output, any simple relationship (or lack of relationship) between crude input and output measures might not accurately reflect the determinants of R & D. In this case, NCEs might not accurately measure R & D output, particularly because of qualitative differences across new drugs. Further, research clearly indicates that R & D output is intertemporally related to expenditures on drug development, suggesting that current R & D spending is not likely to be a good predictor of the number of NCEs developed by pharmaceutical companies. For discussions of the determinants of R & D productivity, see *Pharmaceutical R & D: Costs, Risks and Rewards* (1993), Cockburn and Henderson (1994), Henderson and Cockburn's discussion in Helms (1996), Jensen (1987), and Toole (1995).

**Table A.4**  
**Domestic R & D Expenditures per New Drug Approval**  
**(1985 to 1995)**

Year	Nominal R&D/NCE (Millions)	Constant Dollar R&D/NCE (Millions)
1985	\$135.15	\$135.15
1986	\$227.94	\$208.35
1987	\$264.95	\$223.21
1988	\$327.12	\$258.18
1989	\$301.07	\$221.05
1990	\$295.78	\$204.97
1991	\$264.28	\$173.76
1992	\$358.16	\$225.97
1993	\$419.08	\$259.17
1994	\$504.61	\$306.20
1995	\$423.05	\$250.30

Note: These R & D expenditures understate total domestic expenditures since they exclude investments by non-PhRMA members. Also, these data reflect only average annual expenditures by PhRMA members, and no adjustments were made to estimate the average economic R & D cost over this time period.

Source: Computed from data in Table A.3.

between 1985 and 1995, R & D expenditures for the average NCE increased by more than 200 percent from \$135.15 million to \$423.05 million. Even after adjusting for inflation, R & D expenditures increased by more than 85 percent. Empirical research offers corroborating evidence, indicating that nominal pharmaceutical company R & D costs rose from an average of \$231 million in 1987 to \$359 million in 1990.<sup>5</sup> More current work suggests that the observed decline in the productivity of R & D in the pharmaceutical industry is the result of several

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<sup>5</sup> See, for example, DiMasi and Hansen (1991) and *Pharmaceutical R & D: Costs, Risks and Rewards* (1993).

factors, particularly the rising costs of research and clinical drug development.<sup>6</sup> This research raises the possibility that higher R & D costs are the result of shifts to more complex drug development efforts and more costly regulatory oversight procedures. If so, R & D may still be productive, but drug companies may have fewer opportunities to develop innovative products.<sup>7</sup> At the same time, pharmaceutical R & D expenditures have increased relative to drug sales.<sup>8</sup> This is consistent with a decline in the overall productivity of R & D in the drug industry.<sup>9</sup>

In addition to facing rising R & D costs, pharmaceutical firms also face significant risks. Pre-clinical testing has historically involved the screening of some 5,000 to 10,000 compounds. Of these, only 5 ever reached the clinical phases of the FDA approval process, and only 1 of these 5 received FDA approval.<sup>10</sup> Even at the later stages of the FDA approval process, promising drugs could prove either unsafe or ineffective. For example, evidence indicates that

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<sup>6</sup> Henderson and Cockburn's discussion in Helms (1996) focuses attention on the determinants of R & D productivity in the pharmaceutical industry.

<sup>7</sup> This is consistent with the view that old methods of finding drugs -- screening various compounds and organic materials -- are being replaced by new, more costly methods -- genetic engineering -- that yield more effective treatments for disease states.

<sup>8</sup> In fact, for PhRMA members, domestic R & D expenditures as a percentage of sales increased from about 13 percent to an estimated 20 percent between 1980 and 1996 (See, *Industry Profile* (1996)).

<sup>9</sup> However, aggregate data may not reflect the productivity of individual R & D projects, but detailed data on sales and R & D expenditures for new drugs are not readily available to more carefully assess the variation in productivity across R & D projects.

<sup>10</sup> See, Beary (1996) and Kaitin and Houben (1995). Also, see Federal Trade Commission. *Hearings On Global and Innovation-Based Competition*. Prepared Statement of Dr. Allen Bloom and Stephen A. Stack, Jr., p. 4 and pp. 11-12, (October 23, 1995) for another discussion of R & D risks in the pharmaceutical industry. According to this information, for example, estimates suggest that fewer than 7 percent of today's product candidates that begin the pre-clinical testing phases of drug development will reach the marketplace.

30 percent of potential NCEs fail safety tests in clinical trials, 37 percent prove ineffective in efficacy trials, and 13 percent fail to proceed past later stages of the FDA approval process.<sup>11</sup>

Along with R & D risks, drug companies face market risks as well. For example, as discussed below, competition at the R & D stages often results in the introduction of several competing drugs for treatment of the same disease state. This competition can reduce revenue streams from the marketing of new drugs. Moreover, the R & D process is a lengthy one. In addition to the time spent in the clinical phases of the drug approval process discussed below, estimates indicate that pre-clinical stages take an average of 6.5 years to complete.<sup>12</sup> The combination of high up-front R & D costs, potential competition on final sales, and a lengthy development period serve to make pharmaceutical R & D a higher risk business than other industries.

## **2. Intellectual Property Rights**

The pharmaceutical industry's history of innovation and technological progress can be explained in part by the ability of firms to obtain intellectual property rights. Although intellectual property rights protection might not be necessary to foster innovation in all

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<sup>11</sup> For a discussion of these and other data that relate to the development of new drugs, see Kaitin and Houben (1995).

<sup>12</sup> See, Beary (1996).

industries,<sup>13</sup> pharmaceutical companies rely especially heavily on intellectual property rights in the form of patents and trademarks. In fact, empirical research indicates that new product development in the pharmaceutical industry is more dependent on patent protection than in many other industries,<sup>14</sup> including petroleum refining, steel, semiconductors, computers, automobiles, and beer.<sup>15</sup> In particular, some evidence suggests that 65 percent of pharmaceutical products would not have been introduced and 60 percent would not have been developed without adequate patent protection.<sup>16</sup>

The literature on R & D and innovative activity suggests that patents on prescription drugs might be more effective means of raising imitation costs than patents on other products, possibly explaining their relative importance in the pharmaceutical industry.<sup>17</sup> Arguably, by raising imitation costs, patents allow pharmaceutical companies to capture the profits from their innovative drug development activity. Even so, because patents often issue during the research

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<sup>13</sup> In their report, staff of the FTC discussed the ongoing debate about the degree of intellectual property rights protection necessary to foster innovation, and pointed to empirical literature indicating that, while patents are not important assets in some industries, they provide significant incentives to innovate in others, including the pharmaceutical industry (See, Federal Trade Commission Staff Report. *Competition Policy in the New High-Tech, Global Marketplace*. Volume I, Chapter 6, (May, 1996)).

<sup>14</sup> For example, in a study across several companies and industries, Mansfield found that the pharmaceutical industry ranked highest in its reliance on patent protection (Mansfield (1986)). In addition, see Levin et al. (1987 and 1988) for discussions of the significant role of patents in the pharmaceutical and other industries.

<sup>15</sup> For a discussion of the importance of patents in these industries, see Scherer (1996).

<sup>16</sup> See, Mansfield (1986).

<sup>17</sup> For a survey of this literature, which includes a review of the importance of patents in the pharmaceutical industry, see the discussion by Cohen and Levin in Schmalensee and Willig (1989).



or clinical stages of drug R & D, the effective period of patent protection for a new drug is often significantly less than 17 years.<sup>18</sup> Some observers estimate that the effective period of protection is actually only about 9 years.<sup>19</sup> Nevertheless, patents are a significant form of intellectual property in the drug industry.

Trademarks are also a prominent source of intellectual property for drug companies. Trademark registration in the U.S. extends into perpetuity, and pharmaceutical companies, like consumer product companies, tend to pursue a strategy of adopting the same trademark worldwide, subject to the availability of protection in different countries.<sup>20</sup> One of the more significant issues concerning the value of trademarks, as discussed in Chapter II, is the rising use of generic drugs in the U.S. Commentators suggest that the increasing use of generic drugs, as well as additional scrutiny by regulators such as FDA,<sup>21</sup> could diminish the value of trademarks

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<sup>18</sup> The tradeoff between the duration and scope of market power due to patent protection and optimal levels of innovation is an ongoing public policy issue. A significant literature exists in this area (See, for example, Gilbert and Shapiro (1990), Klemperer (1990), and Lerner (1994)).

<sup>19</sup> See, Scherer (1993). Legislative changes discussed in Chapter II provide for extensions to the 17-year patent terms for improvements in pharmaceutical processes or products.

<sup>20</sup> A typical strategy is for an international drug company to register a trademark first in a major market like the U.S. or the U.K., and then proceed with registrations in other countries. For a discussion of this and other trademark-related issues, see Blackett (1992).

<sup>21</sup> The FDA does not control the trademark registration process, which is under the control of the U.S. Patent and Trademark Office, but FDA can refuse to approve the use of a trademark on brand-name prescription drug labels or packages.

for brand-name drugs.<sup>22</sup> This, like limitations on patent protection, could adversely affect returns to innovation, and reduce the incentives of drug companies to invest in the R & D that leads to new drugs.

### **3. Entry and the FDA**

FDA regulates the approval of prescription drugs in the U.S. To receive marketing approval companies are required to demonstrate that drugs are both safe and effective. Pharmaceutical companies must also secure approval of their production processes and labeling inserts.<sup>23</sup> Estimates indicate that new drug approvals have taken an average of 8.5 years (Table A.5), with the elapsed times varying across the regulatory stages (Table A.5).<sup>24</sup> Major drug companies incurred expenses of some \$6 billion (55 percent of total R & D expenditures) meeting the requirements of these regulatory stages in 1995 (Table A.1).<sup>25</sup>

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<sup>22</sup> See Wild (1995) for a further discussion of the use of trademarks by pharmaceutical companies. It is noteworthy, as discussed in Chapter IV, that the introduction of generics may marginally increase the value of brand-name drugs for some segments of demand.

<sup>23</sup> Prior to the 1962 Kefauver-Harris Amendments to the Federal Food, Drug, and Cosmetic Act of 1938, drug companies were only required to demonstrate safety before marketing new drugs. For background discussions on FDA entry regulations, see Beary (1996), DiMasi, Seibrung, and Lasagna (1994), and Moore (1996).

<sup>24</sup> The approval times reported in Table A.5 are similar to those reported in a report by the Congressional Budget Office (1998) using a sample of drugs over a longer time period. That report indicates that from 1984 to 1995, the clinical testing phases took an average of 5.4 years to complete, while the approval phase took an average of 2.9 years.

<sup>25</sup> Arguably, even without formal FDA requirements, competition among pharmaceutical companies would itself lead to drug testing that would enable drug companies to effectively market their products. If so, then the cost and time involved in meeting FDA requirements for new drug approval are inclusive of the cost and time that would have been incurred in any event.

**Table A.5**  
**Stages of the FDA**  
**Approval Process**

Regulatory Stage	Description	Average Time Lapse
Investigational New Drug Application (IND)	Application for Approval of Human Testing	30 Days
Phase I	Safety Tests	1 Year
Phase II	Efficacy Tests	2 Years
Phase III	Efficacy and Long Term Reactions	3 Years
New Drug Application (NDA)	Application for New Drug Approval	2.5 Years
Phase IV	Post-Market Testing Often Takes Places	N/A

Notes: An IND becomes effective in 30 days if the FDA fails to reject the application. The NDA review elapsed time is the average for new drug approvals over the 1990-1994 period. N/A means not applicable.

Source: Beary (1996).

FDA review time for NDAs has declined in recent years,<sup>26</sup> but other data suggest that both the pre-clinical and clinical phases of drug development have required increasing amounts of time to complete (Table A.6). For example, during the 1990s, drug R & D overall took an average of 14.8 years from initial synthesis to FDA approval.<sup>27</sup> This was more than 80 percent

<sup>26</sup> For instance, the median FDA review time for NCE drug applications was 15.9 months in 1995 and 14.3 months in 1996 (See the related discussion in the Food and Drug Administration's *FDA Talk Paper* (1997)).

<sup>27</sup> This overall time of 14.8 years is consistent with testimony given during the FTC hearings on global competition, indicating that the new product development cycle in the pharmaceutical industry ranges from 10 to 15 years (See, Federal Trade Commission. *Hearings On Global and Innovation-Based Competition*. Transcript, pp. 683 and 693, (October 23, 1995)).

**Table A.6**  
**Prescription Drug Development Times**  
**(1960s to 1990s)**

Time Period	Pre-Clinical Stages	Clinical Stages	NDA Review Stage	Total
1960s	3.2 Years	2.5 Years	2.4 Years	8.1 Years
1970s	5.1 Years	4.4 Years	2.1 Years	11.6 Years
1980s	5.9 Years	5.5 Years	2.8 Years	14.2 Years
1990 to 1994	6.1 Years	6.1 Years	2.6 Years	14.8 Years

Sources: DiMasi (1995) and PhRMA. *Industry Profile* (1996).

longer than in the 1960s. The largest increase involved the clinical stages, requiring an average of some 144 percent more time in the 1990s than in the 1960s. The increase in clinical development time partly stems from satisfying the regulatory requirements for more and larger clinical trials. For example, the number of clinical trials per drug application rose from 30 in the late 1970s to 60 in the early 1990s, and the number of patients in these trials more than doubled over the same time period.<sup>28</sup>

#### **B. Basic Characteristics of Drug Demand**

Important characteristics of the demand for prescription drugs include: (1) the roles of various intermediaries in the purchase process; (2) variations in demand elasticities across product categories and customer classes; and (3) the ongoing growth of demand for pharmaceutical products.

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<sup>28</sup> For a discussion of these and other data on clinical drug trials, see Boston Consulting Group (1993).

## 1. Drug Demand and the Role of Intermediaries

Under the traditional purchase and payment system, consumers depend on several intermediaries in markets for prescription drugs. Physicians and third-party healthcare plans are the most prominent of these agents. According to some analysts,<sup>29</sup> agency problems and information imperfections in prescription drug markets have contributed to the relatively high reported price increases documented in Table A.7.

During most of the period covered by the data in Table A.7, drug price increases outpaced overall measures of inflation. Drug price inflation did moderate to about 2.4 percent per annum during 1995 and 1996, and that moderation could reflect the competition-enhancing changes that are discussed in Chapters II and III.<sup>30</sup> During 1998, however, prescription drug prices increased at faster rates than in the 1995-97 period. At the same time, commentators have found that CPI measures overstate drug price inflation, raising significant doubt about the

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<sup>29</sup> See, Hellerstein (1994) and Scherer (1996).

<sup>30</sup> A closer look at these data suggests that this moderation began prior to 1995. For instance, the consumer price index for prescription drugs rose by about 2.9 percent during 1994, and by approximately 2.8 percent during 1993. The overall consumer price index rose by about 2.5 percent in each of these years. However, according to information on the top 500 prescription drugs obtained in a recent survey by the National Association of Chain Drug Stores (NACDS), drug prices rose by 4.1 percent in 1996, exceeding an overall measure of consumer inflation of 3.2 percent during the same year (See, Tanouye (1997)). At the same time, since the survey obtains average wholesale price data and ignores price discounts to HMOs and others, the NACDS measures of drug price inflation probably overstate actual price increases for prescription drugs.

**Table A.7**  
**Price Changes for Prescription Drugs v. All Commodities**  
**(1975 to 1998)**

Time Period	Prescription Drugs	All Commodities	Difference
1975 to 1980	8.3%	9.5%	-1.2%
1980 to 1985	13.1%	4.5%	+8.6%
1985 to 1990	10.1%	3.5%	+6.6%
1990 to 1994	9.8%	1.0%	+8.0%
1995 to 1996	2.4%	2.6%	-0.2%
1997	2.5%	0.3%	+2.2%
1998	4.7%	0.5%	+4.2%

Notes: The second and third columns contain calculations of annual average price changes over the relevant time periods, and use CPI data for prescription drugs and all commodities, respectively, as bases for these calculations. Data in the third column equal the differences between in the annual price changes of prescription drugs and all commodities. Data for 1997 and 1998 measure inflation using monthly CPI data covering January through December of each year.

Source: *Statistical Abstract of the United States* (1987 and 1995) and *Consumer Price Index* (1993-1999).

accuracy of the data in Table A.7.<sup>31</sup> It is also possible that historical inflation rates for prescription drugs are comparable to inflation rates in other markets that face similar agency and information problems. In fact, Bureau of Labor Statistics data indicate that price changes for

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<sup>31</sup> Research points to two reasons why conventional price indices like the CPI overstate price changes for prescription drugs. First, despite the growing generic share of all prescription drugs, the CPI and other official price indices underweight generic drugs when they are included in the prescription drug market basket. Second, in efforts to account for quality changes, price differentials between goods already in an official index (e.g., a brand-name drug) and comparable new products (e.g., a new generic drug) are assumed to reflect quality differences, and these price differences are not reflected in the price indices. The resulting bias is likely to be more significant in later periods as consumers have increased their consumption of generic relative to name-brand drugs. Consequently, CPI data overstate drug price inflation, particularly as comparable generic forms are increasingly introduced and purchased by consumers (See, Griliches and Cockburn (1994) and Baye, Maness, and Wiggins (1995)). For a more general discussion concerning bias in the consumer price index, see Moulton (1996).

medical care services averaged over 6 percent between 1990 and 1996, or approximately the same as price changes for prescription drugs.

Nevertheless, high prices may still reflect information imperfections in prescription drug markets. Such imperfections arise when physicians and health plans lack complete information about prescription drug prices, alternatives, efficacy, and side-effects.<sup>32</sup> As a result, consumers would not necessarily have access to complete information on available drug alternatives and their prices, and could face higher prices and receive lower quality prescription drugs. Further, while commentators often note that pharmaceutical companies engage in an extensive amount of advertising, traditional advertising messages typically exclude information on price.

Drug promotion focuses on brand-name attributes, and not on price or generic alternatives. Moreover, drug promotion has involved the use of large marketing and detail sales forces that visit physician offices.<sup>33</sup> In fact, the number of pharmaceutical sales representatives increased by 50 percent during the 1980s, and drug companies continue to emphasize their detail activities even in HMO settings.<sup>34</sup> In addition, pharmaceutical companies have financed more direct-to-consumer (DTC) advertising in recent years.<sup>35</sup> This change in the types of advertising undertaken by pharmaceutical companies may increase the amount of information consumers

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<sup>32</sup> See, for example, Hellerstein (1994), Newhouse (1993), and Temin (1980). Also, see Kolassa (1995) for an empirical study that found that physicians were unable to correctly estimate the prices of commonly prescribed drugs.

<sup>33</sup> Research indicates that this often influences physician prescribing behavior, inducing physicians to favor brand-name instead of generic drugs (See, Hurwitz and Caves (1988) and Leffler (1981)).

<sup>34</sup> See, Paul (1993), Ross (1996), and Castagnoli (1994).

<sup>35</sup> See, for example, Williams and Hensel (1995).

have about drug alternatives. Additional DTC advertising may also result in more price and quality competition among pharmaceutical companies, and reduce consumer reliance on physicians as sources of information about prescription drugs.<sup>36</sup>

Physicians are not the only agents making decisions on behalf of drug consumers. Third-party payers often pay for prescription drugs.<sup>37</sup> This payment structure could raise a number of problems in prescription drug markets. For example, difficulties could arise in this industry if the incentives of any of the agents of consumers, including physicians and third-party payers, differ from those of consumers. To illustrate this, assume physicians act as good representatives for consumers, but not for third-party healthcare plans. If so, physicians would only internalize the prescription drug costs facing their patients, and not those facing the healthcare or Medicaid plans providing drug coverage. In this case, the incentives of the third-party payers differ from those of physicians and consumers. These differences may prevent the optimal use of prescription drugs.

The third-party payment system may also cause consumers and their physicians to have reduced incentives to control their expenditures on prescription drugs.<sup>38</sup> In particular, although

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<sup>36</sup> For a discussion of how DTC can increase price and quality competition among drug companies, see Comments of the Staffs of the Bureau of Consumer Protection and the Bureau of Economics of the Federal Trade Commission, Department of Health and Human Services, Food and Drug Administration. *In the Matter of Direct-to-Consumer Promotion; Public Hearings*. (January 16, 1996).

<sup>37</sup> In fact, third-party payment, including Medicaid payments, has increased significantly in recent years. For instance, between 1990 and 1995, the share of retail prescriptions at least partially covered under third-party payment plans rose from about 37 percent to 62 percent (See, "Business Watch." (1996)).

<sup>38</sup> For a discussion of moral hazard in the context of Medicare reform, see Mourey and Eisenberg (1990).



third-party payers have incentives to minimize the costs of providing prescription drug benefits, consumers insured by these payers probably lack incentives to minimize these costs, and are likely to be more concerned about the quality of their drug treatments. Yet, under conditions of imperfect information, physicians might not make optimal decisions for their patients and PBMs might not make optimal decisions for the third-party payers that they represent. All of these problems could lead to some combination of higher drug prices, lower output levels, and poorer quality outcomes for consumers.

## **2. Demand Elasticity Differentials**

It has been widely argued that consumers are insensitive to changes in prescription drug prices -- that consumer demand is price inelastic.<sup>39</sup> The literature contains several explanations for this. First, physicians may lack complete information about drug alternatives and otherwise fail to internalize the cost of prescription drugs. Second, the third-party payment system may give rise to agency problems and moral hazards that inhibit consumer substitution among drug alternatives. Third, consumers may be willing to pay significant amounts for the treatment of diseases, particularly for the treatment of acute disease states, and, as a result, may not be significantly influenced by changes in prescription drug prices.

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<sup>39</sup> For discussions of the various rationales for the apparent consumer insensitivity to prescription drug price changes, see, among others, Congressional Budget Office's report entitled *How Health Care Reform Affects Pharmaceutical Research and Development* (1994), Hellerstein (1994), Scherer (1996), Schwartzman (1979), and Measley's discussion of the pharmaceutical industry in Adams (1977).

Notwithstanding this literature,<sup>40</sup> it is important to account for the complexities of drug markets before reaching conclusions about the price elasticity of drug demand. In particular, in addition to other considerations, demand elasticities arguably depend on the characteristics of particular drug markets and on whether or not identifiable demand segments exist. First, drugs are often categorized into several therapeutic classes that contain alternative treatments for the same disease state. Data for the largest therapeutic categories appear in Table A.8. Although these categories might not correspond to alternative definitions of markets, including antitrust markets,<sup>41</sup> demand elasticities could vary across these or other such categories for several reasons. Elasticities may vary depending on the number and quality of brand-name alternatives within a given class,<sup>42</sup> the number and quality of generic forms available,<sup>43</sup> and the nature of the

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<sup>40</sup> In fact, other empirical literature suggests that overall drug demand is price elastic (See, for example, Alexander, Flynn, and Linkins (1994)). This finding, however, does not necessarily mean that prescription drug markets are free from the agency problems and moral hazards that tend to make consumer purchases insensitive to changes in drug prices. The authors of this study acknowledge that their findings are tentative, and that their model fails to capture all relevant factors that could influence prescription drug prices. As a result, their regression results may not be robust, and could lead to biased estimates of the relevant price elasticities of demand.

<sup>41</sup> For a description of antitrust markets, see Section 1 of the *Horizontal Merger Guidelines* (1992 and 1997).

<sup>42</sup> Prescription drugs fall into either single source or multiple source categories. Single source, unlike multiple source drugs that often have several alternative sources of supply, stem from a single supplier who is not subject to competition from alternative suppliers of drugs in the same therapeutic category. Other factors equal, the market demand for a single source drug is probably more price inelastic than the overall demand for a multiple source drug.

<sup>43</sup> The quality of available generic or brand-name alternatives, particularly their side-effect profiles, impacts on the substitutability among these potential alternatives. Press accounts, discussing switching initiatives by some managed care plans, point to the serious medical consequences of switching patients to lower cost alternatives that produce harmful side-effects (See, Freudenheim (1996)).

**Table A.8**  
**Sales and Prescription Data by Drug Category**  
**(1995)**

Therapeutic Class	Dollar Sales	Number of Prescriptions
Antispasmodics	\$5,400	75.4
Calcium Channel Blockers	\$3,710	90.5
Serotonin Inhibitors	\$2,900	42.6
Cephalosporins	\$2,640	58.8
Angiotensin Converting Enzyme (ACE) Inhibitors	\$2,450	66.4
Cholesterol Reducers	\$2,270	39.1
Systemic Antiarthritics	\$1,810	75.4
Anticonvulsants	\$1,160	31.5

Note: Data are in millions.

Source: "Business Watch." (1996).

disease state.<sup>44</sup> In fact, an empirical study of demand for drugs in four therapeutic categories -- gout therapies, sedatives, tranquilizers, and oral diabetic drugs -- offers evidence of significant substitution among brand-name drugs in these categories. The author of the study argues that competition among competing producers of these drugs serves as a check on the market power of name-brand drug suppliers. Differences in the extent of interbrand and generic competition

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<sup>44</sup> Commentators suggest that demands for drug treatments for chronic disease states are more price elastic than demands for pharmaceuticals intended for acute disorders. This is because the ongoing cost of maintenance drugs for chronic disorders (e.g., hypertension) likely exceeds the drug treatment costs for infrequent acute disease states (e.g., bacteria infection). For a discussion of this issue, and its impact on demand elasticity, see Scherer (1996).

across these categories serve to explain some of the differences in the price elasticity estimates across the four therapeutic categories.<sup>45</sup>

Demand elasticities may also vary across customer classes, and some classes of customers are growing relative to others. For example, Table A.9 reveals that the share of prescriptions accounted for by cash payment has been declining, while the share accounted for by third-party payment has been increasing. It is likely that demand characteristics differ across these and other possible segments. The literature on market definition suggests separate markets could emerge from differences in demand elasticities across identifiable segments.<sup>46</sup> The segmentation of prescription drug markets also has implications for pharmaceutical pricing as discussed below.<sup>47</sup>

### **3. Demand Growth**

Nominal prescription drug sales increased by an annual average of over 11 percent from 1980 to 1996.<sup>48</sup> Rapid growth is likely to continue for several reasons. First, because cost-containment has become increasingly important, the substitution of pharmaceuticals for other health care services will probably accelerate, particularly when prescription drugs produce

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<sup>45</sup> See, Stern (1994). Other studies point to generic substitution and other factors (e.g., higher co-payment costs) as explanations of the sensitivity of drug consumption to variations in price (See, for example, Smith (1993) and Leibowitz, Manning, and Newhouse (1985)).

<sup>46</sup> See, Section 1 of the *Horizontal Merger Guidelines* (1992 and 1997) and Hausman, Leonard, and Velluro (1996).

<sup>47</sup> Pricing implications are also explained in greater detail in the discussion of price discrimination in Chapter IV.

<sup>48</sup> This percentage was computed from data contained in *Industry Profile* (1996). Growth of constant dollar drug sales clearly lagged the growth of current dollar sales, particularly in light of the price increases summarized in Table A.7.

**Table A.9**  
**Retail Prescription Shares by Payment Type**  
**(1990 to 1995)**

Year	Cash Payment	Third-Party Payment	Medicaid Payment
1990	63.1%	26.1%	10.7%
1991	59.2%	28.0%	12.8%
1992	55.6%	30.1%	14.3%
1993	50.5%	34.7%	14.9%
1994	44.7%	42.0%	13.3%
1995	49.1%	38.2%	12.7%

Source: "Business Watch." (1996).

outcomes comparable to non-drug treatment alternatives for diseases.<sup>49</sup> Additional long run substitution is likely to take place as pharmaceutical firms promote disease state management programs to health plan sponsors, providing data on the cost-effectiveness of pharmaceutical alternatives relative to non-prescription drug treatment of disease states.<sup>50</sup>

Second, new solutions to the prescription compliance problem are likely to expand drug usage. Compliance problems include the failure to fill or refill a prescription, and the failure to take the prescribed dosage.<sup>51</sup> According to PhRMA information, only 50 percent of prescription medications are taken correctly, and compliance rates vary by medication. For example,

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<sup>49</sup> In one study, Lichtenberg (1995) found that new drug development leads to reductions in hospital stays and surgical procedures, without increasing death rates among the relevant patient populations.

<sup>50</sup> Chapter III contains a discussion of disease state management, and the programs currently offered by pharmaceutical companies in this area.

<sup>51</sup> These decisions might not reflect any compliance problem if patients stop taking medications because of serious side effects.

compliance rates for antihypertension drugs decline from an average per patient of 94 percent in the first year to 34 percent during the third year of administration. The average compliance rate for various drugs used by the elderly is 41 percent.<sup>52</sup> As discussed in Chapter III, information technology gives rise to several innovations, including drug refill programs, that address the compliance issues in prescription drug markets.

Finally, demand for prescription drugs is likely to increase as the U.S. population ages. Some commentators project an annual average constant dollar sales growth rate through the year 2000 of 7 percent for the domestic drug industry overall, and 14 percent for generic drugs.<sup>53</sup>

### **C. Concentration, Pricing, and Competitive Performance in Traditional Drug Markets**

Concentration of prescription drug sales among the top four brand-name pharmaceutical companies rose from 25 percent in 1977 to 30 percent in 1995 (Table A.10). This slight increase in overall concentration stems partly from horizontal consolidation within the drug industry.<sup>54</sup> Nonetheless, overall concentration measures fail to capture accurately the dynamics of competition among pharmaceutical companies across therapeutic categories. In what follows, we discuss competition across several therapeutic categories, examine a few traditional pricing strategies, and summarize industry performance by looking at the profitability of drug companies.

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<sup>52</sup> See, *Industry Profile* (1996).

<sup>53</sup> For a discussion of these and other projections, see Breindel (1994). For additional projections on growth of the pharmaceutical industry, see *U.S. Industrial Outlook* (1994-96).

<sup>54</sup> This discussion focuses attention on brand-name drug suppliers. Competition from generic suppliers and a more in-depth discussion of horizontal merger activity among pharmaceutical companies are the subjects of Chapter II.

**Table A.10**  
**Sales Concentration Among Leading Brand-Name**  
**Drug Companies (1977 to 1995)**

Year	Four Largest Companies	Eight Largest Companies
1977	25%	41%
1982	26%	41%
1989	30%	55%
1995	30%	54%

Notes: Since the data are derived from different sources, comparisons over time might be inappropriate because of incompatibilities across these alternative sources.

Sources: *Census of Manufacturers* (1986), *Market Share Reporter* (1989), and "Business Watch." (1995).

### 1. Structure and Competition Across Therapeutic Drug Categories

Rivalry among brand-name pharmaceutical companies has traditionally involved new product introductions and entry into the various therapeutic categories, as well as brand development and product differentiation through promotion and detail activity.

Incumbent brands tend to compete with several other brands within the same therapeutic categories.<sup>55</sup> Historical market share and concentration data reveal significant variations in the relative sizes of the leading drug companies in competition in particular drug classes (Table A.11). For example, the four leading name-brand ACE inhibitors (i.e., drug treatments for hypertension) and cholesterol-lowering drugs accounted for over 90 percent of category sales,

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<sup>55</sup> In fact, according to one study, the majority of new prescriptions for brand-name drugs -- 54.5 percent in 1980 and 57.8 percent in 1989 -- were written for multiple source drugs (See, Caves, Whinston, and Hurwitz (1991) for a discussion of the competitive effects of patent expiration and generic entry in the pharmaceutical industry).

**Table A.11**  
**Category Shares of Leading Brands by Drug Class (1992)**

<b>Drug Class</b>	<b>(Brand &amp; Share)</b>				<b>Sub-Total</b>
ACE Inhibitors	Vasotec* 39.8%	Capoten 23.6%	Zestril 15.5%	Prinivil* 11.4%	90.3%
Allergy Drugs	Seldane* 29.2%	Seldane D* 14.4%	Hismanal 10.6%	Tavist 6.4%	60.6%
Analgesics	Anapr. DS* 16.0%	Toradol* 9.3%	Florinal 7.8%	Dolobid 4.7%	37.8%
Antibiotics	Ceclor 7.1%	Augmentin 4.8%	Cipro 3.8%	Biaxin 1.3%	17.0%
Anxiety Drugs	Xanax 22.5%	Valium 4.5%	BuSpar 3.7%	Ativan 3.0%	33.7%
Calcium Antagonist	Procardia 32.1%	Cardizem 26.6%	Calan 17.7%	Veralan 4.0%	80.4%
Cholesterol Drugs	Mevacor 43.5%	Lopid 27.4%	Questran* 11.1%	Pravachol* 9.4%	91.4%
Ulcer Drugs	Zantac 42.8%	Tagamet 19.2%	Pepcid 10.8%	Axid 8.3%	81.1%

Notes: For a given drug class, \* indicates brands owned by the same pharmaceutical company during the time period covered by the data. As a result, during this time period, the sub-totals measure concentration among the top four brands in each category, and not the top four drug companies. More importantly, the various drug classes do not necessarily define relevant markets, raising the possibility of upward or downward bias in these market share data.

Source: Investext Database.

while the four leading antibiotics accounted for only 17 percent of category sales.<sup>56</sup> The share data in Table A.11 also illustrate some variation in the distribution of sales across the leading

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<sup>56</sup> A comparison of share data for antibiotics and ACE inhibitors might not accurately represent any differences in sales concentration across appropriately defined drug classes. Arguably, the fact that there are distinct subclasses of antibiotics suggests that antibiotics is a broader drug category than ACE inhibitors which also compete with other antihypertensive drugs. If so, then the sales concentration data in Table A.11 for these two therapeutic classes are not necessarily comparable. Instead, it might be more appropriate to compare sales concentration data for antibiotics and all antihypertensive drugs, including ACE inhibitors.



brands. For cholesterol and ulcer drugs, for example, the leading brand accounted for about 50 percent of the sales of the four leading brands in 1992. The market shares of the leading brands were more evenly distributed for antibiotic drugs. Different share distributions suggest that brands in certain categories tend to dominate sales, while brands in other categories face significant competition.

This leads to the question of whether or not leading brands tend to retain their dominant shares over time. The market share data in Table A.12 reveal that new product introductions and entry tend to erode the shares of dominant brands in many product categories, but not in all cases. ACE inhibitors are illustrative of how important product development competition can be in some markets. In 1987, Bristol-Myers Squibb and Merck dominated the ACE inhibitor category with their brands, Capoten and Vasotec, respectively. After 1987, however, competitors commercially developed several other name-brand ACE inhibitors, including ICI Pharmaceutical's Zestril and Warner-Lambert's Accupril, and these brands were introduced in competition with the incumbent brands.<sup>57</sup>

In other markets, however, leading brands are capable of maintaining dominant market shares despite new product development and entry. In the case of anxiety drugs, for example, Upjohn's Xanax brand managed to maintain market share, despite competition from several other brands. Economic literature on incentives to innovate raises the possibility that firms with

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<sup>57</sup> A number of studies on the pharmaceutical industry recognize the significant competition among drug companies because of new product development and entry (See, for example, the Congressional Budget Office's report entitled *How Health Care Reform Affects Pharmaceutical Research and Development* (1994), Comanor (1986), and Scherer (1996)).

**Table A.12**  
**Changes in the Category Shares of Select Drugs**  
**(1987 to 1992)**

Drug Class	Brand-Name	1987 Mkt. Share	1992 Mkt. Share
ACE Inhibitors	Capoten	55.5%	23.6%
Analgesics	Anaprox	13.4%	3.7%
Anxiety Drugs	Xanax	19.4%	22.5%
Calcium Antagonists	Cardizem	34.2%	26.6%
Cholesterol Drugs	Questran	24.4%	11.1%
Sedatives	Halcion	37.1%	18.1%
Ulcer Drugs	Tagamet	41.6%	19.2%

Note: The brand-name drugs listed in column two are not necessarily the leading brands in their respective categories.

Source: Investext Database.

leading sales shares retain their dominant positions by investing in R & D projects that deter the entry of others.<sup>58</sup>

The literature identifies several factors that may encourage leading firms to deter new entry. For example, leading firms might anticipate that others would easily succeed in their R & D efforts (i.e., the probability that potential entrants would fail to develop an innovative product is low), or that others are likely to develop products that would significantly reduce the sales share of the leading firm. Alternative explanations of firm dominance also exist. Research conducted in the 1970s and 1980s suggested that promotion, product differentiation, and first-mover advantages might explain the long-term dominance of specific brands in some therapeutic

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<sup>58</sup> See, for example, Baker (1995). In other therapeutic categories that have experienced significant entry by others (See, for example, data on ACE inhibitors in Tables A.11 and A.12), first-movers may have accommodated new entrants. This would explain the significant market share changes over time in these drug categories.

drug categories.<sup>59</sup> More current literature also suggests that promotion in the form of detailing can establish brand loyalty among prescribing physicians.<sup>60</sup>

## **2. Traditional Pricing Strategies of Name-Brand Pharmaceutical Companies**

Pharmaceutical companies also compete by adopting a variety of different pricing strategies. The traditional literature on pricing in the drug industry is summarized in the next section. In this section, we focus on pricing strategies that involve discounts to certain classes of trade and significant product differentiation.<sup>61</sup>

Pharmaceutical companies have traditionally offered different discounts to different classes of trade. Historically, hospitals have often been able to negotiate larger discounts for prescription drugs than other classes of buyers, including retail pharmacies. Commentators often point to the change in Medicare reimbursement procedures as the chief motivation underlying the negotiation of substantial drug price discounts by hospitals. In fact, following implementation of the Tax Equity and Fiscal Responsibility Act in 1983, hospitals no longer received reimbursement on a cost-plus basis for Medicare patients, but faced reimbursement

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<sup>59</sup> Examples of this literature include: Bond and Lean (1977); Goreck (1986); Hurwitz and Caves (1988); Schmalensee (1982); Schwartzman (1976); and Statman (1983). For a more current discussion of first-mover advantages, see Robinson, Kalyanaram, and Urban (1994).

<sup>60</sup> See, for example, Berndt, Bui, Reiley, and Urban (1995) and Scherer (1996).

<sup>61</sup> Much of the prior literature discussed below analyzes both the dynamic behavior of prices over time and the price responses of brand-name drug companies to new entrants. The discussion here describes short-term pricing strategies commonly adopted by drug companies in traditional prescription drug markets. Attention is focused on pricing strategies largely adopted by pharmaceutical companies before the various industry changes described in Chapters II and III, leaving Chapters IV and V for discussions of price and non-price strategies that stem from these industry changes.

limits governed by a "prospective payment" system.<sup>62</sup> Consequently, hospitals sought to minimize the costs of providing health care services by aggressively negotiating discounts with their suppliers, including pharmaceutical companies. Hospitals were also among the first buyers to apply cost-containment measures to their drug purchases, and did so by using restrictive drug formularies and drug utilization review (DUR) programs.<sup>63</sup> As a result, hospitals possessed the incentives and means to negotiate larger discounts for prescription drugs than others. Arguably, these changed incentives may have served to resolve the agency problem associated with cost-based payment systems under which hospitals lacked the incentives to minimize the cost of providing services to Medicare patients. In addition, the use of cost-containment measures may have allowed hospitals to overcome some of the information imperfections on the demand side of prescription drug markets that were discussed above.

The degree of product differentiation also appears to be an important determinant of pricing conduct. The economic literature suggests that drug companies tend to set higher prices when their drugs offer therapeutic advantages over others. In other words, prices will be higher for drugs with relatively inelastic demands. For example, a study of 148 drugs launched domestically between 1978 and 1987 found that: (1) the most innovative drugs were introduced at prices higher than the prices of available alternatives; and (2) imitative drugs, on average,

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<sup>62</sup> A well-developed economics literature exists examining the economic impacts of the prospective payment system (See, for example, Asper and Hassan (1993) and Lave (1990)).

<sup>63</sup> Chapter II contains a discussion of these and other cost-containment mechanisms in use in the pharmaceutical industry.

were launched at lower prices than existing substitutes.<sup>64</sup> The discussion below describes other pricing literature suggesting that substitutability among therapeutic alternatives serves as a check on the market power of brand-name drug companies.<sup>65</sup> These, as well as other studies,<sup>66</sup> indicate that drug companies traditionally have accounted for the degree of product differentiation in establishing prices for prescription drugs.

### **3. Review of Economic Literature on Pricing**

Previous literature on the pharmaceutical industry has generally disregarded models of price discrimination. Instead, the prior literature has addressed a number of other pricing issues, including: (1) possible explanations for price differences among therapeutic substitutes;<sup>67</sup> (2) the dynamic behavior of prescription drug prices over time; (3) price setting behavior in response to entry; and (4) a variety of descriptive treatments addressing specific issues such as drug pricing under the Medicaid best price provisions for prescription drugs. We address these four areas below.

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<sup>64</sup> These and other findings are discussed in greater detail in Lu and Comanor (1994 and 1998). This study also found that, other factors equal, drugs purchased for acute conditions had higher premiums relative to available substitutes than prescription drugs purchased for chronic disorders. This is consistent with the discussion earlier suggesting that the demands for drug treatments for chronic disorders are more price elastic than the demands for drug treatments for acute conditions.

<sup>65</sup> See, Stern (1994).

<sup>66</sup> For example, in a study of drug pricing, Hudson (1992) found that prescription drug prices depend on a number of factors, including the degree of brand loyalty and alternative measures of competition.

<sup>67</sup> The prior literature also contains studies of geographic price differences. For example, Manning (1992) examined differences in prescription drug prices between the U.S. and Canada, and found that different product liability costs contributed to the price differences.

Although a number of early studies examine price differences between and among therapeutic drug alternatives,<sup>68</sup> none of these studies found evidence of economic price discrimination (i.e., differential pricing to distinct segments of demand that leads to profit differences on sales in the segments) within drug markets. In these early studies, price differences were largely attributed to variations in product quality, implying that price competition among therapeutic alternatives would lead to uniform quality-adjusted prices in markets for these prescription drugs.<sup>69</sup> An empirical study of demand for drugs in four therapeutic categories -- gout therapies, sedatives, tranquilizers, and oral diabetic drugs -- offers evidence of significant substitution among name-brand drugs within these categories, and argues that competition among competing producers of these drugs serves as a check on the market power of name-brand drug suppliers.<sup>70</sup> Another empirical study of the demand for cephalosporins, using monthly data for the October 1985 to March 1991 period, found evidence of significant degrees of substitution between generic drug alternatives and modest degrees of substitution between different therapeutic formulations.<sup>71</sup> Empirical results also indicated that cephalosporin demand tended to be more elastic at the dispensing stage than the prescribing

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<sup>68</sup> For a review of these studies, see Comanor (1986).

<sup>69</sup> See, Reekie (1978) and Weston (1979 and 1983). In addition, see Lu and Comanor (1994 and 1998) for more recent discussions on the pricing of new drugs.

<sup>70</sup> See, Stern (1994). This study also finds that name-brand drugs are often substantially differentiated from their corresponding generic alternatives, suggesting that generics are imperfect substitutes for name-brand drugs. This finding is consistent with other research on physician prescribing behavior which finds some evidence indicating that physicians tend to prescribe either name brands or generic forms, suggesting some degree of persistence in the behavior of physicians (See, Hellerstein (1994)).

<sup>71</sup> See Ellison, Cockburn, Griliches, and Hausman (1997).

stage of drug distribution. This suggests that physicians may lack pertinent information on drug alternatives that is available to other downstream intermediaries. A study on the pricing of anti-ulcer drugs applied a hedonic price model, and found some evidence of price differences unrelated to differences in drug quality.<sup>72</sup> A key finding of this paper is that, while new entrants supplied higher quality anti-ulcer treatments, the quality differences could not account for the rising prices of these drugs over time.

In a second series of papers, researchers examine the dynamic behavior of prescription drug prices over time. Three early studies analyzed the pattern of introductory and post-introductory prices for prescription drugs in efforts to understand the path of drug prices over time.<sup>73</sup> These three studies found that prescription drugs are introduced at relatively high initial prices, but that prices decline over time. This is consistent with the so-called price skimming strategy in which firms set high introductory prices for new products, reducing their prices over time.<sup>74</sup> In a more current study of 148 new drugs introduced between 1978 and 1987, Lu and Comanor also examine how prices are initially set, and how prices vary over time.<sup>75</sup> Among

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<sup>72</sup> See, Suslow (1991) and Berndt, Bui, Reiley, and Urban (1995) for another study of pricing in the anti-ulcer drug market.

<sup>73</sup> See, Cocks (1975), Cocks and Virts (1974), and Reekie (1978).

<sup>74</sup> See Dean (1969) for a discussion of price skimming and price penetration strategies for new products. It is noteworthy that a price skimming strategy differs from a learning curve strategy even though the price paths of the two are similar. In the case of a learning curve strategy, costs decline over time and demand remains stable. Firms pursue a price skimming strategy in a stable demand environment with costs declining as output grows over time. As a result, under the learning curve strategy, initial price is relatively high, but declines over time as costs of production fall. For a discussion of this model, see Spence (1981).

<sup>75</sup> See, Lu and Comanor (1994 and 1998).

other, perhaps more complex findings, this study concludes: (1) drug price behavior is consistent with both the price signaling and dynamic demand pricing models;<sup>76</sup> (2) pharmaceutical price behavior is inconsistent with the limit pricing or learning curve pricing models;<sup>77</sup> (3) suppliers of innovative drugs tend to use a price skimming strategy; and (4) producers of “me too” drugs follow a price penetration strategy. Overall, the authors state that rising “... expenditures on pharmaceuticals are due primarily to the introduction of more advanced products.”<sup>78</sup>

A third category of studies analyzes (1) the competitive effects of patent expiration and entry on the prices of generic drugs, and (2) the pricing and other practices of corresponding name-brand drug companies. Early studies on the competitive effects of new entry offer little evidence of resulting price competition in prescription drug markets. Findings in three early studies suggest that, due to considerations like first mover advantages, product differentiation, and brand loyalty, initial entrants do not face significant price competition from subsequent

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<sup>76</sup> The price signaling model suggests that, when consumers understate new product quality, firms can build reputations for new products with lower initial prices and higher post-introductory prices (See, Shapiro (1983)). Under dynamic demand pricing, the volume of future purchases is an increasing function of the number of initial purchases, implying that suppliers of new products should follow a price penetration strategy. Under a price penetration strategy, firms set low introductory prices for new products, but raise their prices over time (For an early discussion of this strategy, see Dean (1969)).

<sup>77</sup> The strategy under limit pricing, which assumes that incumbents expect rapid entry of imitative products, involves setting low initial prices to discourage entry. For discussion of different limit pricing models, see Gaskins (1971), Ireland (1972), and Milgrom and Roberts (1982).

<sup>78</sup> Hudson (1992) also focused attention on the dynamic behavior of prescription drug prices, and developed arguments indicating that drug price changes depend on a number of factors, including the degree of brand loyalty and alternative measures of competition. A different approach was developed by Mullins (1995), who constructed game theoretic models to explain how monopolistically competitive firms can sustain high price strategies.



suppliers of alternative drug treatments.<sup>79</sup> According to one of these studies, "...patent expiration has, at least for the first few years, only a small effect on the market shares and prices of the original drugs."<sup>80</sup>

Three studies focused attention on particular competitive issues (e.g., the impact of generic entry on brand-name prices) associated with the entry of generic drug suppliers. In one study, Morton (1995) analyzed the determinants of generic entry, and found that advertising by brand-name drug suppliers does not alter the anticipated number of generic entrants.<sup>81</sup> The study concludes that brand-name drug advertising is not a barrier to generic entry, but that other factors, including the sales revenues of the brand-name drug and the length of the FDA approval process for generic forms, are important predictors of generic entry. In another paper, Liang (1996) focuses attention on the competitive effects of generic introductions by brand-name drug companies prior to the expiration dates of their own patents for brand-name drugs.<sup>82</sup> Several anticompetitive theories of this practice are explored, including predatory pricing and raising rivals' cost. The paper examines conditions under which generic introductions raise prices and

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<sup>79</sup> See, Schwartzman (1975), Statman (1981), and Bond and Lean (1977).

<sup>80</sup> See, Statman (1981).

<sup>81</sup> See, Morton (1995). In a related paper, Morton (1996) applied a probit model to data on generic entrants during the 1984 to 1994 period, and analyzed factors influencing the entry decisions of generic drug companies. The study found that, in addition to other factors, the experience of generic suppliers (e.g., experience with a particular drug form) influences the likelihood of entry into specific drug categories. In particular, the empirical findings indicate that as entry costs decline because of additional learning on the part of generic companies, entry becomes more likely, other variables constant.

<sup>82</sup> See Liang (1996) for a discussion of several theories that focus attention on the introduction of generic drugs by brand-name drug companies.

delay or deter the entry of other generic suppliers, but does not empirically test these alternative anticompetitive theories. Finally, Frank and Salkever (1997), in a study of 32 drugs that lost patent protection during the 1980s, found that brand-name drug prices increase after generic entry and generic drug prices decline significantly as generic companies enter these product categories.

Three other current studies offer some empirical evidence on the competitive effects of generic entry. Although these studies contain mixed evidence on the effects of new entry on name-brand drug prices, they all indicate that additional generic entry lowers generic prices.<sup>83</sup> In a study of 18 name-brand drugs exposed to generic competition from 1983 to 1987, Grabowski and Vernon (1992) found that name-brand prices rose slightly after generic entry, and that average prices declined by approximately 20 percent two years after the entry of generic competitors.<sup>84</sup> In a study of 30 drugs that lost patent protection from 1976 to 1987, Caves, Whinston, and Hurwitz (1991) found that generic competition reduced name-brand prices by only about two percent.<sup>85</sup> In contrast, Wiggins and Maness (1994) offer empirical evidence of direct and substantial price competition between name-brand anti-infective drugs and their

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<sup>83</sup> See, Grabowski and Vernon (1992), Caves, Whinston, and Hurwitz (1991), and Wiggins and Maness (1994).

<sup>84</sup> Other research efforts have discussed the apparent rise in the prices of name-brand drugs in response to generic entry (See, Stern (1994) and Perloff and Suslow (1993)).

<sup>85</sup> Assessments of these findings give rise to a segmented market model under which generic entry bifurcates the market into price sensitive and price insensitive segments, inducing name-brand drug suppliers to abandon the price sensitive segment of the market after generic entry. As a result, name-brand drug suppliers face little or no competition from generic entrants in the price insensitive segment of the market (See, Scherer (1993) and Frank (1992)).

generic counterparts,<sup>86</sup> and reject the segmented market hypothesis mentioned earlier.<sup>87</sup>

When coupled with current evidence of significant price competition among name-brand pharmaceutical suppliers, the contrasting results of these studies suggest the need for additional theoretical analyses of the pricing behavior by pharmaceutical companies. This is particularly true in light of ongoing market changes such as the aggregation of buyers by HMOs and PBMs and the significant entry by generic drug suppliers.

A fourth and final category of previous literature includes some descriptive analyses of a variety of drug pricing issues. Smythe (1991) describes several policy-related issues involving the health care industry, and discusses the relatively large price increases for prescription drugs in recent years.<sup>88</sup> Bobula (1996) characterizes several market changes contributing to additional price competition and lower prices in the pharmaceutical industry. The changes range from the growing use of drug cost-containment mechanisms to Medicaid program reforms.<sup>89</sup> Jaggar (1996) also reviews various drug industry changes, and discusses the implications of these

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<sup>86</sup> One explanation for this price competition is that physicians tend from early on to prescribe anti-infectives by their chemical names. This could lead to significant substitution between generic and brand-name drugs.

<sup>87</sup> The Wiggins and Maness (1994) analysis uses transactions data for the 1984 to 1990 period, and it offers a few possible explanations for these contrasting empirical results. In addition to vastly different data sets, Wiggins and Maness analyzed only anti-infective agents, suggesting that their results might not generalize to the categories of drugs examined in the two other studies. It should also be noted that the findings by Wiggins and Maness contrast with other research by Stern (1994), who finds evidence of significant differentiation between name-brand and generic drugs in three therapeutic markets.

<sup>88</sup> See, Smythe (1991).

<sup>89</sup> See, Bobula (1996).

changes for retail pharmacies.<sup>90</sup> Other studies, along with general descriptions of the pharmaceutical industry, describe specific policy-related initiatives impacting on prescription drug prices such as the Medicaid program reforms described in Chapter II.<sup>91</sup> Another study traces the history of the pharmaceutical pricing debate in the U.S., beginning with the 1959 Kefauver hearings that focused on concerns over patent-related monopoly power, and ending with policy initiatives of the 1990s.<sup>92</sup> These descriptive studies provide useful background information on pricing issues and policy initiatives applicable to the pharmaceutical industry.

#### **4. Profitability of Pharmaceutical Companies**

Measurement of the profitability of pharmaceutical companies is a very complex and controversial issue. In what follows, the discussion simply summarizes some of the evidence on both sides of this issue without attempting to resolve the debate. Numerous industry observers have suggested that pharmaceutical companies earn relatively high rates of return. For example, one commentator notes that over a 32-year period, the return on equity averaged 18.4 percent for

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<sup>90</sup> For example, the discussion summarizes some evidence indicating that retail pharmacies pay higher prices for certain prescription drugs than other buyers, including HMOs (See, United States General Accounting Office. *Prescription Drug Pricing - Implications for Retail Pharmacies*. Statement of Sarah F. Jaggard, Before the Subcommittee on Oversight and Investigations Committee on Commerce, House of Representatives, (September, 1996)).

<sup>91</sup> See, for example, Jackson (1992), United States General Accounting Office report entitled *Medicaid: Changes in Best Price for Outpatient Drugs Purchased by HMOs and Hospitals*. (August, 1994), and United States General Accounting Office report entitled *Medicaid: Changes in Drug Prices Paid by VA and DOD Since Enactment of Rebate Provisions*. (September, 1991).

<sup>92</sup> See, Kucukarslan (1996).

pharmaceuticals and 11.9 percent for the 500 largest industrial companies.<sup>93</sup> This is consistent with investment reports that also point to the above-average returns earned by pharmaceutical company shareholders.<sup>94</sup> But an evaluation of pharmaceutical industry performance solely on the basis of its profitability to shareholders ignores the social benefits stemming from industry R & D and innovation that accrue to consumers. Among many others, product innovations in the drug industry include: (1) antibiotics of the 1940s and 1950s;<sup>95</sup> (2) serum and vaccine development for the treatment of childhood diseases like the measles; (3) cardiovascular drugs for the treatment of hypertension and high cholesterol; and (4) tranquilizers and other drugs for the treatment of mental illnesses. These innovations benefit society by increasing life expectancy, and by producing drug alternatives to more costly forms of treatment that include surgical procedures and hospitalization.<sup>96</sup>

In addition, studies indicate that accounting measures of profitability might overstate the actual profitability of pharmaceutical companies. Accounting measures of profit fail to take account of the capital nature of investments in R & D and marketing. Corrections for these accounting problems reduce accounting rates in the drug industry. One study suggested that

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<sup>93</sup> It is important to point out that this commentator does recognize that accounting profits overstate actual profits in the drug industry, and that ongoing industry changes could alter the profit outlook for pharmaceutical companies (See, Scherer (1993 and 1996)).

<sup>94</sup> See, *The Value Line Investment Survey, Ratings & Reports* (1996).

<sup>95</sup> See, *Economic Report on Antibiotics Manufacture* (1958).

<sup>96</sup> For discussions of pharmaceutical industry innovations and their beneficial impacts on society, see Boston Consulting Group (1993) and *Industry Profile* (1996).

returns are reduced by 2 to 6 percent, but that return on equity remains above average.<sup>97</sup>

Another study estimated that a corrected rate of return (i.e., accounting rates of return were corrected by capitalizing and depreciating expenditures on advertising, promotion, and R & D activities) for the pharmaceutical industry averaged 8.46 over the 1980 to 1993 period.<sup>98</sup> The same study computed an average corrected rate of return of 10.19 percent over the same time period for the group of 14 industries under study.<sup>99</sup>

Overall, some accounting studies suggest that the profitability of pharmaceutical companies exceeds rates found in other industries, while other research suggests that this industry does not necessarily earn risk adjusted rates of return above the economy-wide average.<sup>100</sup>

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<sup>97</sup> See the Office of Technology Assessment's report entitled *Pharmaceutical R&D: Costs, Risks and Rewards* (1993) and the Congressional Budget Office's report entitled *How Health Care Reform Affects Pharmaceutical Research and Development* (1994).

<sup>98</sup> See, Clarkson (1996).

<sup>99</sup> Still another study focuses attention on the impacts of risk on the cost of capital facing pharmaceutical companies, and discusses the upward adjustments necessary to obtain the appropriate risk-adjusted measures (See, Myers and Shyam-Sunder (1996)).

<sup>100</sup> It is worth noting that while normal rates of return are consistent with competitive behavior, they are not necessarily inconsistent with anticompetitive conduct, either in particular markets or industry-wide.

## Appendix B

### Third-Degree Price Discrimination in Duopoly Markets

This appendix develops a simple duopoly model of price discrimination, and derives equilibrium discriminatory markups.<sup>1</sup> The model assumes that Manufacturers A and B respectively supply differentiated Drugs A and B to consumers partitioned into two identifiable groups, Groups L and S. Group L consumers possess strong brand preferences, while Group S consumers possess weak brand preferences and are price sensitive. We also assume that for a given set of prices for Drugs A and B,  $\{P_A \text{ and } P_B\}$ , the segment demands facing Manufacturers A and B are symmetric (i.e., these demands are identical for any given set of prices) as described below.

$$(B.1) \quad Q_{iA}(P_A, P_B) = Q_{iB}(P_B, P_A),$$

where  $i$  identifies either Group L or Group S consumers,  $Q_A$  is the demand for Drug A, and  $Q_B$  is the demand for Drug B.

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<sup>1</sup> This model largely derives from an analysis of third-degree price discrimination by Holmes (1989) (See, Holmes (1989)). In the typical textbook case, third-degree price discrimination occurs when different groups of buyers are charged different prices, but consumers in any given group pay the same price for all units of a product purchased (See the discussion by Varian on price discrimination in Schmalensee and Willig (1989)). The model developed in this appendix segments consumers into the two identifiable groups described below.

Manufacturers A and B set the prices for their products,<sup>2</sup> and are subject to the discriminatory price equilibrium conditions in (B.2) and (B.3) below.

$$(B.2) \quad P_{Ai} = P_{Bi} = P_L \quad \text{for } i = \text{Group L}$$

and

$$(B.3) \quad P_{Ai} = P_{Bi} = P_S \quad \text{for } i = \text{Group S},$$

where  $P_L$  and  $P_S$  are the equilibrium prices for Drugs A and B facing Group L and Group S consumers, respectively. At a symmetric equilibrium, the segment demands facing each of the drug manufacturers are as follows:

$$(B.4) \quad Q_{Lk} = Q_{Lk}(P_L)$$

and

$$(B.5) \quad Q_{Sk} = Q_{Sk}(P_S),$$

where  $Q_L$  and  $Q_S$  respectively are Group L and Group S demands for Drugs A and B and  $k$  identifies the manufacturer.

Profit functions for Manufacturers A and B for each of the demand partitions

are

$$(B.6) \quad \Pi_{Lk} = (P_L - mc)[Q_{Lk}(P_L)]$$

and

$$(B.7) \quad \Pi_{Sk} = (P_S - mc)[Q_{Sk}(P_S)].$$

$\Pi_L$  and  $\Pi_S$  respectively are profits from sales to Group L and Group S consumers and  $mc$  represents the constant marginal cost facing each of the manufacturers.

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<sup>2</sup> In particular, the model assumes that Manufacturers A and B are Bertrand competitors. Each manufacturer sets price under the assumption that the other firm will hold its price constant.



The model described in (B.1) through (B.7) underlies the elasticity conditions discussed in Chapter IV. To derive these conditions, Drug Manufacturer A maximizes (B.6) and (B.7), resulting in the following first-order conditions:<sup>3</sup>

$$(B.8) \quad d\Pi_{LA}/dP_{AL} = 0 = [Q_{LA}(P_L) + (P_L - mc)[\partial Q_{LA}(P_L)/\partial P_{AL}]$$

and

$$(B.9) \quad d\Pi_{SA}/dP_{AS} = 0 = [Q_{SA}(P_S)] + (P_S - mc)[\partial Q_{SA}(P_S)/\partial P_{AS}].$$

Given the symmetric demand conditions in (B.1), we define the last terms in (B.8) and (B.9) as

$$(B.10) \quad [\partial Q_{LA}(P_L)/\partial P_{AL}] = [[\partial Q_{LA}(P_L)/\partial P_{AL}] + [\partial Q_{LA}(P_L)/\partial P_{BL}] - [\partial Q_{LB}(P_L)/\partial P_{AL}]]$$

and

$$(B.11) \quad [\partial Q_{SA}(P_S)/\partial P_{AS}] = [[\partial Q_{SA}(P_S)/\partial P_{AS}] + [\partial Q_{SA}(P_S)/\partial P_{BS}] - [\partial Q_{SB}(P_S)/\partial P_{AS}]].$$

By respectively incorporating (B.10) and (B.11) into (B.8) and (B.9), and by rearranging terms, we define the profit-maximizing discriminatory markups for each of the two demand partitions.

$$(B.12) \quad (P_L - mc)/P_L = 1/(E_L + E_{LC})$$

and

$$(B.13) \quad (P_S - mc)/P_S = 1/(E_S + E_{SC}),$$

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<sup>3</sup> We focus attention below on Drug Manufacturer A, but, in light of the symmetry and equilibrium conditions, analysis of Manufacturer A's segment profits would parallel a similar analysis for Manufacturer B.

where  $E_L$  and  $E_S$  are price elasticities of demand and  $E_{LC}$  and  $E_{SC}$  denote the cross-price elasticities of demand by Group L and Group S consumers, respectively.<sup>4</sup> The results in (B.12) and (B.13) indicate that the extent to which prices exceed marginal cost depends on: (1) the price elasticity of demand in each segment; and (2) the cross-price elasticity of demand in each segment. In other words, other factors equal, these price-cost margins are higher (lower) if buyers are less (more) willing to exit the market as prices increase, and/or if buyers are less (more) willing to substitute between Drugs A and B as relative prices change.

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<sup>4</sup> It is noteworthy that the sums of the price and cross-price elasticities of the segment demands define firm-level elasticities for these market segments. To illustrate this, assume that  $(E_L + E_{LC}) = E_{LF}$  and  $(E_S + E_{SC}) = E_{SF}$ . Given the symmetry and equilibrium assumptions described earlier,  $E_{LF}$  and  $E_{SF}$  are residual demand elasticities facing each of the duopolists. In the case of Firm A, for example,  $E_{LF}$  measures the impact of a departure from equilibrium pricing by Firm A on the quantity of Drug A demanded by Group L consumers, while  $E_{SF}$  measures the impact of a departure from equilibrium pricing by Firm A on the quantity of Drug A demanded by Group S consumers.