United States General Accounting Office

GAO

Report to the Honorable
Ron Wyden, House of Representatives

November 1995

PHARMACY BENEFIT MANAGERS

Early Results on Ventures With Drug Manufacturers

GAO/HEHS-96-45

GAO

United States
General Accounting Office
Washington, D.C. 20548

Health, Education, and
Human Services Division

B-257388

November 9, 1995

The Honorable Ron Wyden
House of Representatives

Dear Mr. Wyden:

Some of the largest pharmaceutical manufacturers have recently merged or formed alliances with some of the largest companies that manage prescription drug benefits for health plans, called pharmacy benefit managers (PBM). These ventures represent a recent trend in the pharmaceutical marketplace that involves vertical integration—manufacturers merging or allying with companies that represent buyers of the manufacturers' products. The ventures gained immediate attention from industry observers not only because of their size but also because of concerns about their effect on competition in markets for drug manufacturers' products and PBMs' services. Some industry observers contended that the ventures would reduce competition in both markets because the PBMs involved would give preference to their manufacturer partners' drugs over those sold by competing manufacturers.[1] Such preference could include collaboration between a manufacturer and PBM partner to ensure that the manufacturer's drugs were the most economical for the PBM's customers.

Because of these concerns, you requested that we study the mergers and alliances to determine (1) the role of the PBMs in the health care industry; (2) the objectives of these ventures; (3) specific concerns about the effect of these ventures on competition in markets served by drug manufacturers and PBMs; and (4) the extent, if any, to which the PBMs have given preference to their manufacturer partners' drugs.

To address the study's objectives, we reviewed pertinent literature, interviewed officials of companies involved in recent mergers and alliances, and obtained documents from the companies related to these ventures. (See app. I for additional information on the study's scope and methodology.) We also contacted Wall Street analysts, pharmaceutical economists, health plan sponsors, and pharmaceutical trade associations, such as the National Association of Chain Drug Stores (NACDS) and the American Pharmaceutical Association (APhA). Further, we obtained information from Medco Containment Services, Inc. and Diversified

[1]For the purpose of this report, "partner" refers to any manufacturer or PBM involved in a merger or alliance.

Pharmaceutical Services, Inc. (DPS) on formularies they managed before and after their mergers with Merck & Co., Inc. and SmithKline Beecham Corporation, respectively.

Our work was performed between June 1994 and September 1995 in accordance with generally accepted government auditing standards.

Results in Brief

Drug manufacturers have merged or allied with PBMs because they believe that the PBMs' market power will help maintain the manufacturers' profits at a time when their drugs face increased competition. The role of PBMs in health care has evolved from simply administering prescription drug benefits for health plan sponsors to helping them contain their overall drug costs. Representing millions of health plan enrollees, PBMs have developed formularies for many large health plans and have been able to obtain significant rebates or discounts for their customers from both drug manufacturers and pharmacies.

To bolster profits, manufacturers are relying on their PBM partners to help them increase market share for their drugs and develop new programs for treating specific diseases. To increase market share, manufacturers anticipate that their partner companies will include their drugs on formularies—a listing of preferred prescription drugs by therapeutic class often with cost designations—that the PBMs manage. The manufacturers will also join their PBM partners in developing cost-effective treatment programs for specific diseases that affect many of the health plan enrollees the PBMs cover and eventually sell such programs as products in the health care marketplace.

Critics of the mergers and alliances have focused on how PBMs may help their drug manufacturer partners increase market share. Manufacturers can increase the sales and market share of their drugs by obtaining their inclusion, as well as a low-cost designation, on their PBM partners' formularies. A primary concern is that the companies involved in these ventures will collaborate or act to prohibit other manufacturers from effectively competing for inclusion or low-cost designation of their drugs on the PBMs' formularies. The Federal Trade Commission's (FTC) review of the merger between Eli Lilly and Company and PCS Health Systems, Inc. resulted in a consent agreement between FTC and Lilly that established safeguards against such behavior.

Our review of changes in the formularies managed by Medco and DPS showed differences in the extent to which these PBMs have given preference to their respective partners' drugs. Of the eight products that represent almost all Merck sales of brand-name products to Medco enrollees, only one was on Medco's formulary in January 1993. In May 1993, 2 months before reaching their decision to merge and 6 months before closing their merger, Merck and Medco established an agreement to add the remaining seven products to Medco's formulary. After the merger, from 1994 to 1995, four of these eight drugs faced less competition after non-Merck products were dropped from Medco's recommended formulary. From January 1994, several months before its merger with DPS, to January 1995, SmithKline Beecham experienced little change in the number and cost designation of its drugs on DPS' recommended formulary.

The changes in Medco's formulary that favor Merck drugs do not necessarily demonstrate that Medco automatically gave preference to Merck drugs without considering competitors' products. Because Medco's negotiations with Merck and with other manufacturers are proprietary, we could not verify how Merck drugs achieved their inclusion and cost designations on Medco's formulary. However, the extent to which Medco gave preference to Merck products supports FTC's decision to continue monitoring the Merck/Medco merger and other ventures between drug manufacturers and PBMs. Such monitoring will help to ensure that the PBMs maintain competitive processes that allow manufacturers, other than their partners, to compete for inclusion and low-cost designation for their drugs on the PBMs' formularies.

Background

PBMs administer the prescription drug part of health insurance plans on behalf of plan sponsors, such as self-insured employers, insurance companies, and health maintenance organizations (HMO). In 1989, PBMs managed prescription drug benefits for about 60 million people. In 1993, they managed drug benefits for about 100 million, or almost 40 percent of the U.S. population.[2] Should this rate of growth continue, by the end of 1995 PBMs will provide services for health plans covering about 50 percent of the population.

While the number of people covered by PBMs has increased significantly, the market for PBMs' services continues to involve a small number of firms. Although there are over 40 PBMs in the United States, some estimates suggest that the 5 largest manage benefits for over 80 percent of the health

[2]Sanford C. Bernstein & Co.

plan enrollees covered by PBMs.[3] They include PCS Health Systems, Medco, Value Rx, DPS, and Caremark International Inc.'s Prescription Service Division. All five PBMs were included in our study.

A common technique PBMs use to manage pharmacy care is formulary development. A formulary is a list of prescription drugs, grouped by therapeutic class, that are preferred by a health plan sponsor. Drugs are included on a formulary not only for reasons of medical value but also on the basis of price.[4] PBMs provide physicians and others with printed formularies that often use dollar sign designations to identify drugs according to their relative cost within a therapeutic class. For example, "$" can signify a low-cost product, while "$$$$" can signify a higher-cost product.[5]

Both the inclusion of a drug on a formulary and its cost designation can affect the utilization of a manufacturer's products. PBMs and the health plan sponsors they represent encourage physicians to prescribe lower-cost formulary drugs over both nonformulary drugs and higher-cost formulary drugs for health plan enrollees. The extent to which the PBMs and their sponsors are successful in obtaining physician compliance with formularies can increase the sales and market share within a therapeutic class of a prescription drug, particularly for products on the formulary with the lowest cost designations. Because of this potential effect on the sales and market share of a drug, manufacturers offer PBMs rebates on drugs that face competition in return for both inclusion on a formulary and a low-cost designation.

Because of the relationship between formularies and drug sales, FTC has reviewed the recent mergers on antitrust grounds to determine their potential impact on competition in the markets involved.[6] Although FTC did not challenge mergers between Merck and Medco or SmithKline Beecham and DPS, it did challenge the merger that followed between Lilly and PCS

[3]Sanford C. Bernstein & Co.; Deloitte & Touche LLP.

[4]"The Changing Environment for U.S. Pharmaceuticals: The Role of Pharmaceutical Companies in a Systems Approach to Health Care," Boston Consulting Group (Apr. 1993), p. 18.

[5]Jeannie Mandelker, "Formularies: Balancing Cost and Quality," Business & Health, Special Report (1995), p. 25.

[6]FTC's role in antitrust enforcement is based on (1) section 5 of the Federal Trade Commission Act, authorizing the Commission to review the actions of companies that may result in "unfair methods of competition in or affecting commerce"; and (2) section 11 of the Clayton Act, authorizing the Commission to enforce compliance with certain provisions of that act, including section 7, which prohibits acquisitions, the effect of which "may be substantially to lessen competition, or tend to create a monopoly."

Health Systems. FTC entered into a consent agreement with Lilly that established safeguards against the merger's potential anticompetitive effects and also stated that it would continue to monitor the integration of drug manufacturers and PBMs.

PBMs Contain Customers' Drug Costs

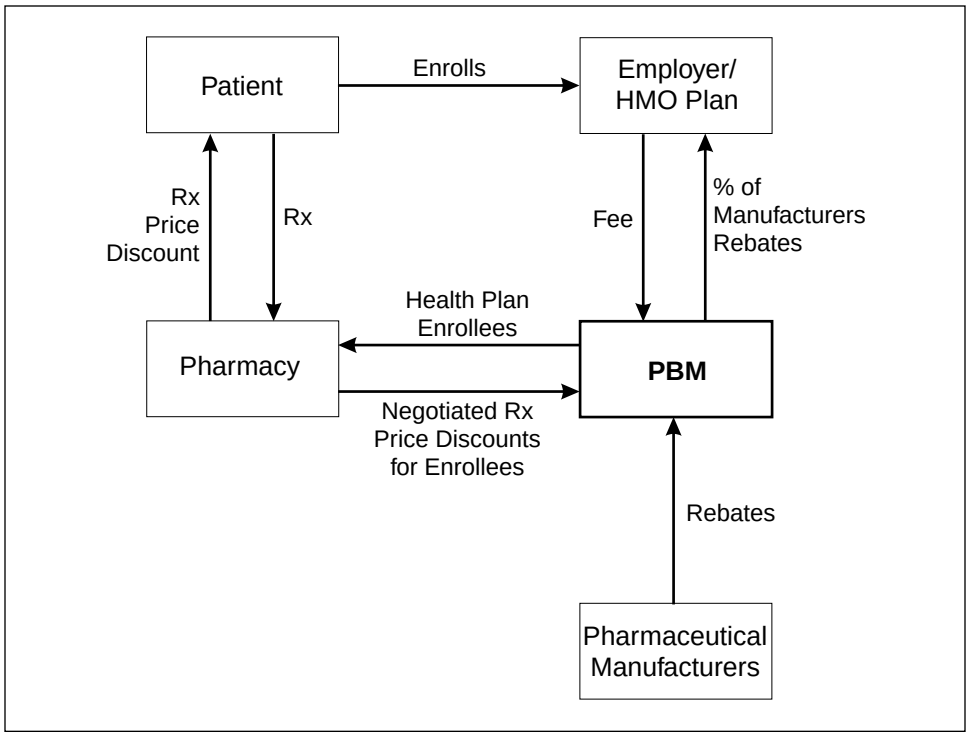
PBMs manage prescription drug coverage on behalf of health plan sponsors. Their objective is to provide high-quality pharmaceutical care at the lowest possible cost. PBMs are a relatively new type of firm that became a major market force only during the late 1980s. Their precursors were firms that provided prescription claims processing or mail-service pharmacy on behalf of insurers. While PBMs continue to provide these services, many provide additional services, such as formulary development and management, the development of pharmacy networks to serve health plan enrollees, negotiating drug rebates with manufacturers, generic substitution, and drug utilization review. Many PBMs are also developing products called "disease management" programs, which will attempt to provide the most cost-effective treatments for specific diseases.[7]

PBMs represent health plans and their enrollees in dealing with other participants in the prescription drug market. For example, a PBM negotiates with drug manufacturers to obtain rebates for a plan sponsor. PBMs also negotiate with retail pharmacies to obtain discounts on prescription drug prices and dispensing fees for health plan enrollees.[8] In exchange for such services, a PBM may receive a percentage of manufacturer rebates or a fee per prescription. Figure 1 shows the typical network in which a PBM and other participants operate.

[7]See pp. 8-11 for additional information on these services.

[8]See pp. 7 and 8 for additional information on such discounts.

Figure 1: The PBM Network



PBMs we studied operate in networks that are structured similarly to the network shown in figure 1 and use several similar techniques to help control their customers' drug costs. These techniques are applied in providing services related to formularies, pharmacy networks, claims administration, drug utilization review, and disease management.

PBMs use formularies to help control drug costs by (1) encouraging the use of formulary drugs through compliance programs that inform physicians and enrollees about which drugs are on the formularies; (2) limiting the number of drugs a plan will cover; or (3) developing financial incentives to encourage the use of formulary products. Although PBMs develop formularies that they recommend to customers, health plan sponsors may work with them to develop customized formularies. In developing formularies, PBMs rely on pharmacy and therapeutic (P&T) committees, consisting of pharmacists and physicians, to analyze the safety, efficacy, and substitutability of prescription drugs. PBMs then rely on the recommendations of the P&T committee to determine the number of drugs

to include on the formulary to give physicians a sufficient number of treatment options.

Formularies can be open, incentive-based, or closed. Open formularies are often referred to as "voluntary" because enrollees are not penalized if their physicians prescribe nonformulary drugs. Thus, under an open formulary, a health plan sponsor provides coverage for both formulary and nonformulary drugs.[9] Unlike an open formulary, an incentive-based formulary provides enrollees financial benefits if their physicians prescribe formulary drugs. Under this arrangement, the health plan sponsor still reimburses enrollees for nonformulary drugs but requires them to make higher co-payments than for formulary drugs. A closed formulary takes these financial incentives one step further by limiting coverage to formulary drugs only. Therefore, if an enrollee's physician prescribes a nonformulary drug, the enrollee may have to pay the full cost of that prescription. However, the health plans cover nonformulary products when physicians determine that they are medically necessary for their patients.

PBMs we studied reported that the vast majority of formularies they manage are open. For example, Medco officials told us that of the more than 2,000 plans Medco represents, only 4 of the plans (comprising just 3 percent of the enrollees covered by Medco) have adopted either an incentive-based or closed formulary. In another example, DPS officials determined that of about 90 formularies DPS manages (mainly for HMOs), about one-third are incentive-based or closed. However, officials of these PBMs expect that a greater number of health plan sponsors will adopt incentive-based and closed formularies in the future because of their potential to help reduce a plan's drug costs. Incentive-based and closed formularies increase competition among drug manufacturers with competing drugs to get their drugs on PBMs' formularies.

PBMs also contract with networks of pharmacies to obtain discounts per prescription for the health plan enrollees PBMs represent. For each prescription, a PBM typically reimburses participating pharmacies according to a formula based on a drug's average wholesale price (AWP) less a percentage, plus a dispensing fee.[10] PBMs also encourage pharmacies to support other cost-reduction techniques, such as substituting a generic

[9]According to APhA, during 1994, over 90 percent of formularies managed by PBMs were open.

[10]Drug manufacturers suggest a list price that wholesalers charge pharmacies. The average of the list prices, collected for many wholesalers, is called a drug's AWP. The dispensing fee covers a pharmacy's labor and overhead costs, such as pharmacists' salaries, drug packaging, rent, and utilities.

for a name brand when appropriate.[11] Pharmacies accept set levels of reimbursement and other PBM cost-reduction techniques in order to attract or retain the potential customer base represented by a PBM's millions of enrollees.

In addition, PBMs we studied can reduce their customers' administrative costs by using on-line computerization to verify claims and process payments. This is highly efficient compared with methods that rely on mailed-in claims. PBMs provide their customers' enrollees with magnetically encoded cards that a pharmacist uses to confirm their health plan membership and to access the PBM screen on the pharmacy's computer terminal. This screen lists the drugs on a plan's formulary, any requirements for enrollee co-payments, and allows the pharmacist to request payment on-line from the PBM after dispensing a prescription.

PBMs we studied also conduct retrospective and prospective drug utilization review (DUR) both to enhance the quality of pharmaceutical care and to potentially generate savings.[12] Under retrospective review, PBMs study the drug utilization statistics of a customer's enrollees to identify any instances in which physicians prescribed potentially inappropriate medications. If PBMs identify inappropriate patterns of prescribing or consumption, they will attempt to contact and educate physicians about more appropriate and potentially cost-effective treatments. Under prospective review, PBMs use a computer link with network pharmacists to review each prescription before it is dispensed. Prospective DUR helps PBMs to identify whether there is a generic or formulary alternative to the prescribed drug and whether the drug will duplicate an existing prescription or will adversely interact with other drugs the patient is using. If a nonrecommended, redundant, or potentially harmful drug is identified, the pharmacist is notified on the computer screen. PBMs we studied are working to add physicians to this on-line network to help reduce prescribing errors by communicating DUR results, as well as patients' medical histories, as care decisions are being made.

PBMs we studied also plan to help contain spending for chronic conditions, such as asthma and diabetes, by developing "disease management"

[11]The involvement of pharmacists in PBM efforts to switch such prescriptions have raised questions about how independent pharmacists should be. A recent agreement reached between Merck/Medco and 17 state attorneys general requires that Medco pharmacists disclose their affiliation with Merck in connection with such activities. Officials of the PBMs studied emphasized that they do not require, or provide special incentives for, generic drugs manufactured by their partner companies.

[12]For additional information on the application of DUR, see Prescription Drugs: Automated Prospective Review Systems Offer Potential Benefits for Medicaid (GAO/AIMD-94-130, Aug. 5, 1994).

programs to manage the care of enrollees with these illnesses. To develop these programs, PBMs are evaluating various treatment options, or therapies, discussed in existing medical research to identify those that are associated with better therapy management as well as low overall spending. PBMs then intend to educate both health plan enrollees and their physicians about these more cost-effective treatments and to monitor the degree of their compliance with related protocols over time. For example, officials of one PBM explained that when an enrollee enters its program for diabetes, the PBM notifies the enrollee's physician and provides both the enrollee and the physician information on its disease management protocol. Regarding one such treatment, the PBM seeks to help reduce the risk of complications and costly additional care by encouraging enrollees to monitor their glucose levels and to adjust their insulin intake more frequently than is commonly recommended.[13]

Manufacturers Seek to Increase Market Share and Develop Disease Management Programs

The growth of PBMs and other industry developments have forced drug manufacturers to find ways to prevent profits from declining. At the same time that more drugs on the market face competition, purchasers have become more price-focused and organized. In particular, PBMs and other buyers have been able to use formularies to obtain significant rebates from manufacturers. Rather than lose market share, manufacturers have provided discounts on drugs that face competition to obtain inclusion and low-cost designation on PBMs' formularies. Furthermore, many manufacturers believe that, in the future, pharmaceutical care will involve disease management. Currently, prescription drugs are managed separately from other components of health care. This approach may result in higher overall spending for a health plan sponsor than the management of all aspects of care for plan enrollees with similar illnesses.

In response to a changing environment, large pharmaceutical manufacturers have vertically integrated into the market for PBM services. Merck was the first manufacturer to acquire a PBM partner when it purchased Medco in November 1993. In 1994, SmithKline Beecham acquired DPS and Lilly acquired PCS. Rather than acquire a PBM, Pfizer, Inc. contracted to form strategic alliances with two PBMs, Caremark International[14] and Value Rx—plus Value Rx's parent company, Value Health, Inc. Table 1 provides information about each merger or alliance.

[13]See pp. 10 and 11 for additional information related to disease management.

[14]Caremark's relationship with Pfizer is a part of Caremark's Drug Alliance Program, which also includes Rhone-Poulenc Rorer, Inc., Bristol-Myers Squibb Company, and Lilly.

(See app. II for additional information on the companies involved in these ventures.)

Table 1: Companies Involved in Recent Mergers and Alliances

Date	Manufacturer	PBM(s)	Covered lives (millions)	Price (billions)
November 1993	Merck	Medco	42	$6.6
May 1994	SmithKline Beecham	DPS	14	2.3
May 1994	Pfizer	Value Rx Caremark	32 13	[a]
November 1994	Lilly	PCS	56	4.0

Note: The number of lives covered by each PBM may be overstated because of double counting that results from some health plan enrollees being covered by more than one PBM.

[a]Alliance terms were undisclosed.

The manufacturers believe that merging or allying with a PBM will provide competitive advantages that will enable them to maintain profits. Among other things, each venture provides the manufacturer access to the PBM's formularies, which can help a manufacturer increase market share while developing programs to compete in a market for disease management products. For example, formulary access can help to increase the market share of a manufacturer's drug, particularly if it was not on the PBM partner's formulary before a merger or alliance. Market share can be further enhanced if the manufacturer gives the PBM sufficient price discounts to gain a low-cost designation for its drug on the PBM's formularies. According to representatives of several PBMs, their contacts with physicians to encourage them to prescribe drugs that are on formularies and have low-cost designations usually result in the physicians' compliance. Because of the increase in market share resulting from formulary inclusion and low-cost designation, manufacturers may also reduce the sales and marketing costs for a product.

The manufacturers also believe that PBMs will provide them the cornerstones of disease management programs, namely the abilities to uncover the most cost-effective treatments for various diseases, such as asthma and diabetes, and to ensure that patients comply with them. Specifically, the manufacturers and their PBM partners seek to contain health plan sponsors' overall health care costs by establishing programs to encourage more cost-efficient care for patients with particular illnesses. The extent to which prescription drugs, particularly those sold by the

manufacturer partners, will be used in these disease management programs will depend on their cost-effectiveness as part of overall treatment.[15]

However, because the ventures are new, it is too soon to determine whether each manufacturer has achieved its objective of enhancing profits by increasing market share and marketing disease management programs. Among the manufacturers we studied, only Merck has acknowledged an increase in its share of the drug sales managed by its PBM partner. In addition, the manufacturers and their PBM partners are in varying stages of developing disease management products and the success of these products is not yet known. Medco has six disease management programs either fully operational or in the pilot stage, including programs for diabetes and asthma.[16] The other PBMs have launched either diabetes or asthma programs. However, all the PBMs are developing additional programs to treat these illnesses and others, including depression, ulcers, and cardiovascular disease.

Concerns About Reduced Competition

Critics of the recent mergers and alliances believe that the ventures will reduce competition in markets for pharmaceutical and PBM services. This concern is based on several contentions. First, competition in the pharmaceutical market would be reduced as aligned PBMs and their manufacturer partners collaborate to ensure inclusion and low-cost designation for the partners' drugs over competitors' on the PBMs' formularies. This preference for a partner's products would preclude other manufacturers from effectively competing with its products on the formularies managed by the PBM partner. Such preference would be exacerbated as the PBMs move to more restrictive formularies. Second, competition in the market for PBM services would be substantially lessened as the aligned PBMs would be able to obtain their partners' products at extremely advantageous prices over nonaligned PBMs. This would give additional market power to the aligned PBMs, which already cover most health plan enrollees, and make it more difficult for new PBMs to enter the market or for smaller, existing PBMs to stay competitive.

Several industry analysts contend, however, that it is too soon to determine the overall effects, either negative or positive, of the ventures

[15]A number of drug manufacturers are developing their own independent disease management programs, and not all PBM disease management programs are developed in concert with a manufacturer.

[16]Other Medco programs cover chronic obstructive pulmonary disease, allergic rhinitis, smoking cessation, and hypercholesterolemia.

on competition in the markets for either pharmaceutical products or PBM services.[17] For example, these analysts contend that it is not possible to determine in the short term how competitive new or existing PBMs may be in this market. They believe that the PBM market may become more competitive as health plan sponsors begin to analyze the effectiveness of PBMs that represent them. They noted that if the PBMs that are the largest now do not continue to perform for their customers in controlling drug costs, the customers can switch to other PBMs.

Industry analysts are more concerned, however, about the influence drug manufacturers may have on their PBM partners' formulary decisions. They believe that any collaboration between aligned companies, or actions taken by a PBM partner, to ensure competitive advantages for the manufacturer partner's drugs over competitors' could reduce competition significantly in the manufacturer partner's market, such as the market for an individual therapeutic class of drugs. Competitive advantages can be gained by eliminating opportunities for other manufacturers to compete for inclusion and low-cost designation for their drugs on the PBM partner's formularies.

FTC reviewed the recent mergers to determine their potential impact on the markets for drug manufacturers and PBMs.[18] It issued a complaint against the Lilly/PCS merger and determined that safeguards were necessary to ensure that Lilly and PCS maintain a competitive process for determining which drugs to include on PCS' formulary and the drugs' cost designations. Accordingly, FTC entered into a consent agreement with Lilly, requiring that (1) PCS maintain an "open" formulary, defined as one that includes any drug that PCS' P&T committee deems appropriate; (2) PCS appoint an independent committee to oversee this formulary, consisting of a majority of persons outside of either Lilly or PCS; (3) Lilly and PCS establish safeguards that prevent each from sharing nonpublic information concerning other drug manufacturers' and other PBMs' bids, proposals, contracts, prices, rebates, discounts, or other terms of their mergers; and (4) PCS accept all discounts, rebates, or other concessions offered by other manufacturers and reflect these when determining the ranking of products on the open formulary.

[17]Economic analysis can help determine conditions under which vertical integration may restrict or enhance competition. However, these industry analysts contend that because the ventures are so recent, the empirical data necessary for such an analysis, including changes in drug prices and health plan drug costs, are currently limited.

[18]FTC has the authority to review again mergers that have been consummated. It has made public statements that it will continue to monitor these markets. (See pp. 13 and 14 for information on these statements.)

Manufacturers we studied and their PBM partners told us that they had established safeguards similar to those accepted by Lilly. Like PCS, the other PBMs indicated that they offer an open formulary, which the majority of payers adopt. With one exception, the PBMs also noted that they had already established independent P&T committees.[19] Furthermore, officials for each PBM said that they had established "fire walls" that prevent the PBMs from providing their manufacturer partners with confidential price information, such as bids from other manufacturers.[20] Industry observers agree that these fire walls are the most essential part of the Lilly/PCS agreement for ensuring a competitive bidding process. Officials from each PBM also told us that they continue to consider bids from manufacturers whose drugs compete with drugs sold by their respective partners. Since the Lilly agreement, Medco has developed written policies that establish and govern fire walls as well as other safeguards that are intended to address FTC's concerns.

Critics of the Lilly/PCS merger have contended that the safeguards established by FTC in the consent agreement are inadequate to address their concerns about the venture's potential anticompetitive effects. For example, before final approval of the consent agreement, NACDS contended that the agreement did not address the issue of aligned PBMs having the option to develop closed formularies that could favor their manufacturer partners' drugs and exclude those sold by competitors. Furthermore, NACDS believed that the fire walls were inadequate to prevent the exchange of sensitive competitive information between aligned companies, including market shares for specific drugs. In addition, NACDS expressed concern that the agreement did not address the merger's potential effect on drug prices paid by retail drug stores and consumers.

In addition to approving the Lilly consent agreement, FTC said that it would continue to monitor several aspects of vertical integration of drug manufacturers and PBMs. Such monitoring includes whether and to what extent products of drug manufacturers, especially those not vertically integrated with PBMs, are prohibited (foreclosed) from formularies managed by aligned PBMs. The monitoring also includes whether and to what extent the vertical integration of drug manufacturers and PBMs results in anticompetitive interaction among integrated companies as well

[19]Caremark was the exception. Company officials contended that an independent committee was unnecessary because they consult many sources outside the firm on formulary development and health plan sponsors ultimately determine which drugs to include on the formulary.

[20]DPS officials specifically noted that SmithKline Beecham voluntarily adopted such a fire wall in response to FTC's review of its acquisition of DPS.

as any increase in drug prices or reduction in choice of drugs for consumers.

Determining whether PBMs involved in these ventures maintain fire walls and refrain from collaborating to give preference to their manufacturer partners' drugs requires access to proprietary information. Such information includes the process used by a PBM to consider which drugs are to be added to or deleted from a formulary, the reasons for changes, and whether competitive bids were sought and considered. To obtain such information requires an extensive right of access, such as that given to FTC.

Formulary Changes Show Mixed Results on PBM Preference for Partners' Drugs

Absent proprietary information from PBMs related to formulary development, changes in formularies can be reviewed to determine whether there are signs of potential problems. For example, if a pattern developed in which a manufacturer partner's drugs received the lowest-cost designations on its PBM partner's formularies, it would raise questions from competing manufacturers and others about the process used by the PBM to make such formulary decisions.

We reviewed formularies managed by Medco and DPS several months before and after their mergers to determine any changes in the preference given to their respective manufacturer partner's products. Two months before concluding its agreement to merge with Merck, Medco increased its preference for Merck drugs by adding a number of Merck's large-dollar-volume products to its formulary and dropping several drugs that competed with Merck's drugs. In contrast, the number of SmithKline Beecham's products on DPS' formulary and their cost designations changed little.

Merck Gains Access to Medco Formulary

In January 1993, few Merck products were on Medco's recommended formulary. Of the eight Merck products that represent almost all Merck sales to Medco enrollees, only Proscar was on Medco's formulary.[21] However, according to Medco officials, Merck and Medco established an agreement to add the remaining seven products to Medco's formulary during May 1993, 2 months before reaching their decision to merge and 6 months before closing their merger. Specifically, these products were Prinivil and Vasotec, two cardiovascular drugs known as ACE inhibitors;[22]

[21]According to Medco officials, these eight drugs accounted for about 90 percent of Merck's brand-name product sales to Medco enrollees.

[22]ACE is an acronym for angiotensin-converting enzyme.

Mevacor and Zocor, two cholesterol-lowering agents; Prinzide and Vaseretic, two antihypertensive combination drugs; and Pepcid, an antiulcer drug known as a histamine H_2 receptor antagonist. Including these products increased the number of drugs in their respective therapeutic classes on the formulary, except for Prinivil and Prinzide, which replaced their chemical equivalents, Zeneca's Zestril and Zestoretic.

Table 2 shows changes to Medco's formulary from 1994 to 1995 that could benefit the sale of Merck products. For example, between 1994 and 1995 one cardiovascular drug, Monopril, was dropped from the formulary. This change left Prinivil and Vasotec with fewer competitors on the formulary and Prinivil with one, rather than two, competitors with the lowest cost designations. Not only have cardiovascular drugs been Merck's top-selling class of drugs in worldwide sales, but Vasotec has been Merck's number one sales product. Table 2 also shows that, by 1995, Zocor and Mevacor faced fewer competitors after three non-Merck products were dropped from the cholesterol-lowering class. As with the cardiovascular class of drugs, Merck has dominated worldwide sales in the cholesterol-lowering class.

Table 2: Medco Formulary Changes, 1993-1995

Class/product	1993	1994	1995	Manufacturer
ACE inhibitors				
Zestril	$$			Zeneca
Monopril	$$	$$		Bristol-Myers Squibb
Lotensin	$$	$$	$$	Ciba
Accupril	$$	**$$$$**	**$$$**	Parke-Davis
Capoten	$$$$	$$$$	$$$$	Bristol-Myers Squibb
Prinivil		$$	$$	Merck
Vasotec		$$$	$$$	Merck
Antihypertensive combinations				
Hydropres[a]	$	$	$	Merck
clonidine	$$	**$**	$	generic
hydralazine/HCTZ	$$	**$**	$	generic
Zestoretic	$$			Zeneca
methyldopa/HCTZ	$$	**$**	$	generic
propranolol/HCTZ	$$	**$**	$	generic
Capozide	$$$	**$$$$**		Bristol-Myers Squibb
Prinzide		$$	$$	Merck
Lopressor HCT		$$	$$	Ciba
Timolide		$$	$$	Merck
Vaseretic		$$$	**$$**	Merck
Corzide		$$$	**$$$$**	Bristol-Myers Squibb
Ziac			$$	Lederle
Lotensin HCT			$$	Ciba
Cholesterol-lowering agents				
nicotinic acid	$	$	$	generic
clofibrate	$	$		generic
Colestid	$$	**$$$**	$$$	Upjohn
Lopid[a]	$$$$	**$$$**	**$$**	Parke-Davis
Pravachol	$$$$	$$$$		Bristol-Myers Squibb
Questran, Questran Light	$$$$	$$$$		Bristol-Myers Squibb
Lorelco	$$$$	$$$$	**$$$**	Marion Merrell Dow
Zocor		$$$$	**$$$**	Merck
Mevacor		$$$$	$$$$	Merck

(continued)

Class/product	1993	1994	1995	Manufacturer
H_2 antagonists				
Tagamet[b]	$$$	$$$	**$$**	SmithKline Beecham
Zantac	$$$$	**$$$$$**	**$$$$**	Glaxo
Pepcid		$$$	$$$	Merck
Axid		$$$$	**$$$**	Lilly
Axid (GERD)		$$$	$$$	Lilly

Notes: Dollar sign designations are relative indicators within a therapeutic class (that is, $$ in one class is not the same absolute value as $$ in another class).

Dollar signs in bold indicate a change in dollar status from the prior year.

Generic drugs may be sold by multiple manufacturers.

[a]Generic available in 1994.

[b]Generic available in 1995.

In contrast to these gains, however, Merck products in the antihypertensive combinations and H_2 antagonist classes were, by 1995, less competitive on the basis of cost designation. Table 2 shows that since 1994 the number of other manufacturers' antihypertensive combination drugs that compete with Prinzide and Vaseretic increased from eight to nine. Also, most of these products retained the same or a lower cost ranking than both Merck products. Likewise, because a competing product (cimetidine, the generic version of Tagamet) achieved a new, lowest cost designation, Merck's Pepcid now shares the second to lowest dollar-sign designation with Lilly's Axid, rather than the lowest cost ranking among H_2 antagonists.

Some industry observers believe that the gains made by Merck in the cholesterol-lowering and ACE inhibitor classes are indications that Merck has influenced Medco to prohibit some competing drugs from its formulary. For example, in a letter to FTC, one law firm commented that Medco's formulary excluded Sandoz's Lescol, a cholesterol-lowering agent, even though Lescol was sold on the market at a substantially lower price than other cholesterol-lowering agents and other PBMs have Lescol on their formularies. Other questions concern why Medco's 1995 formulary favors Merck products so much more than DPS' 1995 formulary. For instance, while Medco lists only one ACE inhibitor in addition to Merck's Prinivil in the lowest cost category, DPS lists three additional products. Also, DPS included not only Merck's Mevacor and Zocor in the

cholesterol-lowering class but also two competitors, Bristol-Myers Squibbs' Pravachol and Sandoz's Lescol.

In response to these concerns, Medco officials told us that Merck's products were included on Medco's formulary through careful and fair P&T committee and other company deliberations that considered both the medical value and costs of competing drugs. They added that Medco did not exclude any drugs from its formulary because they compete with large-dollar-volume Merck products.

Little Change in DPS Formularies

Before the SmithKline Beecham/DPS merger in May 1994, DPS' formulary contained SmithKline Beecham's four largest-dollar-volume outpatient drugs. Distributed among four therapeutic classes, these were Augmentin, an antibacterial penicillin drug; Tagamet, an H_2 antagonist; Relafen, a nonsteroidal anti-inflammatory drug (NSAID); and Paxil, an antidepressant referred to as a selective seretonin reuptake inhibitor (SSRI). Tagamet was in a higher cost category than one competitor, while Paxil shared the same cost designation with the two others listed in its class. Augmentin and Relafen not only faced generic competition but also, along with others, had the highest cost designation among brand-name products in their respective classes.

Table 3 shows that following the merger, the number and cost designation of SmithKline Beecham's large-dollar-volume products on DPS' formulary remained largely unchanged. For example, Famvir, an antiviral therapy introduced during the third quarter of 1994, was added to the formulary for 1995, but Tagamet's generic equivalent is now available. In addition, although table 3 shows that Paxil lost one competitor and gained a lower cost ranking than the remaining product, the table also shows that Relafen gained both an additional competitor and a higher cost designation. Furthermore, table 3 shows that Augmentin continued to have the same number of competitors and the highest cost designation in its class.

Table 3: DPS Formulary Changes, 1994-1995

Class/product	1994	1995	Manufacturer
Penicillins			
penicillin VK	$	$	generic
ampicillin	$	$	generic
amoxicillin	$	$	generic
dicloxacillin	$	$	generic
Augmentin	$$$$	**$$$**	SmithKline Beecham
Oral antiviral			
amantadine	$	$	generic
Zovirax (herpes simplex dosage)	$$$	$$$	Burroughs Wellcome
Zovirax (herpes zoster dosage)		•	Burroughs Wellcome
Videx	$$$$	$$$$	Bristol-Myers Squibb
Hivid	$$$$$	$$$$$	Roche Labs
Retrovir	$$$$$	$$$$$	Burroughs Wellcome
Zerit		$$$$$	Bristol-Myers Squibb
Famvir		•	SmithKline Beecham
SSRIs			
Prozac	$$$$	$$$$	Lilly
Paxil	$$$$	**$$$**	SmithKline Beecham
Zoloft	$$$$		Pfizer
H_2 antagonists			
Zantac	$$$	**$$$$**	Glaxo
Tagamet[a]	$$$$	**$$$**	SmithKline Beecham
Axid	$$$$	$$$$	Lilly
Pepcid		$$$$	Merck
NSAIDs (2nd line)			
Children's Advil	$	**$$**	Wyeth-Ayerst
indomethacin	$	$	generic
meclofenamate	$	**$$**	generic
naproxen	$$	$$	generic
Anaprox[a]	$$	**$$$**	Syntex
Daypro	$$	**$$$**	Searle
piroxicam	$$	**$$$$**	generic
sulindac	$$	**$$$**	generic
Lodine	$$$	**$$$$**	Wyeth-Ayerst
Relafen	$$$	**$$$$**	SmithKline Beecham
tolmetin	$$$		generic
ketoprofen		$$$	generic
Oruvail		$$$$	Wyeth-Ayerst

(Table notes on next page)

Notes: Dollar sign designations are relative indicators within a therapeutic class (that is, $$ in one class is not the same absolute value as $$ in another class).

Dollar signs in bold indicate a change in dollar status from the prior year.

Generic drugs may be sold by multiple manufacturers.

• indicates that a product is substantially more expensive than other products.

[a]Generic available in 1995.

Conclusion

Our review of changes in Medco and DPS formularies is but one way to help assess how the independence of PBMs may have changed since their mergers with manufacturers. PBMs in our study contend that they remain independent of their manufacturer partners in serving their customers, particularly in containing their customers' overall drugs costs. Although Medco's preference for Merck products increased substantially 2 months before their merger agreement, the results of our review of formulary changes do not necessarily mean that changes in Medco's, or any other aligned PBM's, formularies were the result of anticompetitive behavior on the part of the PBMs or manufacturers. However, changes in formularies can serve as an indicator that additional questions may be warranted about the processes aligned PBMs use in making formulary decisions. Given FTC's antitrust role, its access to proprietary information, and its experience in reviewing recent mergers, our findings support FTC's decision to continue monitoring ventures involving drug manufacturers and PBMs to assure participants in the PBM and prescription drug markets that these markets remain competitive.

A draft of this report was reviewed by officials of Merck, Medco, SmithKline Beecham, DPS, Lilly, FTC, and two leading analysts of the pharmaceutical industry. In general, they agreed with the information presented in the report. Where appropriate, the report reflects their technical comments.

We will make copies of this report available upon request. The report was prepared by John C. Hansen, Assistant Director, and analysts Joel Hamilton and Patricia Barry. Please call Mr. Hansen at (202) 512-7105 if you or your staff have any questions about this report.

Sincerely yours,

Jonathan Ratner
Associate Director
Health Financing Issues

Contents

Abbreviations

ACE	angiotensin-converting enzyme
APhA	American Pharmaceutical Association
AWP	average wholesale price
DPS	Diversified Pharmaceutical Services
DUR	drug utilization review
FTC	Federal Trade Commission
HMO	health maintenance organization
NACDS	National Association of Chain Drug Stores
NSAID	nonsteroidal anti-inflammatory drug
P&T	pharmacy and therapeutic (committee)
PBM	pharmacy benefit manager
SSRI	selective seretonin reuptake inhibitor

Scope and Methodology

To address the study's objectives, we first determined the role of PBMs in the health care industry. We reviewed pertinent literature and interviewed officials of companies involved in the ventures. These companies included Merck & Co., Inc., SmithKline Beecham Corporation, Eli Lilly and Company, and their respective PBM subsidiaries: Medco Containment Services, Inc., Diversified Pharmaceutical Services, Inc., and PCS Health Systems, Inc. We also interviewed officials of Pfizer, Inc. and its allied partners, Caremark International, Inc. and Value Rx. In addition, we met with several Wall Street analysts familiar with the PBM market to obtain a history of its evolution.

Second, to determine the objectives of the ventures, we again interviewed officials of the companies in our study. We also reviewed internal documents, press releases, and annual reports provided by these officials that helped expand on their comments.

Third, to understand specific concerns about the mergers and alliances, we contacted nonaligned PBMs, health plan sponsors, and pharmaceutical economists. We also interviewed officials of pharmaceutical trade associations, such as the National Association of Chain Drug Stores and the American Pharmaceutical Association. We asked these sources about changes to the pharmaceutical industry following the mergers and alliances as well as their views on the conditions established by FTC in its consent agreement with Lilly. In addition, we reviewed public comments FTC received regarding Lilly's acquisition of PCS and asked officials of the companies in our study whether they had policies or procedures that would meet the conditions set forth in the consent agreement.

Fourth, to assess the extent to which PBMs may have given preference to their manufacturer partners' drugs over competitors' drugs, we compared formularies for DPS and Medco before and after the mergers. We compared formularies that existed several months before each merger to 1995 formularies to determine changes to (1) the drugs listed and (2) the cost designation of the manufacturer partner's drugs versus other manufacturers' drugs. We reviewed formulary changes for DPS and Medco because they were the PBMs involved in mergers for the longest period of time and, therefore, had had the most time to make any formulary changes.

Our work was performed between June 1994 and September 1995 in accordance with generally accepted government auditing standards.

Additional Information on the Mergers and Alliances

The various manufacturer and PBM ventures are similar in that each one provides a manufacturer access to a PBM's formularies and aggregate data concerning its enrollees. This enables the manufacturer to improve its marketing strategies, enhance market share, and develop disease management programs. The mergers and alliances are described below.

Merck/Medco

On November 18, 1993, Merck & Co., Inc. purchased Medco Containment Services, Inc. for $6.6 billion. Headquartered in Whitehouse Station, New Jersey, Merck manufactures human and animal health care products. During 1993, it had net revenues of $10.5 billion, making it the largest company in terms of U.S. pharmaceutical sales. Principal products include Prinivil and Vasotec, two cardiovascular products; Mevacor and Zocor, two cholesterol-lowering agents; and Pepcid, an antiulcerant.

At the time of its acquisition, Medco, based in Montvale, New Jersey, was the second largest PBM, covering more than 33 million lives and managing about 95 million prescriptions or $4 billion in drug expenditures annually. During 1995, Medco expects to manage benefits for about 40 million people and remain the second largest PBM.

Immediately after the merger, Medco operated as a subsidiary of Merck under Medco's existing senior management. In January 1994, Merck and Medco formed the Merck-Medco U.S. Managed Care Division, which initially included a unit that marketed Merck products to managed care organizations as well as Medco, which marketed PBM services to health plan sponsors. The Merck managed care product unit was transferred back to Merck's Human Health Division in October 1994. The Merck-Medco Managed Care Division now consists of Medco only and no longer has any responsibility for managed care product sales. In early 1995, Merck formally adopted a policy under which Medco operates independently of Merck. Merck markets its pharmaceutical products through its U.S. Human Health Division.

SmithKline Beecham/DPS

Following the Merck/Medco merger, SmithKline Beecham Corporation, the U.S. operating subsidiary of United Kingdom-based SmithKline Beecham plc, announced on May 3, 1994, that it would acquire Diversified Pharmaceutical Services, Inc. (DPS) from United HealthCare Corporation for $2.3 billion in cash. Based in Philadelphia, SmithKline Beecham manufactures therapeutics for human and veterinary use and was the seventh largest manufacturer in terms of U.S. pharmaceutical sales for

1993. Its products include Tagamet, an antiulcerant; Relafen, a nonsteroidal anti-inflammatory drug; Famvir, an oral antiviral; and Paxil, an antidepressant.

Bloomington, Minnesota-based DPS was founded in 1976 as a wholly owned subsidiary of United HealthCare Corporation, an operator of HMOs, preferred provider organizations, and other health care organizations. During 1993, DPS was the third largest PBM, managing pharmaceutical benefits for about 14 million people or $2 billion in drug expenditures. Following its acquisition, DPS continued to operate as an independent company under its existing senior management.

In addition to acquiring DPS, SmithKline Beecham will maintain, for a minimum of 6 years, a two-part relationship with United HealthCare that SmithKline Beecham believes provides advantages over other manufacturer/PBM partnerships. First, SmithKline Beecham will have exclusive rights to the medical records of United HealthCare's 1.6 million members. When integrated with drug utilization data, such data could substantially augment studies concerning cost-effective drug treatments and the development of disease management programs. Second, United HealthCare plans to continue to use DPS as its PBM for its own managed care operations, encourage affiliated plans to rely on DPS, and not compete with DPS in the pharmacy benefit management business.

Lilly/PCS

In November 1994, Eli Lilly and Company purchased PCS Health Systems, Inc. from McKesson Corporation for $4 billion in cash. Located in Indianapolis, Indiana, Lilly manufactures pharmaceuticals, medical devices, diagnostic products, and animal health products. In 1993, Lilly had net revenues of $6.45 billion and the fifth highest level of U.S. pharmaceutical sales. Its pharmaceutical products include Prozac, an antidepressant; Axid, an antiulcer agent; and Iletin and Humulin, antidiabetic agents.

Based in Scottsdale, Arizona, and founded in 1968, PCS Health Systems was formerly a wholly owned subsidiary of McKesson Corporation, the world's largest distributor of pharmaceuticals and related health care products. Originating as a claims processor, PCS has consistently ranked as the largest PBM. At the time of its acquisition, it administered pharmaceutical benefits on behalf of roughly 1,300 customers who accounted for over 50 million lives and as much as $9 billion in drug expenditures.

Under the terms of the agreement, PCS will continue to operate as an independent company under its existing senior management. Also, McKesson will continue to have access to certain PCS capabilities and services, such as its information systems. In addition, Lilly has agreed to develop a series of strategic alliances with the remaining McKesson pharmaceutical distribution businesses.

Pfizer/Value Health

On May 3, 1994, Pfizer, Inc. announced a strategic relationship with Value Health, Inc., the parent company of Value Rx. New York-based Pfizer is a multinational producer and distributor of health care, animal health, food science, and consumer products. During 1993, it had net sales of $7.5 billion and ranked eighth among manufacturers in terms of U.S. pharmaceutical sales. Its health care products include Feldene, an anti-inflammatory agent; Procardia, a cardiovascular agent; and Zoloft, an antidepressant.

Value Health is a provider of specialty managed care benefit programs and health care information services. It comprises six companies, including Value Health Sciences and Value Rx Pharmacy Program. Value Health Sciences, located in Santa Monica, California, is a provider of clinical software and physician review services. Value Rx, a PBM located in Scottsdale, Arizona, and Bloomfield Hills, Michigan, was the sixth largest at the time of the announcement, covering about 11 million lives.

Although the financial terms of the various contracts were not announced, the relationship has three parts. First, in return for rebates, several Pfizer drugs will be included on Value Rx's drug formularies. Second, Value Health Sciences has agreed to develop programs, such as clinical protocols, physician and patient education materials, and outcomes analyses, to increase physician and patient use of Pfizer products. Third, Value Health and Pfizer each contributed $50 million to fund a new company to establish disease management programs. Value Health has emphasized that, unlike an acquisition, this contractual relationship does not affect its operating independence.

In a related event, during May 1995, Value Health announced its acquisition of Diagnostek, Inc. for $480 million. Headquartered in Albuquerque, New Mexico, and founded in 1983, Diagnostek is a provider of diagnostic-imaging centers, PBM services, and pharmacy services to institutions such as hospitals and nursing homes. Just before the merger, its PBM business unit covered approximately 16 million lives. Because of

the acquisition, Value Rx will now cover approximately 32 million lives, making it the largest independent PBM and the third largest overall.

Pfizer/Caremark

Pfizer also partnered with Caremark International, Inc. during 1994. Headquartered in Northbrook, Illinois, and incorporated in 1992, Caremark International operates in two business segments: patient care and managed care. The managed care segment includes Caremark's Prescription Service Division, a PBM and mail-service pharmacy. In 1994, it ranked fourth among PBMs, managing benefits on behalf of 1,100 customers who together covered about 13 million lives.

Pfizer's relationship with Caremark is a part of Caremark's Drug Alliance Program. Established in April 1994, this program involves contractual relationships with four major pharmaceutical manufacturers: Pfizer; Rhone-Poulenc Rorer, Inc. of Collegeville, Pennsylvania; Bristol-Myers Squibb Company; and Eli Lilly. Although the amount Caremark received from each partner was not disclosed, each relationship gives the manufacturer access to both Caremark's formulary and the drug utilization statistics of its covered lives. By partnering with four manufacturers, Caremark will receive rebates on products in over 85 percent of the therapeutic classes on its formulary. It also expects to gain advantages in the development of disease management programs by merging the research capabilities of each manufacturer.

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