156151

United States General Accounting Office

GAO

Testimony

Before the Committee on Insurance
California State Senate

For Release on Delivery
Expected at 1:00 p.m.
Wednesday
February 7, 1996

PHARMACY BENEFIT MANAGERS

Early Results on Ventures With Drug Manufacturers

Statement of John C. Hansen, Assistant Director
Health Financing and Public Health Issues
Health, Education, and Human Services Division

GAO/T-HEHS-96-85

Mr. Chairman and Members of the Committee:

We are pleased to be here today to discuss the growing role of pharmacy benefit managers (PBMs) in the rapidly changing health care marketplace. PBMs manage the prescription drug part of health insurance plans that cover millions of Americans. Their customers are the health plan sponsors, such as self-insured employers, insurance companies, and health maintenance organizations (HMOs).

Recently, some of the largest pharmaceutical manufacturers have merged or formed alliances with some of the largest PBMs. These ventures gained attention not only because of their size, but also because of concerns that the PBMs would automatically give preference to their manufacturer partners' drugs over those sold by competing manufacturers. Because of these concerns, then Representative Ron Wyden asked us to conduct a study of these mergers and alliances.[1]

Our study was based on interviews with officials of companies involved in recent mergers and alliances, and company documents related to these ventures. We also contacted Wall Street analysts, pharmaceutical economists, and officials of health plan sponsors and pharmaceutical trade associations. In addition, we contacted officials of the Federal Trade Commission (FTC) about their review of mergers between drug manufacturers and PBMs and obtained public comments FTC received regarding Eli Lilly and Company's acquisition of PCS Health Systems, Inc. Further, we obtained information from Medco Containment Services, Inc. and Diversified Pharmaceutical Services, Inc. (DPS) on formularies they managed before and after their mergers with Merck & Co., Inc. and SmithKline Beecham Corporation, respectively.

Today, drawing on the results of our study, I will address several key questions concerning PBMs:

-- What is the role of PBMs in the health care industry?

-- Why have the pharmaceutical manufacturers purchased or allied with the largest PBMs?

-- What are the concerns about the effect of these ventures on competition in markets served by drug manufacturers and PBMs?

-- To what extent, if any, have the PBMs given preference to their manufacturer partners' drugs?

---

[1]Pharmacy Benefit Managers: Early Results on Ventures With Drug Manufacturers (GAO/HEHS-96-45, Nov. 9, 1995).

In summary, the results from our analysis of PBM formularies[2] indicate that continued oversight of mergers and alliances between drug manufacturers and PBMs is warranted to ensure that the markets for their products and services remain competitive. For example, the changes in Medco's formulary that appear to favor Merck drugs do not necessarily demonstrate that Medco automatically gave preference to Merck drugs over those of competitors. However, the formulary changes support FTC's decision to continue monitoring the Merck/Medco merger and other such ventures.

BACKGROUND

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.[3] Given this rate of growth, PBMs had been expected to provide services for health plans covering about 50 percent of the population by the end of 1995.

Although the number of people covered by PBMs has increased significantly, the market for PBMs' services continues to involve a small number of firms. Some estimates suggest that of the more than 40 PBMs nationwide, the 5 largest manage benefits for over 80 percent of the health plan enrollees covered by PBMs.[4] These five firms, all of which were included in our study, are PCS Health Systems, Medco, Value Rx, DPS, and Caremark International Inc.'s Prescription Service Division.

Because of its role in antitrust enforcement, FTC has reviewed the recent mergers between drug manufacturers and PBMs on antitrust grounds to determine their potential impact on competition in the markets involved. 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 Health Systems. FTC entered into a consent agreement with Lilly to address the merger's potential anticompetitive effects.

---

[2]A formulary is a list of preferred prescription drugs by therapeutic class often with cost designations.

[3]Estimates were provided by Sanford C. Bernstein & Co.

[4]Estimates were obtained from Sanford C. Bernstein & Co. and a paper presented by Mark Twomey, Deloitte & Touche Management LLP, "The Relationship Between PBM, MCO, and Pharmaceutical Company," IBC Pharmaceutical Pricing Conference, Philadelphia, June 13, 1995.

ROLE OF PBMs IS TO CONTROL DRUG COSTS

PBMs' role in health care has evolved from simply administering prescription drug benefits to helping health plan sponsors control their overall drug costs. They are a relatively new type of firm that became a major market force during the late 1980s. Their precursors were firms that provided prescription claims processing or mail-order pharmacy services on behalf of insurers.

PBMs use a variety of techniques to help control drug costs. These include formulary development and management, development of pharmacy networks to serve health plan enrollees, negotiation of drug rebates with manufacturers, generic substitution, and drug utilization review. Many PBMs are also developing "disease management" programs, which will attempt to provide the most cost-effective treatments for specific diseases.

My main focus today is on formulary development because of its importance in the relationship between PBMs and their manufacturer partners.

Formularies Are Key to Controlling Costs

PBMs use formularies to help control drug costs in several ways. First, PBMs encourage the use of formulary drugs through compliance programs, which inform physicians and enrollees about which drugs are on formulary. Second, PBMs limit the number of drugs a plan covers. Third, they develop financial incentives to encourage the use of formulary drugs.

Although PBMs develop formularies that they recommend to health plan sponsors, it is especially important to note that the sponsors can customize formularies. Plan sponsors are, in fact, ultimately responsible for determining a plan's specific formulary objectives. In developing formularies, PBMs use 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 P&T committees to determine the number of drugs to include on formulary that will give physicians a sufficient number of treatment options.

Drugs are included on a formulary not only on the basis of medical value, but also on the basis of price. 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, "$" signifies a low-cost drug, while "$$$$" signifies a more costly drug. PBMs and the health plan sponsors they represent encourage physicians to prescribe less costly formulary drugs over both more

costly drugs and nonformulary drugs for health plan enrollees. Therefore, the extent to which the PBMs and their sponsors succeed in obtaining physician compliance with formularies increases the sales and market share of a prescription drug within a therapeutic class, especially for a drug on formulary with the lowest cost designation.

Formularies can be open, incentive based, or closed. Open formularies are often referred to as "voluntary" because enrollees are not penalized if their physician prescribes a nonformulary drug. Thus, with an open formulary, a health plan sponsor provides coverage for both formulary and nonformulary drugs. Unlike an open formulary, an incentive-based formulary provides enrollees financial benefits if their physicians prescribe on-formulary drugs. Under this scheme, the health plan sponsor still reimburses enrollees for nonformulary drugs but requires enrollees to make higher co-payments than for formulary drugs. With a closed formulary, the financial incentives are even greater because coverage is limited to formulary drugs only. In this case, if an enrollee's physician prescribes a nonformulary drug, the enrollee may have to pay the full cost of that prescription, unless the nonformulary drug is deemed medically necessary.

The PBMs we studied reported that the vast majority of formularies that they manage are open.[5] 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.

Other Methods for Controlling Drug Costs

In addition to developing formularies, PBMs contract with networks of pharmacies to obtain discounts per prescription for the health plan enrollees that the 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.[6] Pharmacies accept reimbursement levels and other PBM cost-control techniques to attract or retain the potential customer base represented by a PBM's millions of enrollees.

---

[5]According to the American Pharmaceutical Association, during 1994, over 90 percent of formularies managed by PBMs were open.

[6]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 is intended to cover a pharmacy's labor and overhead costs, such as pharmacists' salaries, drug packaging, rent, and utilities.

Although PBMs have succeeded in negotiating discounts for their customers, some pharmacies have been dissatisfied with the reimbursement levels that PBMs offer. For example, several large chain drug stores in Maryland recently refused to participate in the network of pharmacies Medco had established to serve state employees because the stores contended that Medco's reimbursement levels were inadequate. After the pharmacies refused to participate, the state terminated its contract with Medco because it lacked a sufficient number of pharmacies in its network to serve state employees and retirees. The state of Maryland has indicated that it will rebid the contract. FTC is reportedly investigating whether the drug stores colluded to boycott Medco.

PBMs also encourage pharmacies to support other cost-control techniques, such as substituting a generic for a name-brand drug when appropriate. While this technique has proven successful, the involvement of pharmacists in PBM efforts to switch these and other types of prescriptions has raised questions about how independent pharmacists should be in serving their customers. A recent agreement reached between Merck/Medco and 17 state attorneys general requires that Medco pharmacists disclose their affiliation with Merck in connection with switches.

MANUFACTURERS SEEK VENTURES WITH PBMS TO INCREASE MARKET SHARE AND DEVELOP DISEASE MANAGEMENT PROGRAMS

The manufacturers believe that merging or allying with a PBM will provide competitive advantages that will enable them to maintain profits. The growth of PBMs and other industry developments have forced drug manufacturers to find ways to prevent declining profits. While more drugs on the market face competition, purchasers have become more price focused and organized. In particular, PBMs and other purchasers have used formularies to obtain significant rebates from manufacturers. Rather than lose market share, manufacturers have provided rebates on drugs that face competition to obtain inclusion and low-cost designation on PBMs' formularies.

Among other things, each venture provides the manufacturer access to the PBM's formularies, which can help a manufacturer increase market share, particularly for a drug not on the PBM's formulary before the venture. Market share can be further enhanced if the drug receives a low-cost designation, which provides an extra incentive for physicians to prescribe it to save the health plan and its enrollees costs.

The manufacturers also believe that PBMs will provide them the cornerstones of disease management programs, namely the abilities to find the most cost-effective treatments for various diseases, and to ensure that patients comply with them. Currently, prescription drugs are managed separately from other components of

health care, which may result in higher overall spending for a health plan sponsor than would managing all aspects of care for plan enrollees with similar illnesses.

To develop disease management programs, PBMs are evaluating various treatment options or therapies discussed in medical research to identify those associated with better therapy management as well as low overall spending. All the PBMs we studied have launched either diabetes or asthma management programs with others to follow.

Because the mergers and alliances are recent, it is too soon to determine whether each manufacturer has achieved its objective of enhancing profits by increasing market share and developing disease management programs. This is particularly true for disease management programs because manufacturers and their PBM partners are in varying stages of developing them.

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 drugs would preclude other manufacturers from effectively competing with its drugs 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 could obtain their partners' drugs at extremely advantageous prices compared with those of 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 smaller existing ones 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 on competition in the markets for either

pharmaceuticals or PBMs' services.[7] For example, these analysts contend that it is impossible 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 the PBMs that represent them. They noted that if the largest PBMs do not continue to control drugs costs for their customers, the customers can take their business to other PBMs providing similar services.

Industry analysts are more concerned, however, about the influence of drug manufacturers 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 significantly reduce competition in the manufacturer partner's market. This market could be limited to an individual therapeutic class of drugs. A manufacturer can gain competitive advantages if opportunities are eliminated for other manufacturers to compete for inclusion and low-cost designation for their drugs on the PBM partner's formularies.

FTC Requires Safeguards

FTC has reviewed the recent mergers to determine their potential impact on the markets for drug manufacturers and PBMs. The Commission subsequently issued a complaint against the Lilly/PCS merger and determined that safeguards are 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 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.

---

[7]Economic analysis can help determine conditions under which mergers and alliances 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.

FTC has indicated that it will continue to monitor several aspects of the mergers between drug manufacturers and PBMs. Such monitoring includes whether, and to what extent, products of drug manufacturers, especially those not aligned with PBMs, are prohibited (foreclosed) from formularies managed by aligned PBMs. The monitoring also includes determining whether the integration of drug manufacturers and PBMs results in anticompetitive behavior among integrated companies, as well as any increase in drug prices or reduction in choice of drugs for consumers.

Determining whether PBMs involved in these ventures maintain certain safeguards and refrain from collaborating to give preference to their manufacturer partners' drugs requires access to proprietary information. Such information includes a PBM's process for deciding which drugs are to be added or deleted from a formulary, the reasons for changes, and whether competitive bids were sought and considered.

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 for 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, competing manufacturers and others would raise questions about the PBMs' process in making 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.

Merck Products Added 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 one was on Medco's formulary.[8] However, according to Medco officials, Merck and Medco had established an agreement to add the remaining seven products to Medco's formulary in May 1993, 2 months before reaching their decision to merge and 6 months before closing their merger. These seven products increased the number of drugs in their respective therapeutic classes or replaced their chemical equivalents.

---

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

Other changes in Medco's formulary from 1994 to 1995 could benefit the sale of Merck products. For example, between 1994 and 1995, one cardiovascular drug was dropped from the formulary. This change left two of Merck's cardiovascular drugs with fewer competitors on formulary and one of these drugs 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 Merck has the top-selling product in this class. Also, by 1995, Merck's two cholesterol-lowering drugs faced fewer competitors after three non-Merck products were dropped from this therapeutic class.

Little Change in
DPS Formulary

The extent to which DPS has given preference to SmithKline Beecham's products contrasts with the Merck/Medco experience. Before the merger between SmithKline Beecham and DPS in May 1994, DPS' formulary contained SmithKline's four largest dollar-volume outpatient drugs. Following the merger, the number and cost designation of these products on DPS' formulary remained largely unchanged.

CONCLUSIONS

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 by the PBMs or manufacturers. However, changes in formularies can indicate that additional questions may be warranted about the processes that aligned PBMs use in making formulary decisions. Continued monitoring of ventures involving drug manufacturers and PBMs can help to assure participants in the PBM and prescription drug markets that these markets remain competitive.

- - - -

Mr. Chairman, this concludes my prepared statement. At this time, I will be happy to answer any questions you or other Members of the Committee may have.

For more information on this testimony, please call John Hansen, Assistant Director, at (202) 512-7105 or Joel Hamilton, Senior Evaluator, at (202) 512-7142.

(101404)

Ordering Information

The first copy of each GAO report and testimony is free. Additional copies are $2 each. Orders should be sent to the following address, accompanied by a check or money order made out to the Superintendent of Documents, when necessary. VISA and MasterCard credit cards are accepted, also. Orders for 100 or more copies to be mailed to a single address are discounted 25 percent.

Orders by mail:

U.S. General Accounting Office
P.O. Box 6015
Gaithersburg, MD 20884-6015

or visit:

Room 1100
700 4th St. NW (corner of 4th and G Sts. NW)
U.S. General Accounting Office
Washington, DC

Orders may also be placed by calling (202) 512-6000 or by using fax number (301) 258-4066, or TDD (301) 413-0006.

Each day, GAO issues a list of newly available reports and testimony. To receive facsimile copies of the daily list or any list from the past 30 days, please call (202) 512-6000 using a touchtone phone. A recorded menu will provide information on how to obtain these lists.

For information on how to access GAO reports on the INTERNET, send an e-mail message with "info" in the body to:

info@www.gao.gov

PRINTED ON RECYCLED PAPER

United States
General Accounting Office
Washington, D.C. 20548-0001

Bulk Rate
Postage & Fees Paid
GAO
Permit No. G100

Official Business
Penalty for Private Use $300

Address Correction Requested