Federal Trade Commission

RESPONSES TO THE MANAGED CARE REVOLUTION:
A COMPETITION POLICY PERSPECTIVE

PREPARED REMARKS OF COMMISSIONER CHRISTINE A. VARNEY

FEDERAL TRADE COMMISSION

BEFORE THE

NATIONAL ASSOCIATION OF RETAIL DRUGGISTS

LOEWS L'ENFANT PLAZA
WASHINGTON, D.C.

March 27, 1995

The views expressed in these remarks are my own, and do not necessarily reflect those of the Federal Trade Commission or any other individual Commissioner.

I appreciate the opportunity to speak before the National Association of Retail Druggists. Community pharmacists have always played an important role in the delivery of health care services and, like all health care providers today, pharmacists face pervasive pressure to control health care costs.

Today, I'd like to discuss some of the changes in the pharmaceutical industry brought on by the emergence of managed care and other new forms of provider arrangements. First, I'll discuss the antitrust ramifications of pharmaceutical companies' acquisition of pharmacy benefit management programs. Second, I'll discuss pharmacists' collaborative efforts to compete in the newly emerging managed care markets. In doing so, I hope to reassure you that the antitrust laws should not prevent pharmacists from competing in managed care markets.

I. The Managed Care Revolution and Pharmacies

Until quite recently, physicians who had not been trained in cost containment prescribed pharmaceuticals without much regard to price. Physicians were often unaware of lower priced generic substitutes,[1] and even where generics were available, anti-substitution laws often prevented pharmacists from suggesting lower priced drug equivalents. Consumers generally ended up paying top dollar for whatever drug their physician prescribed.

The emergence of managed care has changed that landscape dramatically by eliminating fee-for-service or cost-based reimbursement in favor of schemes that encourage providers to control costs. Managed care organizations, especially HMOs, have developed a number of cost

---

[1] See Miller and Blum, Physician Awareness of Prescription Drug Costs, J. Family Practice (Jan. 1992).

containment strategies for prescription drugs including generic substitution, drug utilization review, formularies and therapeutic interchange.

An FTC study in the late 1970's demonstrated the cost saving potential of generic substitution. This study analyzed the ways in which state anti-substitution laws prevented pharmacists from recommending, and consumers from choosing, lower priced alternatives.[2] As a result of the FTC study, many states changed their generic substitution laws to increase the ability of pharmacists to inform consumers of lower priced alternatives. Since then, generic substitution has increased from about 20% to 40% of new prescriptions. Generics are now a significant market force, resulting in lower prices for consumers.[3]

The emergence of professionally managed prescription drug benefit programs ("PBMs") is a significant aspect of the managed care revolution. As you are all well aware, PBMs provide managed prescription drug programs to managed care providers, corporations, labor unions, retirement systems, and federal and state employee plans and other plan sponsors. PBMs typically select participating pharmacists, drug manufacturers and suppliers, administer point of sale claims processing systems, negotiate quantity discounts with pharmaceutical manufacturers and pharmacists, administer plan record keeping and payments systems, and maintain quality control. A PBM often influences product selection -- relying in part on generic and therapeutic substitution to encourage the most cost-effective therapies. Additional PBM services include

---

[2] FTC, Bureau of Consumer Protection, Drug Product Selection (1979).

[3] An FTC Bureau of Economics study found that generics accounted for 23.3% of prescriptions in the study's 1980 sample. Alison Masson & Robert Steiner, Generic Substitution and Prescription Drug Prices 112-13 (FTC 1985). More recent studies have found that the share of generics increased to 27% in 1988 and is currently 37%. Drug Topics 8s (1993 supp.).

drug utilization review and quality control. PBMs attempt to control costs by negotiating discounts, usually in the form of rebates, from manufacturers in return for placing the manufacturer's drug on the PBM's formulary.[4] Additional rebates are also paid based on the number of units sold or share of the PBM's sales in a therapeutic category. Over 125 million Americans currently benefit from PBMs and that number is expected to increase to 200 million by the end of the decade.

II. The Lilly Acquisition of PCS: Concerns about Foreclosure and Collusion

While recently, groups of pharmacies are beginning to form joint venture PBMs, most PBMs are still owned by single firms, including pharmacies. In the past year, however, pharmaceutical manufacturers have acquired some of the largest PBMs -- Medco/ PAID, PCS and DPS. These acquisitions are controversial because a manufacturer's acquisition of PBMs may threaten the PBM's independence and, as a result, its ability to create purchasing efficiencies and secure lower prices for plan sponsors and their subscribers.[5] Critics worry that manufacturers will utilize captive PBMs to foreclose competitor's products from the market and that manufacturer-ownership of PBMs will facilitate collusion in the pharmaceutical manufacturing and PBM markets.

---

[4] A formulary is a PBM-produced list of FDA-approved drug products by therapeutic category, along with relative cost information. These formularies are made available to pharmacies, physicians, third-party payers, or other persons involved in the health care industry, to guide in the prescribing and dispensing of pharmaceuticals. An "open" formulary allows for the reimbursement of any drug a physician prescribes, whether or not it is actually listed on the formulary, whereas a "closed" formulary limits reimbursement to the specific drugs listed. Thus, closed formularies, by providing a mechanism for restricting reimbursement to certain drugs, can influence the prescribing patterns of physicians.

[5] See "The ABCs of PBMs," Drug Topics 67 (Sept. 5, 1994).

Eli Lilly's proposed acquisition of PCS Health Systems, the largest PBM in the country and the third in a series of manufacturer-acquisition of PBMs in the last twelve months, focused the FTC's attention on these matters last year. After an extensive investigation, in which the Commission staff received the opinions of various parties, including community pharmacists, the Commission concluded the acquisition was not free of competitive risk and issued a complaint against Eli Lilly charging that the PCS acquisition would harm competition in the national full-service PBM market.[6] The complaint alleged that the acquisition might foreclose non-Lilly products from the PCS formulary and that PCS would be eliminated as an independent negotiator of pharmaceutical prices with manufacturers. The complaint also alleged that the acquisition could facilitate collusion through reciprocal dealing, coordinated interaction, and interdependent conduct among Lilly and other vertically integrated pharmaceutical companies. In addition, the complaint alleged that the acquisition could raise entry barriers by effectively requiring an competitor to enter at more than one level. The complaint finally alleged that the acquisition would likely increase prices, diminish quality, and reduce the innovation incentives of other pharmaceutical manufacturers.

Lilly has offered to enter into a consent order with the Commission with respect to the acquisition. The proposed consent order addresses foreclosure and collusion concerns, respectively, by 1) requiring Lilly to maintain an open formulary, which would not give unwarranted preference to Lilly products, while allowing Lilly to offer a closed formulary and 2)

---

[6] Eli Lilly & Co., File No. 941-0102 (Nov. 3, 1994).

by creating a "firewall" to preclude communications between Lilly and PCS concerning bids, proposals, prices or other information related to other drug manufacturers' products.

The Order's open formulary requirement would help prevent anticompetitive foreclosure of competing drug manufacturers. As used in the Order, an "open formulary" is not one on which every FDA-approved drug must be listed, nor would the Order require that any manufacturer that offered a rebate be listed. Rather, under the Order, an independent Pharmacy and Therapeutics Committee, utilizing only objective criteria, would decide which drug products should be included on the formulary. To ensure that Lilly cannot thwart the intent of the Order by refusing to accept discounts or rebates on other products (thereby giving Lilly products preference on the formulary or making the formulary so expensive that no one will use it), the Order prohibits Lilly from refusing to accept discounts and from inaccurately reflecting such discounts on the formulary.

The Order's open formulary would help prevent anticompetitive foreclosure in another respect. Without an open formulary, new entrants might have to enter the industry at both the manufacturing and the PBM levels. By providing an open formulary, entry barriers are lower which should facilitate enhanced consumer access to new products.

The Commission has recognized in related contexts that selective contracting -- limiting the suppliers in order to secure volume discounts -- can be procompetitive. For this reason, the Order also permits Lilly to offer closed formularies to contain costs. PBM customers could then select between a closed formulary with greater price protection or an open formulary with greater drug choices.

The Order also addresses the concern that Lilly's access to competitively sensitive information may facilitate collusion or price fixing by requiring Lilly to maintain a firewall between the two businesses with respect to other drug manufacturers' or other PBM's bids, proposals, contracts, prices, rebates, discounts, or other terms and conditions of sale.

I want to emphasize that this Order is not final yet. It has been placed on the public record and the Commission has received comments from a wide range of interested parties, including groups representing pharmacists. The Commission is analyzing these comments carefully and will be considering whether to accept the consent as final in the near future.

III. Vertical Mergers and Competition Generally

The Commission may determine that the proposed Lilly Order adequately addresses foreclosure and collusion concerns in this case. Questions remain as to the overall competitive effect of PBM ownership by pharmaceutical companies. As Chairman Steiger and I said in our public statement regarding Lilly, "[w]e are concerned about the overall competitive impact of vertical integration by drug companies into the pharmacy benefits management market." Lilly reflects the Commission's recognition that vertical integration may cause competitive problems. Some have criticized these actions and suggest that any enforcement against vertical integration is misguided. Our hope is that through monitoring this proposed order and through analysis of these evolving markets, the Commission can better assess all the ramifications of vertical integration in these markets.

Let me set out the debate for you. Antitrust enforcers classify mergers as either "horizontal" because they involve direct competitors, or "vertical" because they involve firms at different levels of a particular market. Vertical integration involves a producer that either by

contract or merger enters into an adjacent level of business. Most economists consider vertical mergers efficient because, for example, they may integrate producers into a distribution network. But I disagree with the theorists who insist the vertical merger enforcement is unwarranted under any circumstances. Vertical integration can, under certain circumstances, become the vehicle for exclusion or collusion.

We do not need to look to theory for proof -- there is a real world example that offers an interesting, although imperfect, analogy to manufacturer-owned PBMs. Computer reservation systems (CRS), an electronic point of sale transaction system that permits airline reservation and ticketing by travel agents, are like PBMs in a number of ways. Like PBMs, a CRS network facilitates exchange of transactions and data among a group of firms.

When airlines first formed CRS systems in the mid-1970s, few recognized the opportunities for either foreclosure or collusion. By the mid-1980s, however, private litigants and regulators forcefully articulated foreclosure and access issues. Might CRS owners foreclose smaller airlines from the market by giving them inferior access to the CRS network? This articulation led to development of complex set of regulations, administered by the Department of Transportation, to control access and attempt to provide some level of non-discriminatory treatment.[7]

Collusion concerns also arose. Might airlines use the tariff publishing system to engage in price signalling leading to higher consumer prices? Ultimately, both the Department of Justice

---

[7] See Margaret E. Guerin-Calvert, "Vertical Integration as a Threat to Competition: Airline Computer Reservation Systems," in The Antitrust Revolution (2d ed. 1994); see also American Airlines, Inc. v. United Airlines, Inc., 948 F.2d 536 (9th Cir. 1991), cert. denied, 112 S. Ct. 1603 (1992).

and private litigants successfully challenged these practices, and consumers received several hundred million dollars in damages.[8]

I provide this example not to suggest it is a perfect analogy. I present it because it suggests that vertical integration is not perfectly benign, especially where a firm acquires a network that serves as a gateway to competition. A gateway can be utilized to keep competitors from effectively competing in the market: the CRS experience makes that clear. These concerns must also be addressed in the context of manufacturer-owned PBMs.

IV. Competition and Pharmacy-Owned Joint Venture PBMs

Just as pharmaceutical manufacturers are integrating "downward" into the PBM market, some pharmacies are trying to integrate "upward" into the PBM market. Of course, most community pharmacies do not have the breadth of geographic coverage and financial wherewithal to do so on their own, and have sought to act collectively to compete in these new markets. Although there are some potential antitrust pitfalls, I believe that it is quite possible for a pharmacy-owned PBM joint venture to operate consistently with the antitrust laws.

The antitrust analysis of joint ventures like these PBMs is generally twofold. First, is the cooperative undertaking a legitimate joint venture or simply a disguise for collective price fixing? Second, can the arrangement raise prices through the exercise of market power?

---

[8] See United States v. Airline Tariff Publishing Co., 1994-2 Trade Cas. (CCH) ¶ 70,687 (D.D.C. 1994) (consent decree); In re Domestic Air Transportation Antitrust Litig., No. 1:90-cv-2485-MHS & MDL No. 861 (N.D. Ga. March 22, 1993) (awarding class of passengers between $254 and $356 million).

A. Legitimate or Sham

In a number of cases, the Commission has challenged the formation of alleged joint ventures that were little more than thinly-veiled attempts by bands of health care providers to defeat cost containment efforts.[9] But what about when a group of pharmacies forms a PBM in order to compete in the PBM market? How can a joint venture PBM avoid antitrust risk?

One approach to avoiding prohibited price fixing is to use something called a "messenger" model.[10] Under a messenger model, the joint venture PBM simply provides price and other information about the joint venture's pharmacy members to plan sponsors, and transmits proposed contracts from payers, including fee schedules, to the pharmacy members for their individual consideration. Each pharmacy individually decides whether or not to accept a proposed contract offered by a payer. Assuming that information about an individual member's business practices is not shared among the joint venturers, a messenger model does not appear to involve any horizontal agreement by competitors on their terms of doing business. It therefore

---

[9] The Commission has brought several cases involving efforts by groups of pharmacists to boycott managed care providers in order to defeat those providers' efforts to reduce costs. See Maryland Pharmacists Association, D. 9262 (Dec. 6, 1993); Southeast Colorado Pharmacal Association, C-3410 (Jan. 15, 1993); Peterson Drug Company of North Chili, New York, Inc., No. 9227 (Apr. 22, 1992).

[10] See, e.g., ABA, Section of Antitrust Law, Managed Care and Antitrust: The PPO Experience at 27-28 (1990); Lerner and Narrow, "PPO Programs and the Antitrust Laws" at 858, in The New Healthcare Market: A Guide to PPOs for Purchasers, Payers and Providers (P. Boland ed. 1985).

generally would not raise concerns under the antitrust laws. Indeed, pharmacy-owned PBMs under a messenger model have been approved by antitrust agencies in the past.[11]

But what if a pharmacy-owned PBM joint venture wants to engage in collective price setting? Joint price setting is generally permissible where the venture and the price restraints produce some type of significant efficiency through integration, that is, where the joint venture and its associated price restraints contribute to a significant efficiency-enhancing integration of economic activity that outweigh any countervailing anticompetitive effects. There are generally two means of demonstrating the existence of efficiencies: first, where the joint venture offers a product that the venture's members could not offer individually,[12] and second, where there is sufficient financial or productive integration among the members of the venture. Let me explain how both of these concepts could apply to pharmacy-owned PBM joint ventures.

In order to assess such efficiencies in the new product context, antitrust enforcers must ask whether the pharmacy members could individually offer the same product. PBM joint ventures, especially those involving large numbers of community pharmacies, ought to have a credible argument on this issue: community pharmacies are generally too small to form their own

---

[11] Business Review Letter to Robert Taylor, antitrust counsel for Pharmacy Care Network (Oct. 8, 1986). See also Statement No. 9, U.S. Department of Justice and Federal Trade Commission, Statements of Antitrust Enforcement Policy in the Health Care Area, 4 Trade Reg. Rep. (CCH) ¶ 13,152 at 20,794-95 (Sept. 27, 1994) (describing messenger model in context of multiprovider networks).

[12] The "new product" concept is derived from a seminal Supreme Court case involving ASCAP and BMI, organizations that offer blanket licenses covering their member's musical compositions. Broadcast Music, Inc. v. CBS, 441 U.S. 1 (1979). A mere allegation that something is a new product will not necessarily carry the day. See Arizona v. Maricopa County Medical Society, 457 U.S. 332 (1982).

PBMs, but using a joint venture arrangement small pharmacies may be able to acquire the economies of scale and scope of large chains.

Another question relevant to the new product inquiry is whether the joint venture practice -- and here we are discussing joint price setting -- "facially appears to be one that would always or almost always tend to restrict competition and decrease output," or whether it is designed to "increase economic efficiency and render markets more, rather than less, competitive."[13] Here again, joint venture PBMs among community pharmacists should have credible arguments. The joint venture itself may constitute a new product: an electronic network that features efficient point-of-sale claims processing, information gathering utilization review, and establishes a formulary, a group buying arrangement with increased purchasing power, and a joint sales agent. The network benefits pharmacy members, plan sponsors and consumers, and may, in turn, enable community pharmacies to compete more effectively with pharmacy chains in both the pharmacy and PBM markets.

The existing capabilities of the joint venture members is the key focus of the new product efficiency inquiry. Antitrust enforcers ask 1) whether the individual members are capable of competing independently in the PBM market and 2) what new efficiencies does the joint venture bring to the market. Consider a joint venture PBM consisting of all the largest pharmacy chains in a single metropolitan area, each of which operates its own PBM. In this situation, the existence of the individual PBMs likely makes it more difficult for the joint venture PBM to make the case that its operation truly constitutes a "new product" that its members could not put together on

---

[13] BMI, 441 U.S. at 19-20, citing United States v. United States Gypsum Co., 438 U.S. 422, 441 n.16 (1978).

their own. On the other hand, a joint venture of community pharmacies throughout the United States that seek to compete in the "national PBM" market might show efficiencies, especially where individual members alone could not compete in that market and the presence of the community pharmacy joint venture could enhance competition in the national PBM market. It should be noted that both PBM joint ventures[14] and a wide variety of other joint ventures have been approved where, among other things, the venture offered a product that the individual members were not capable of producing.[15]

I want to emphasize, however, that the "new product" analysis must be approached with extreme care. "New product" analysis is potentially limitless in its application: even naked cartels could argue that they had created a new market or new product as a result of their combination.[16] The inquiry must carefully consider all the factors surrounding the particular market at issue. Consequently, what may make sense as a "new product" argument in one market may not make sense in another. Furthermore, each aspect of a joint venture requires scrutiny: the fact that one aspect may be procompetitive does not immunize the venture if there are other anticompetitive aspects. Finally, a venture that looks procompetitive on its face may in practice be used as a vehicle for anticompetitive conduct by facilitating collusion.

---

[14] Business Review Letters to Robert Taylor, antitrust counsel for Pharmacy Care Network and to Frank Sanchez, coordinator for Service For You (Oct. 8, 1986).

[15] See, e.g., Business Review Letter to Newspaper Ass'n of America (Dec. 10, 1993) (joint venture network for selling advertising space for national advertising campaigns); Business Review Letter to Affiliated Distributors (May 5, 1992) (creation of joint venture to provide national accounts program); Business Review Letter to Independent Drug Wholesalers Group (May 21, 1987) (same).

[16] See Arizona v. Maricopa County Medical Society, 457 U.S. 332 (1982).

A related approach to joint price setting analysis is the level of financial integration involved. The Health Care Policy Statements on physician joint ventures, jointly issued by the FTC and DOJ last fall, justified financial integration on the basis of risk sharing under certain conditions.[17] Why is risk sharing important? When the provider group bears substantial economic risk, each member of the group has an incentive to ensure that the cost-containment goals of the venture are met. Under such circumstances, the price-fixing aspects of the arrangement are actually necessary to ensure the success of the venture. Consequently, a physician joint venture that shares risk among the members is less likely to be a sham created simply to frustrate cost containment efforts or to fix prices. The Health Care Policy Statements acknowledge that risk sharing may be achieved in any number of ways, and identify capitation and fee-withhold arrangements as a common form of risk sharing.

This standard was adopted for physician joint ventures only after several years of extensive investigations, enforcement actions, academic commentary, and a lengthy dialogue with the industry, and may be inapplicable in the pharmaceutical context. Because a physician joint venture's primary goal is to contain costs by reducing inappropriate or excessive treatment or utilization, segregation of risk may provide evidence that the venture is merely a sham to frustrate cost containment efforts or fix prices. Unlike physicians, however, pharmacists do not prescribe treatment or otherwise substantially control utilization levels. Consequently, it may not

[17] Statement No. 8, U.S. Department of Justice and Federal Trade Commission, Statements of Antitrust Enforcement Policy in the Health Care Area (hereafter "Health Care Policy Statements"), 4 Trade Reg. Rep. (CCH) ¶ 13,152 at 20,788 (Sept. 27, 1994).

be appropriate to view financial integration based on risk-sharing as the sine qua non of legitimacy in examining pharmacy-owned PBM joint ventures.

This does not mean that cost containment measures such as capitation and withholds are not strong evidence of the procompetitive nature of a joint venture. They are, and where they are present in a joint venture PBM, they will be acknowledged as an important efficiency. Indeed, one of the important recent innovations in PBMs is the use of capitated plans.[18] Requiring demonstration of the existence of efficiencies via a particular path, or imposing a certain structure on these joint ventures, does not respond to the defining characteristics of these emerging markets: the analysis should be sensitive to new methods of integration as they evolve.

B. Analysis of Market Power

Even where we believe that a venture is legitimate, we must also consider whether there is the potential for the exercise of market power that could ultimately lead to higher prices to consumers. A PBM joint venture, by combining an overly inclusive group of pharmacies, might inhibit the formation of competing PBMs or prevent payers who wish to deal with pharmacists individually from being able to enter and operate in the market. Two important factors in determining the likelihood of the exercise of market power are (1) whether the joint venture is exclusive -- that is, whether its members are permitted to compete separately with the venture, either individually or through a competing venture; and (2) whether the venture is overinclusive, in that it includes so many competing providers in the market that an insufficient number of other

[18] See Anita R. McGahan, "Industry Structure and Competitive Advantage," Harvard Business Review 115 (Nov.-Dec. 1994); "Capitation: however you view it, it's a potent new force" Drug Topics 40 (Jan. 23, 1995).

providers are not available to form competing arrangements. Where both of these factors are found -- overinclusiveness and exclusivity -- the risks of the exercise of market power may be especially pronounced.

Whether market power exists is an extremely fact-based determination. We have not yet had much opportunity to determine whether PBM joint ventures enjoy significant market power, although the pharmacy mergers we have reviewed to date offer relatively limited evidence of such market power.

Non-exclusive arrangements diminish, although they do not extinguish, concerns about market power. Where each pharmacy member is free to participate in alternative ventures, foreclosure risks should diminish. As one court observed, in analyzing price setting by a joint venture credit card network "a practice is not unlawful per se where . . . there is no legal, practical or conspiratorial impediment to making alternate arrangements."[19]

C. Efficiencies

Antitrust enforcers would be remiss if they did not recognize the opportunities for efficiencies from collaboration, and I think there may be significant procompetitive benefits from the emergence of pharmacy-owned PBM joint ventures. These ventures increase competition by providing new PBM offerings. Moreover, these ventures often enable community pharmacies to bear the transactions cost internalized in the structure of a chain pharmacy. Absent these ventures, community pharmacies might be unable to participate in PBMs, and PBM consumers might have less choice in their selection of a pharmacist.

---

[19] See, e.g., National Bancard Corp. ("NaBanco") v. VISA U.S.A., 596 F. Supp. 1231, 1254-55 (S.D. Fla. 1984), aff'd, 779 F.2d 592 (11th Cir.), cert. denied, 479 U.S. 923 (1986).

These ventures may also improve the efficiency and competitiveness of their members by aggregating buying power of both the pharmacies and the plan sponsors. These savings could not be achieved by a joint buying group alone, because only a PBM has the power to solicit discounts based on share shifting (e.g., preferential listing on the formulary). The savings from the joint buying arrangement should enable community pharmacies to compete more effectively.

Finally, it is important to recognize that the existence of independent PBMs may help deter the opportunities for collusion or foreclosure that are at the center of the concerns in the Lilly-PCS matter. This is not to say that an otherwise illegal venture is permissible where it provides a counterweight to potentially anticompetitive activity. Rather, it suggests that antitrust enforcers must act cautiously and not condemn, or indirectly inhibit, procompetitive collaborations that have the potential for improving the competitive process.

V. Conclusion

I have focused today on the conditions under which the acquisition of a PBM by a manufacturer might raise competitive concerns, and how pharmacies themselves might create joint venture PBMs without running afoul of the antitrust laws. I hope that these thoughts will enhance your consideration of these issues, and I would be pleased to answer any questions you might have at this time.