A Whole New World?: Pharmaceutical Responses to the Managed Care Revolution

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I. INTRODUCTION

The managed care revolution has made its way to pharmaceuticals. Buyers, faced with increasing pharmaceutical costs, have tried to export innovations in controlling other health care costs to the pharmaceutical arena. Many managed care providers include pharmaceuticals as part of their benefit programs. This article generally addresses how an important group in the managed care environment — pharmacists — can respond to the managed care revolution. In particular, it looks at the development of pharmaceutical benefit managers (PBMs), which play an important role in controlling health care costs, and how the acquisition of PBMs by pharmaceutical manufacturers may raise competitive concerns.

II. THE MANAGED CARE REVOLUTION AND PHARMACIES

To understand the significance of the managed care revolution for pharmaceuticals, one need only look to the unmanaged past. Pharmaceuticals were prescribed by physicians who usually were unaware of and unconcerned with either their costs[1] or the availability of lower priced generic substitutes. Even where these substitutes were available, antisubstitution laws frequently prevented pharmacists from suggesting equivalent, lower priced alternatives. Ultimately, consumers had little choice but to pay the full price for whatever drugs their physicians prescribed.

The emergence of managed care has changed the landscape dramatically. The core of managed care involves the replacement of fee-for-service or cost-based reimbursement with direct incentive schemes for providers to control costs. Managed care organizations, especially health maintenance organizations (HMOs), have developed a number of cost containment strategies for prescription drugs in recent years, including generic substitution, drug utilization review, formularies, mail-order pharmacies, and therapeutic interchange.

The development of generic substitution was aided by a Federal Trade Commission (FTC) study in the early 1980s, which surveyed state antisubstitution laws and discussed how these laws prevented pharmacists from recommending, and consumers from choosing, lower priced alternatives.[2] Because of the FTC study, many states changed their generic substitution laws, which increased the ability of pharmacists to inform consumers of lower priced alternatives. Since then, generic substitution has increased from approximately twenty percent to forty percent of new prescriptions, and generics

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[1] *See* Lucinda Miller & Alan Blum, *Physician Awareness of Prescription Drug Costs*, 36 J. FAMILY PRACTICE 33 (1993).

[2] ALISON MASSON & ROBERT STEINER, GENERIC SUBSTITUTION AND PRESCRIPTION DRUG PRICES (Fed. Trade Comm'n 1985).

have become a far more significant force in the market, leading to lower prices for consumers.[3]

Perhaps the most significant change in the managed care revolution is the recent development of prescription drug benefit programs managed through PBMs. A PBM provides managed prescription drug programs to organizations such as managed care providers, corporations, labor unions, retirement systems, and federal and state employee plans (plan sponsors). PBMs typically select participating pharmacists and drug manufacturers and suppliers, create and administer a point-of-sale claims processing system, negotiate quantity discounts with pharmaceutical manufacturers, administer the record keeping and payments systems of the plans, and maintain quality control. A PBM typically acts as the agent for the plan sponsor to influence product selection — encouraging generic and therapeutic substitution based on negotiated prices with manufacturers. Additional services offered by a PBM may include drug utilization review, quality control, and mail-order service. Over 135,000,000 Americans currently receive benefits from PBMs, and that number is expected to increase to 200,000,000 by the end of the decade.[4]

One recent development in PBMs is the emergence of a service known as "disease state management," which involves monitoring a patient's use of pharmaceuticals to ensure that they are used in both a therapeutic and a cost effective fashion. Some have suggested that pharmacists may play an important role in disease state management programs, by counseling patients to make certain that they are using their medications properly.

Most PBMs are owned by single firms, but some are owned by individual pharmacy chains, and recently some groups of pharmacies have formed joint venture PBMs. In the past few years, many of the most prominent PBMs — Medco Containment Services, PCS Health Systems, and Diversified Pharmaceutical Services (DPS) — have been (or are being) acquired by pharmaceutical manufacturers. These acquisitions have raised a great deal of controversy in the press and before Congress.[5] Because the purpose of PBMs, in part, was to aggregate buying power on behalf of plan sponsors and their subscribers to secure lower drug prices, it is understandable why the acquisition of the most prominent PBMs by manufacturers would raise concerns. Two specific concerns are that manufacturers will use the PBMs they purchase to foreclose competitors' products from the market, and that manufacturers will use PBMs or PBM-directed incentives to encourage or force pharmacists to favor the manufacturers' drugs.

The next two sections of this article address two questions, both related to the emergence of PBMs: under what conditions does the acquisition of a PBM by a pharmaceutical manufacturer raise competitive concerns; and how can pharmacies participate collectively in the managed care revolution?

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[3] An FTC Bureau of Economics study found that generics accounted for 23.3% of prescriptions in the study's 1980 sample. MASSON & STEINER, *supra* note 2, at 111. More recent studies have found that the share of generics increased to 27% in 1988, and to 37% in 1993. Greg Muirhead, *There's Room for Managed Care to Cut Drug Costs,* DRUG TOPICS, June 24, 1996, at 19 (reporting that in managed care organizations, 42.4% of the prescriptions were generic).

[4] HEALTH INDUSTRIES RESEARCH CENTER, NATIONAL ACCOUNTS: MARKETING CHALLENGES AND OPPORTUNITIES FOR THE 1990s, at II-7 (1996).

[5] *See Drug Industry Finds New Partners in Cost-Containment Quest*, J. AM. HEALTH POL'Y, July-Aug. 1994, at 6 (reporting Congressman Wyden's request that the Government Accounting Office (GAO) investigate the acquisition of PBMs by pharmaceutical manufacturers).

III. THE ACQUISITION OF PBMs: CONCERNS OF FORECLOSURE AND COLLUSION

The FTC is responsible for reviewing mergers, and in 1994, Eli Lilly's acquisition of PCS Health Systems, the pharmacy benefits management subsidiary of McKesson Corp., focused the FTC's attention on the PBM market.[6] PCS is the largest PBM in the United States, with over 50,000,000 covered persons.[7] Antitrust enforcers classify mergers as either horizontal (between direct horizontal competitors) or vertical (between firms in different levels of the market) mergers. The acquisition of PCS by Lilly was vertical because it involved the acquisition of a distribution outlet for its drugs.

A PBM attempts to control costs by negotiating discounts, usually in the form of rebates, from a given manufacturer in return for placing the manufacturer's drug on the PBM's formulary. Additional rebates also may be paid, based on the number of units sold or the share of the PBM's sales in a therapeutic category. A formulary is a PBM-produced list of drug products approved by the Food and Drug Administration (FDA), arranged by therapeutic category, along with the reimbursement rate for the drug. These formularies are made available to pharmacies, physicians, third-party payors, and 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 actually is 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.

After an extensive investigation, in which FTC received and considered the opinions of various parties, in November 1994, the Commission accepted for public comment a consent agreement resolving allegations that Eli Lilly's PCS acquisition would harm competition in the national full-service PBM market.[8] The complaint accompanying the consent agreement alleged that, as a result of the acquisition, products of drug manufacturers other than Eli Lilly would be foreclosed 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 would facilitate collusion through reciprocal dealing, coordinated interaction, and interdependent conduct among Eli Lilly and other vertically integrated pharmaceutical companies. In addition, the complaint alleged that entry into the relevant markets would be more difficult because it might require entry at more than one level. The complaint further asserted that the impact of the acquisition in the affected pharmaceutical markets likely would be to increase prices, diminish quality, and reduce the incentives of other manufacturers to develop innovative pharmaceuticals.

The Commission accorded final approval to the complaint and consent order in July 1995. The consent order has two principal provisions that address potential foreclosure and collusion. The first provision requires Eli Lilly to maintain an open formulary that does not give unwarranted preference to the company's products, but also

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[6] Eli Lilly, No. C-3594 (July 28, 1995) (Azcuenaga, Comm'r, dissenting); 59 Fed. Reg. 60,815 (Nov. 28, 1994) (proposed consent agreement and analysis to aid public comment); 61 Fed. Reg. 31,117 (July 31, 1996) (final consent order and Commission statement).

There were two additional acquisitions of PBMs that occurred during this period: the acquisition of DPS by SmithKline Beecham PLC and the acquisition of Medco Containment Services by Merck.

[7] *See supra*, note 4.

[8] *Lilly*, No. C-3594, complaint ¶ 13.

allows Eli Lilly to offer a closed formulary.[9] The second provision creates a "firewall" that precludes communications between Eli Lilly and PCS concerning bids, proposals, prices, or other information related to other drug manufacturers' products.[10]

The consent order's open formulary requirement helps 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 does the order require that any manufacturer that offered a rebate be listed. Rather, under the order, an independent Pharmacy and Therapeutics Committee (P&T Committee), utilizing only objective criteria, will decide which drug products should be included on the formulary. To ensure that Eli Lilly cannot thwart the intent of the order by refusing to accept discounts or rebates on other products (thereby giving Eli Lilly products preference on the formulary or making the formulary so expensive that no one will use it), the order prevents Eli Lilly from refusing to accept discounts and from inaccurately reflecting such discounts on the formulary.

Because the order requires an open formulary, new entrants to pharmaceutical markets face lower entry barriers because they do not need to enter at both levels of the industry. The open formulary thus provides access for new products that offer an objective advantage over existing products.

If the potential for foreclosure exists, however, why not prohibit Eli Lilly from using closed formularies altogether? Although that alternative may be appropriate in some cases, here FTC recognized the potential that closed formularies may offer to contain costs. As some commentators have observed in related contexts, selective contracting (i.e., limiting the panel of providers to secure contracts in which lower prices are offered in exchange for assurance of higher volume) can be procompetitive.[11] Because pharmaceutical manufacturers may offer greater rebates for placement on a closed (or restricted) rather than open formulary, the order does not prohibit Eli Lilly from offering closed (or restricted) formularies to its customers. Thus, potential customers of the PBM can choose either the closed formulary, with its potential for lower prices, or the open formulary, which provides a greater choice of drugs.

The consent order also deals directly with concerns that access to competitively sensitive information may facilitate collusion in either industry, or permit Eli Lilly to submit higher bids to other PBMs than it otherwise would. The order requires Eli Lilly to maintain a firewall between the two businesses with respect to other drug manufacturers' bids, proposals, contracts, prices, rebates, discounts, or other terms and conditions of sale. This firewall should prevent the flow of competitively sensitive information between Eli Lilly and PCS that otherwise could assist in maintaining or monitoring tacit collusion at either level of the industry, or give Eli Lilly access to information that might enable it to submit higher bids to other PBMs than it otherwise would.

There remains, however, the question of the overall competitive effect of pharmaceutical manufacturers owning PBMs. As with any markets that are undergoing structural changes, evolving market conditions in the pharmaceutical and PBM markets can affect FTC's analysis of a particular transaction. Each merger must be viewed in the context of the current and likely future market structure. In the *Lilly* case, the Commission promised continued scrutiny of the competitive environment by issuing a state-

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[9] *Lilly*, No. C-3594, consent order ¶ II.

[10] *Id.* ¶ III.

[11] *See* Note, *HMO Regulation — Arkansas Requires HMOs to Accept Any Provider Willing to Join Their Network*, 109 HARV. L. REV. 2122 (1996).

ment with the July 1995 final consent order,[12] noting, *inter alia*, that it remains concerned that vertical integration in these markets could lead to anticompetitive consequences requiring additional relief. Thus, FTC will continue to monitor this industry carefully, through both ongoing investigations and enforcing Lilly's compliance obligations under the order. More specifically, FTC stated that it will continue to assess, among other things, the extent and effects of foreclosure of the products of other pharmaceutical manufacturers, especially those not vertically integrated with a PBM; whether and to what extent vertical integration in this industry fosters anticompetitive reciprocal dealing, coordinated interaction, or interdependent conduct among vertically integrated firms; and whether vertical integration among pharmaceutical manufacturers and PBMs increases the prices or diminishes the availability of pharmaceuticals to consumers. The Commission specifically noted that if it concluded that competition was being reduced as a result of these vertical arrangements, it would seek appropriate relief against any firms engaged in anticompetitive conduct, including, if necessary, postacquisition divestitures.[13]

Several recent developments suggest that the controversy surrounding PBM acquisitions is unlikely to dissipate. First, at the request of Congress, the General Accounting Office conducted a study of PBM acquisitions.[14] The report focused on all three prominent PBM acquisitions, and described both the procompetitive and anticompetitive aspects of them. In particular it noted the opportunity for manufacturer-owned PBMs to exclude drugs that competed with the parent's drugs and ultimately harm competition. The report noted that the Medco formulary was changed around the time of the Merck acquisition to favor several Merck drugs and exclude some competitive drugs.[15] Although the study found that, for example, Medco did not universally favor Merck drugs, "the formulary changes support FTC's decision to continue monitoring the Merck/Medco merger and other such ventures. Such monitoring will help to ensure that PBMs maintain competitive processes that allow manufacturers, other than their partners, to compete for inclusion and low-cost designation for their drugs on the PBM formularies."[16]

Second, in October 1995 Pfizer brought suit against PCS, charging that its failure to include a number of Pfizer's drugs on certain PCS closed formularies violated a contractual agreement between PCS and Pfizer. A New York Supreme Court judge found in favor of Pfizer and required PCS to retain seven Pfizer drugs on all its formularies until 1998.[17] Of particular interest in the trial was PCS' exclusion of Pfizer's Zoloft, which is an antidepressant and the major competitor for one of Eli Lilly's key products — Prozac. Zoloft costs less than Prozac and the exclusion of a lower priced drug could raise competitive concerns.

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[12] Statement of the Commission, Dkt. No. C-3594 (July 31, 1995).

[13] Other commentators have identified similar concerns. *See* Christine Dodd, *The Merck-Medco Merger: An Isolated Incident or a Catalyst for the Transformation of an Industry?*, 63 U. CIN. L. REV. 1767 (1995) (suggesting that PBM acquisitions may diminish the incentives for research and development).

[14] *See* GENERAL ACCOUNTING OFFICE, PHARMACY BENEFIT MANAGERS — EARLY RESULTS ON VENTURES WITH DRUG MANUFACTURERS (1995) [hereinafter GAO REPORT]; *see also Hearings before the Committee on Insurance of the California State Senate* (Feb. 7, 1996) (statement of John C. Hansen, Ass't Dir. Health Financing & Public Health Issues, Health, Educ., and Human Servs. Div., GAO).

[15] After the Medco acquisition, Merck's volume for its own drugs increased by 10% in the second quarter of 1994 and by 15% in the third quarter of 1994. *See* Kevin A. Schulman et al., *The Effect of Pharmaceutical Benefit Managers: Is it Being Evaluated?*, 124 ANNALS INTERNAL MED. 906, 911 (1996).

[16] GAO REPORT, *supra* note 14, at 3.

[17] *PCS Ordered to Include Pfizer Products on Formularies Thru 1998 by the New York Court, PCS Performance Drug Plan Violates 1994 Pfizer-PCS Rebate Agreement*, F-D-C REP. ("The Pink Sheet"), June 10, 1996, at 15.

Third, in July 1996, the National Association of Chain Drug Stores (NACDS) and a group of consumer advocates (Citizen Action, Consumer Federation of America, Families USA, and the National Consumers League) filed separate petitions to the Commission asking the FTC to issue an order to show cause why the *Lilly* order should not be reopened.[18] The concerns expressed in the petitions were that Lilly was increasingly using closed formularies, that the independence of the P&T committee could not be verified, and that contrary to the efficiency claims of the firms, drug prices actually had increased. Because of this, NACDS, in particular, had recommended that the Commission require:

- the elimination of all financial incentives for PCS and its employees to use Lilly products in PCS formularies;
- disclosure to payors and physicians, who are involved in switches of prescription medication, of all financial incentives to PCS for use of Lilly drugs;
- that Lilly/PCS develop an oversight body, to include customers and patients, that would monitor the activities of the P&T committee;
- prohibiting PCS from specifying the use of particular manufacturers' generic drugs for filling prescriptions in accordance with a formulary;
- development of an objective clinical evaluation system for inclusion of prescription drugs on any formulary offered by PCS; and
- a most favored nation provision in the sale of Lilly drugs to PCS, which would require that Lilly's pricing to PCS be offered to other PBMs.

Finally, there have been other studies by government agencies — including the Inspector General of the Department of Health and Human Services and the Public Advocate of the City of New York — that have questioned the potential anticompetitive effects of these acquisitions and adverse effects on consumers.[19]

FTC's law enforcement action in Eli Lilly has generated a debate about the potential for competitive abuse from vertical integration. This debate has occurred in several markets that are undergoing regulatory change — telecommunications and electricity are examples — where regulators grapple with the potential for competitive abuse.

Vertical integration involves a producer that either by contract or merger enters into an adjacent level of business. Most economists consider vertical integration efficient — provided that it does not facilitate the individual or collective creation or maintenance of monopoly power — and it may create certain efficiencies in a situation where an upstream producer of a good integrates into a downstream distribution network, such as where a pharmaceutical manufacturer acquires a PBM network. Some even might question whether any law enforcement action in this situation would be prudent, given their "assumption" that such consolidation is efficient. Such a position, however, would be short sighted. There is a concrete debate about the competitive effects of vertical integration.[20] Although vertical integration can be procompetitive, that does not

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[18] *See* Letter from the Nat'l Ass'n of Chain Drug Stores to the Federal Trade Comm'n (July 30, 1996); Letter from the Consumer Federation of America et al. to the Federal Trade Comm'n (July 31, 1996).

[19] *See* MARK GREEN (Public Advocate for the City of New York), COMPROMISING YOUR DRUG OF CHOICE: HOW HMOS ARE DICTATING YOUR NEXT PRESCRIPTION (1996); OFFICE OF THE INSPECTOR GENERAL, DHHS, EXPERIENCES OF HEALTH MAINTENANCE ORGANIZATIONS WITH PHARMACY BENEFIT MANAGEMENT COMPANIES (1996).

There also have been private studies of the conflict-of-interest issues raised by manufacturer-owned PBMs. *See* Schulman et al., *supra* note 15, at 911.

[20] Thus, for example, the Commission extensively discussed the competitive effects of vertical integration in B.F. Goodrich Co. et al., 110 F.T.C. 207, 329-38 (1988).

mean it cannot, under certain circumstances, become the vehicle for exclusion or collusion.[21]

There is a real-world example that offers an interesting, although imperfect, analogy. Computer reservation systems (CRSs) are like PBM networks in a number of respects. A CRS network is an electronic point of sale transaction system that permits airline reservation and ticketing by travel agents. Similar to a PBM, a CRS involves a mixture of facilities and rules that allows a firm or group of firms to exchange or share transactions and data. There are four primary CRS networks in the United States, all of which are owned by various airlines.

When CRS networks first were formed in the mid-1970s, few recognized the opportunities for either foreclosure or collusion. The CRS networks entered into exclusive arrangements with travel agents, which made entry by new competing networks — to serve other airlines — nearly impossible once virtually all of the agents committed themselves to one of the first networks.[22] By the mid-1980s, concerns over exclusion and collusion led to a spate of private antitrust litigation and major regulatory proceedings before the Department of Transportation. Some of the litigation and proceedings focused on the issue of foreclosure and access: whether the owners of each CRS could foreclose smaller airlines from the market by giving them inferior or no access to the CRS network.[23] Although the private litigation was not successful, the regulatory proceedings (which lasted several years) led to a complex set of regulations, administered by the Department of Transportation, to control access and attempt to provide some level of nondiscriminatory treatment.[24]

The concern about collusion also appears to be well founded. Through the use of the airline tariff publishing system, several airlines allegedly engaged in price signaling that ultimately led to higher prices to consumers. These practices were challenged successfully in a Justice Department suit and private antitrust litigation that resulted in the award of several million dollars in damages to consumers.[25]

The CRS example 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.

IV. EMERGING ROLES FOR PHARMACIES IN THE MANAGED CARE REVOLUTION

Rather than simply participating as individual distribution outlets, pharmacies may choose to collectively create procompetitive joint ventures to compete in these new

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[21] CHRISTINE A. VARNEY, WHY VERTICAL MERGER AND INNOVATION MARKET ENFORCEMENT CHALLENGES MAKE SENSE; Michael H. Riordan & Steven C. Salop, *Evaluating Vertical Mergers: A Post-Chicago Approach*, 63 ANTITRUST L.J. 513 (1995).

[22] *See* John Helliwell, *Networks Provide a Critical Competitive Edge for Airlines*, PC WEEK, Jan. 19, 1988, at C1.

[23] *See generally* Marj P. Leaming, *Enlightened Regulation of Computerized Reservations Systems Requires a Conscious Balance Between Consumer Protection and Profitable Airline Marketing*, 21 TRANSP. L.J. 469 (1993) (describing history of regulation and litigation).

[24] 14 C.F.R. pt. 255 (1996). The initial version of the regulations was upheld by the Seventh Circuit. *See* United Airlines v. CAB, 766 F.2d 1107 (7th Cir. 1985) (Posner, J.) (upholding regulations based in part on threat that CRS owners would be able to discriminate against nonowner airlines and reduce competition).

[25] United States v. Airline Tariff Publishing Co., 1994-2 Trade Cas. (CCH) ¶ 70,687 (D.D.C. Aug. 10, 1994).

markets, through vehicles such as PBMs. Although there are complaints that the antitrust laws constitute an obstacle to such collective action, any such impediment is relatively limited. As an example, this section discusses joint buying and joint selling arrangements.

A. *Joint Buying*

Joint purchasing is an increasingly common feature of health care markets. Both health care providers (such as hospitals) and many of their customers (such as self-insuring employers) participate in joint buying activities, and hundreds of group purchasing organizations have been formed to purchase pharmaceuticals, medical equipment, and other goods and supplies.

The Supreme Court recognized the competitive benefits of joint purchasing arrangements in *Northwest Wholesale Stationers, Inc. v. Pacific Stationary & Printing Co.*[26] In holding that a wholesale buying cooperative's membership rules should be analyzed under the rule of reason, the Court analyzed its efficiencies, and observed that the type of purchasing cooperative operated by Northwest was "not a form of concerted activity characteristically likely to result in anticompetitive effects."[27] Wholesale buying cooperatives offered economies of scale in both the purchase and the warehousing of wholesale supplies, and assured access to goods on short notice. These efficiencies reduced costs and ultimately led to lower prices. Thus the Court concluded that these types of arrangements reduced cooperative members' costs, enabled members to compete effectively with larger firms, and led to lower prices.

Joint purchasing arrangements routinely have been upheld against antitrust challenges.[28] Virtually every case finding joint buying unlawful essentially has involved a naked price fixing conspiracy.[29] In such cases, the purchasers did not integrate purchasing or other operations to achieve efficiencies — either by buying jointly or offering sellers a guaranteed level of sales from the buyers as a group — but merely conspired to lower the price they paid for an input.

Guidance on the antitrust treatment of joint purchasing arrangements can be found in the Health Care Policy Statements, jointly issued by FTC and the Department of Justice's Antitrust Division.[30] The seventh of these policy statements provides that "most joint purchasing arrangements among hospitals or other health care providers do not raise antitrust concerns." Moreover, it creates a safety zone for certain joint purchasing arrangements among hospitals or other health care providers.[31] This safety zone covers purchasing arrangements where the joint purchases account for less than thirty-five percent of the total sales of the purchased product or service in the relevant market, and

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[26] 472 U.S. 284, 295 (1985).

[27] *Id.* at 295.

[28] *See* Webster County Memorial Hosp. v. United Mine Workers, 536 F.2d 419, 420 (D.C. Cir. 1976) (per curiam); Sewell Plastics, Inc. v. Coca Cola Co., 720 F. Supp. 1186, 1219-20 n.6 (W.D.N.C. 1988); Medical Arts Pharmacy v. Blue Cross & Blue Shield, 518 F. Supp. 1100, 1108 n.9 (D. Conn. 1981), *aff'd per curiam*, 675 F.2d 502 (2d Cir. 1982).

[29] *See, e.g.*, Mandeville Island Farms v. American Crystal Sugar Co., 334 U.S. 219 (1948) (conspiracy among three sugar refiners, collectively controlling 100% of the market, to purchase sugar beets at agreed-upon prices).

[30] Dep't of Justice & Fed. Trade Comm'n, Statements of Antitrust Enforcement Policy in the Health Care Area [Policy Statements], 4 Trade Reg. Rep. (CCH) ¶ 13,153 (Aug. 28, 1996); Business Review Letter from U.S. Dep't of Justice to Nickel Users' Purchasing Ass'n (June 2, 1993); Business Review Letter from U.S. Dep't of Justice to FRA Shippers' Ass'n (June 17, 1989).

[31] Policy Statements, *supra* note 30, at 20,812-13 (Statement No. 7).

the cost of products and services purchased jointly accounts for less than twenty percent of the total revenues from all products or services sold by each competing participant in the joint purchasing arrangement.

Outside of the safety zone there are many ways to structure the arrangement to avoid antitrust risk. As the statements set forth, competitive concerns may be eliminated where members are allowed to make purchases outside the group, where the group's negotiations are conducted through a negotiator who is not employed by one of the group's members, and where communications between the group and each individual member are kept confidential.[32]

The strictures of the safety zone help to ensure that the protected venture does not give rise to either of two potential competitive problems that may result from joint purchasing. The first is that the arrangement may account for such a large portion of the purchases of a product or service that the venture can exercise market power as a purchaser to depress prices below the competitive level and thereby reduce the quantity supplied below competitive levels. The second problem occurs when the products or services being purchased jointly account for so large a proportion of the total cost of services being sold by the participants that the purchasing arrangement, by standardizing costs, might facilitate price fixing or otherwise reduce competition among the competing joint venturers in the services they offer.

In the absence of these concerns, joint purchasing arrangements usually are competitively benign and a number of such arrangements have been approved under the Health Care Policy Statements.[33]

B. *Joint Selling: Pharmacy-Owned Joint Venture PBMs*

Perhaps the most interesting and more complicated question is whether groups of pharmacies can act collectively to form their own PBMs in a manner consistent with the antitrust laws. Unlike joint buying arrangements, this type of activity typically raises more significant competitive concerns — primarily because price setting may be involved. Recent experience, however, indicates that a pharmacy-owned PBM can operate consistently with the antitrust laws.

Antitrust concerns in analyzing the creation of a joint selling arrangement are generally twofold: is the arrangement a legitimate joint venture or simply a guise for collective price fixing, and can the arrangement raise prices through the exercise of market power?

1. *Legitimate or Sham*

Most of the antitrust guidance in this area involves joint ventures by health care providers. In a number of cases, FTC has challenged the formation of alleged joint ventures that were little more than thinly-disguised attempts by health care providers to defeat cost containment efforts. Efforts by pharmacists to band together simply to derail aggressive bargaining by managed care providers may be the subject of FTC enforcement efforts. Indeed, the Commission has approved several consent orders resolving allegations that groups of pharmacists had boycotted managed care providers that sought

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[32] *Id.* at 20,813.

[33] *See* Business Review Letter from U.S. Dep't of Justice to Bay Area Business Group on Health (Feb. 18, 1994); Business Review Letter from U.S. Dep't of Justice to Houston Health Care Coalition (Mar. 23, 1994); FTC Staff Opinion Letter to Elmore Community Hospital (June 20, 1995).

to reduce costs.[34]

What about when a group of pharmacies forms a PBM to compete in the PBM market? How can a joint venture PBM avoid antitrust risk? First, if a joint venture does not actually set prices, price-fixing concerns will not be present. One approach is to use what sometimes has been termed a "messenger" model.[35] Under a messenger model, the joint venture PBM provides potential plan sponsors with price and other information about the joint venture's likely pharmacy members, and transmits proposed contracts from payors, including fee schedules to be used under such contracts, to the pharmacy members for their individual consideration. Each pharmacy independently decides whether or not to accept the proposed contract offered by the payor. A messenger model does not appear to involve any horizontal agreement by competitors on terms of doing business, including price. It therefore generally would not raise concerns under antitrust law. In this situation, however, the venture also must ensure that the decisions by pharmacies on whether or not to accept the proposed contracts in fact are made individually, and do not involve any tacit or explicit agreement not to deal or to deal only on certain jointly agreed-upon terms. Pharmacy-owned PBMs using a messenger model have been allowed without challenge by antitrust agencies in the past.[36]

Pharmacy-owned PBM joint ventures might avoid antitrust challenge even when they engage in collective price setting. Joint price setting is generally permissible where the venture produces some type of efficiency through integration; that is, the joint venture and its associated restraints create an efficiency-enhancing integration of economic activity. There are two basic means of demonstrating such efficiencies: where the joint venture offers a product that the venture members could not offer individually, and where there is sufficient integration among the members of the venture. Both of these concepts could apply to pharmacy-owned PBM joint ventures.

To assess whether there is some type of efficiency, the new product inquiry asks the straightforward question whether the pharmacy members individually could offer the same product. PBM joint ventures, especially those between large numbers of localized community pharmacies, may have a very credible new product argument. For example, the purpose of this type of venture often is to enable small pharmacies to acquire the economies of scale and scope of large chain pharmacies. A joint venture PBM might create a new product in the form of a network that includes a computer system, point-of-sale claims processing and information gathering, a formulary, a group buying arrangement, and a joint sales agent. The joint venture could facilitate the functioning of the market by providing a claims transaction system and allowing for negotiations among a large number of market participants. It could provide benefits for pharmacy members, plan sponsors, and consumers by providing an efficient means of claim processing and utilization review. In addition, by amassing purchasing power, the joint venture might negotiate aggressively for discounts from pharmaceutical manufacturers on behalf of its members. This in turn could enable small pharmacies to compete more effectively with pharmacy chains in both the pharmacy and the PBM markets.[37]

Because new product efficiency inquiry focuses on the capabilities of the mem-

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[34] Maryland Pharmacists Association, No. 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).

[35] *See* Policy Statements, *supra* note 30, at 20,831 (Statement No. 9).

[36] Business Review Letter from U.S. Dep't of Justice to Robert Taylor, Antitrust Counsel, Pharmacy Care Network (Oct. 8, 1986).

[37] A group of independent pharmacies recently formed a national prescription drug network known as "American Family Pharmacy." *See* DRUG STORE NEWS, Dec. 9, 1996, at 33.

bers, a far more critical inquiry may be appropriate where the members are capable of competing independently in the PBM market. For example, a joint venture that consisted of all the largest chains in a single metropolitan area, each of which operated its own PBM, likely would have a more difficult time proving that its operation truly constituted a new product that its members could not put together on their own. On the other hand, a joint venture of pharmacies throughout the United States that sought to compete in the national PBM market might have a valid efficiency argument if individual members could not otherwise effectively compete in that market. Indeed, similar national accounts programs arising in other industries have been allowed without challenge by antitrust agencies in the past.[38] Analogously, PBM joint ventures[39] and a wide variety of other joint ventures have been allowed without challenge where the venture offered a product that the individual members were not capable of producing.

A related approach to determining whether joint price setting is permissible focuses on whether the joint venture has sufficient integration. The Health Care Policy Statements on physician joint ventures set a standard for integration that focuses on a variety of factors, including risk sharing. Risk sharing is important in this particular context because it can create a disincentive for individual health care providers to maximize their revenues through increasing the number of services they each render, to their individual benefit but to the harm of the joint venture. In the physician joint venture context, where the members bear substantial economic risk, each member has a direct stake in the success of the group as a whole and therefore has an incentive to ensure that all members practice high quality medicine and avoid unnecessary utilization of services.

The 1994 Health Care Policy Statements acknowledged that risk sharing may be achieved in any number of ways, and identified two examples of the more common varieties: capitation and fee-withhold arrangements. In August 1996, FTC and the Antitrust Division issued revised policy statements that amplified the types of activities that qualify as risk sharing.[40] Qualified activities now also include providing designated services or classes of services to a health plan for a predetermined fee,[41] or providing a complex or extended course of treatment that requires the substantial coordination of care of complimentary managed care providers.[42] In addition, the 1996 statements recognize cost containment incentives other than withholds (such as financial rewards).[43]

These standards were adopted for physician joint ventures only after several years of extensive investigation, law enforcement actions, academic commentary, and a lengthy dialogue with the industry. They were created in response to extensive law enforcement experience with sham joint ventures that allegedly were devised simply to frustrate cost containment efforts. Whether pharmacy-owned PBM joint ventures should be required to meet these standards for financial integration developed in the physician joint venture context is a question that will be evaluated carefully by law enforcement agencies.

Because the PBM environment is rapidly evolving, there are no simple answers;

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[38] *See, e.g.,* Business Review Letter from U.S. Dep't of Justice to Newspaper Ass'n of America (Dec. 10, 1993) (joint venture network for selling advertising space for national advertising campaigns); Business Review Letter from U.S. Dep't of Justice to Affiliated Distributor (May 5, 1992) (creation of joint venture to provide national accounts program); Business Review Letter from U.S. Dep't of Justice to Independent Drug Wholesalers Group (May 21, 1987) (creation of joint venture to provide national accounts program).

[39] Business Review Letters from U.S. Dep't of Justice to Robert Taylor, antitrust counsel, Pharmacy Care Network, & Frank Sanchez, coordinator, Service For You (Oct. 8, 1986).

[40] Policy Statements, *supra* note 30, at 20,814 (Statement No. 8).

[41] *Id.* at 20,816.

[42] *Id.*

[43] *Id.*

arguably, however, it may be inappropriate to transfer these standards in a wholesale fashion to the PBM setting because the reasoning behind the physician joint venture standards may not apply in the pharmacy joint venture context. For example, the policy statement standard uses financial incentives to meet cost-containment goals as one indicia of integration because of the concern that a member may attempt to "free ride" on the venture and overprescribe treatment;[44] this objective seems inappropriate in the pharmacy setting, because pharmacists do not prescribe treatment. More generally, the purpose of risk-sharing standards, in part, is to change member incentives to ensure that the venture members are committed fully to the success of the venture. In the pharmacy-owned PBM setting, there may be other equally probative evidence of commitment. For example, in a situation where a pharmacy-owned PBM joint venture produced something its members could not produce individually, the incentives of the members already may have been changed. Thus, for pharmacy-owned PBMs, other indicia of integration, such as financial investment and the creation of a network, may be sufficient.

This does not mean that cost containment measures such as capitation and withholds are not procompetitive. When they are present in a joint venture PBM, they will be recognized as an important efficiency. One of the significant recent innovations in PBMs is the use of capitated plans.[45] To require only a single path to demonstrate the existence of efficiencies, or to require a certain structure for these joint ventures, however, seems inappropriate because other methods of integration may evolve in this emerging market. Applying a single standard might prevent community pharmacists from collaborating and effectively competing in the PBM market.

2. *Analysis of Market Power*

Even where a venture is legitimate, the enforcement agencies will analyze whether there is the potential for the exercise of market power that could lead ultimately to higher prices to consumers. The concern is that a PBM joint venture, by combining an overly inclusive group of pharmacies, might be able to inhibit the formation of competing PBMs or prevent payors who wish to deal with pharmacists individually, rather than through the venture, from being able to enter and operate in the market. Two important factors in determining the likelihood of the exercise of market power are 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 whether the venture is overinclusive (in that it includes so high a proportion of competing providers in the market that a sufficient number of other actual or potential 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.

In terms of market power, the Health Care Policy Statements provide some guidance. The statement on physician network joint ventures provides that, absent extraordinary circumstances, federal antitrust enforcement agencies will not challenge an exclusive joint venture with a market share of twenty percent or less, or a nonexclusive venture with a market share of thirty percent or less.[46] Even outside this threshold, there

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[44] *Id.*

[45] *See* Robert McCarthy, *Is It Risky to Ride with a Drug Company?*, 14 BUS. & HEALTH 30 (1996); Anita R. McGahan, *Industry Structure and Competitive Advantage*, HARV. BUS. REV., Nov.-Dec. 1994, at 115; *Capitation: However You View It, It's a Potent New Force*, DRUG TOPICS, Jan. 23, 1995, at 40.

[46] Policy Statements, *supra* note 30, at 20,815.

are several ways that a venture can avoid antitrust risk, especially if it is nonexclusive.[47]

3. *Efficiencies*

Antitrust enforcers recognize the opportunities for efficiencies from collaboration, and there may be significant procompetitive benefits from the emergence of pharmacy-owned PBM joint ventures. These ventures increase competition by providing new entrants that offer new PBM services. The use of such joint venture PBMs (in subcontracting arrangements) by some of the largest PBMs demonstrates the value of the service in reducing transactions costs. Moreover, these ventures often enable community pharmacies to bear the transactions cost internalized in the structure of a chain pharmacy. Absent such ventures, these community pharmacies might not be able to participate in a PBM, and PBM consumers who would prefer to use their community pharmacy would have less choice.[48]

These ventures also may improve the efficiency and competitiveness of their members by aggregating buying power of both the pharmacies and 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). Because of the savings from the joint buying arrangement, small pharmacies are able to compete more effectively.

Finally, the existence of independent PBMs may help deter the opportunities for collusion or foreclosure that were at the center of FTC's concerns in the Eli Lilly-PCS matter. This does not mean 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 before condemning or indirectly inhibiting procompetitive collaborations that have the potential for improving the competitive process.

V. MOST FAVORED NATION PROVISIONS

Early in 1996, FTC accepted for public comment a consent agreement involving a pharmacy network's use of a most favored nation (MFN) clause, settling allegations that the clause restricted price competition.[49] This was the Commission's most recent order directed against the use of an MFN clause, a contractual provision that is increasingly a subject of antitrust enforcement.[50]

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[47] For example, the enforcement agencies have approved a number of nonexclusive physician or provider networks in which the percentage of participating physicians or providers in the market exceeded the 30% criterion of the safety zone. *See, e.g.*, Business Review Letter from U.S. Dep't of Justice to John F. Fischer, Oklahoma Physicians Network, Inc. (Jan 17, 1996) ("substantially more" than 30% of several specialties in a number of local markets, including more than 50% in one specialty); Business Review Letter from U.S. Dep't of Justice to Melissa J. Fields, Dermnet, Inc. (Dec. 5, 1995) (44% of board-certified dermatologists); Business Review Letter from U.S. Dep't of Justice to Dee Hartzog, Int'l Chiropractors' Ass'n of Cal. (Oct. 27, 1994) (up to 50% of chiropractors). *See also* Business Review Letter from U.S. Dep't of Justice to Frank Sanchez, coordinator, Service For You (Oct. 8, 1986) (approving PBM joint venture with market share between 30% and 50%).

[48] *See* Calvin H. Knowlton, Amer. Pharmaceutical Ass'n, Testimony before FTC Hearings on the Changing Nature of Competition in a Global and Innovation-Driven Age (Nov. 8, 1995) (describing the efficiencies from pharmacy-sponsored PBMs).

[49] RxCare of Tennessee, Inc., C-951 0059 (Jan. 18, 1996) (consent order).

[50] JOSEPH KATTAN & SCOTT A. STEMPEL, ANTITRUST ENFORCEMENT AND MOST FAVORED NATION CLAUSES; Anthony J. Dennis, *Most Favored Nation Contract Clauses Under the Antitrust Laws*, 20 DAYTON L. REV. 821 (1995). There are judicial decisions upholding the use of MFN clauses against antitrust challenge. *See,*

RxCare is the leading pharmacy network in Tennessee. It serves as the pharmacy network for approximately 2,400,000 Tennessee residents, which is well over half of the Tennessee citizens with third-party pharmacy benefits. Because the RxCare network is the largest source of their third-party business, Tennessee pharmacies as a practical matter must participate in the RxCare network and virtually all do participate. The Tennessee Pharmacists Association (TPA) owns RxCare.

RxCare member pharmacies signed an MFN clause that required an RxCare pharmacy that accepted a reimbursement rate lower than the RxCare rate to accept the lower reimbursement rate for all its RxCare business. RxCare's business is a large percentage of the pharmacies' third-party business. As a result, the clause made it very expensive for pharmacies to discount their reimbursement rates to other payers and thus they rarely did so. RxCare enforced the MFN clause. As a result, in the words of the complaint that accompanied the consent agreement, RxCare and TPA acted as "combination of competing pharmacies . . . to maintain reimbursement levels for pharmacy services. Their use of the MFN clause and other activities have restrained rivalry . . . among Tennessee pharmacies and thereby harmed consumers by limiting price competition and entry into pharmacy network services."[51]

Several factors explain the complaint allegations concerning FTC's challenge to the RxCare MFN clause, even though such clauses may be procompetitive. First, in contrast to pharmacy networks that PBMs establish, the pharmacies themselves established and controlled RxCare. This meant that although RxCare nominally operated as a purchaser of pharmacy services, as well as a seller, it lacked the same incentive as a "pure" purchaser to use the MFN clause as a device to lower prices. Indeed, the complaint alleged that RxCare sought to use the MFN clause to stabilize, rather than lower, prices. Moreover, according to the complaint, RxCare discouraged pharmacies from participating in rival networks seeking to offer prices below the RxCare level, by urging them to refrain from such participation, and by warning that acceptance of such rates might trigger the MFN clause.

Second, according to the complaint, RxCare possessed market power. Market shares traditionally are used to assess the level of market power, and in this case, virtually every pharmacy was a member of the RxCare network and thus subject to the MFN clause. Most pharmacies, however, also were part of rival networks offered by other payors and pharmacy benefit managers. What distinguished RxCare, according to the complaint, was its control over so many covered lives, because its clients included the major providers to Tennessee's Medicaid program. With so much business flowing through RxCare, pharmacies had to be part of the RxCare network and adhere to the MFN clause.

Third, according to the complaint, the MFN clause produced actual anticompetitive effects. According to the complaint, third-party payors frequently had to give Tennessee pharmacies the RxCare reimbursement rate, rather than the lower rates routinely given to pharmacies in other states. Indeed, according to the complaint, some chain pharmacies and payors had agreed to a national rate, but used the RxCare rate in Tennessee. The MFN clause thus injured consumers, according to the complaint, by effectively establishing the RxCare network rate as a price floor and by inhibiting the entry

e.g., Blue Cross and Blue Shield United of Wisconsin v. Marshfield Clinic, 65 F.3d 1406, 1415 (7th Cir. 1995) (MFN clauses "are standard devices by which buyers try to bargain for low prices"); Ocean State Physicians Health Plan, Inc. v. Blue Cross and Blue Shield of Rhode Island, 883 F.2d 1101 (1st Cir. 1989), *cert. denied*, 494 U.S. 1027 (1990).

[51] RxCare Complaint ¶ 8.

of lower-priced pharmacy networks.

Nevertheless, a great deal of what RxCare does may be good for both Tennessee pharmacies and consumers. As FTC Commissioner Varney noted when the proposed consent agreement was accepted for public comment, "[J]oint ventures by retail pharmacists can be procompetitive by injecting new competition into the market for pharmacy benefit management services."[52] In particular, the complaint did not challenge RxCare efforts to improve health care by enhancing quality and controlling costs by, for example, educating pharmacists. Nor did the FTC require the dissolution of RxCare or restrict its size. Indeed, the Commission's order was very narrow; it prohibited only the use of the MFN clause, the only RxCare activity that, according to the complaint, injured competition.

VI. BOYCOTTS

There is one area where pharmacists, like many health care providers, must act with great caution: attempting to boycott cost control efforts by managed care providers. From an antitrust perspective, the rule is relatively straightforward. If parties choose not to participate in a cost containment program, they face no antitrust risk. If they act collectively to derail or boycott cost containment efforts, however, antitrust risks may be substantial.

Price-fixing concerns are raised when competing providers of goods band together to oppose cost-containment efforts. FTC's 1994 consent agreement in the *Maryland Pharmaceutical Association* matter settled charges that the members of the Maryland Pharmacists Association and the Baltimore Metropolitan Pharmaceutical Association illegally conspired to boycott a plan for Baltimore City government employees.[53] The city had made available to its employees and retirees a plan under which the plan manager, an insurance company, compensated pharmacies directly under a specified formula. According to the allegations in the complaint, when the insurance company proposed a reduction in reimbursement rates, the two associations reacted by organizing their member pharmacists to refuse to participate in the plan under the reduced rates. More particularly, the Commission's complaint charged that the associations orchestrated a group boycott by their member pharmacies of the pharmacy benefit program, in response to the proposed reimbursement reduction. According to the complaint, the associations sought to restore the plan's original reimbursement rate through their boycott efforts. The associations allegedly notified their members of the number of participating pharmacies required by the benefit contract, requested their members to notify them of their decisions regarding participation, kept a list of members who were planning not to participate, and informed their members when a sufficient number of them had agreed to stop participating to put the plan in violation of its contract. The complaint further asserted that the pharmacies in fact did refuse to participate and the insurer that ran the benefit plan raised the reimbursement rate. The consent order prohibits the associations from entering into, organizing, or encouraging any agreement among pharmacies to refuse to enter into or to withdraw from any participation agreement offered by a third-party payor.

In the *Chain Pharmacy Association of New York State* matter,[54] FTC charged nu-

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[52] RxCare of Tennessee, Inc. (statement of Christine A. Varney, Comm'r, FTC).

[53] Baltimore Metropolitan Pharmaceutical Ass'n, Inc. et al., 59 Fed. Reg. 15,733 (Apr. 4, 1994) (consent order).

[54] Peterson Drug Co. of North Chili, New York, Inc., Trade Reg. Rep. (CCH), Complaints and Orders

merous retail pharmacy chains, their trade associations, independent pharmacy trade associations, and two individuals with illegally agreeing to boycott New York State's Employee Prescription Plan. The complaints accompanying several consent agreements alleged that the purpose of the boycott was to force the state plan to increase its reimbursement rate for prescriptions. The Commission issued an administrative complaint against one respondent, Peterson Drug Company, and an FTC administrative law judge thereafter issued an initial decision finding that Peterson illegally agreed to boycott the plan. When Peterson declined to pursue the litigation, the Commission adopted the administrative law judge's initial decision as its own. The other respondents in the matter agreed to settle with the Commission through the issuance of cease and desist orders. According to the Administrative Law Judge, the alleged agreements may have cost consumers up to $7,000,000.[55]

As these two cases demonstrate, the Commission will not hesitate to challenge collective action among pharmacies that seeks to forestall efforts to lower prices. Pharmacies, however, can collaborate to petition a governmental body under the *Noerr-Pennington* doctrine, which provides First Amendment protection for petitioning the government and seeking redress through the judicial process.[56] All of the consent orders discussed above contained safe harbors for *Noerr-Pennington* protected activity.

VII. CONCLUSION

As with other aspects of the health care environment, managed care is having a tremendous impact on pharmaceutical delivery and competition. Both drug manufacturers and pharmacies face many challenges in adapting to this "whole new world." Antitrust enforcement has a vital role to play here; to ensure that markets develop effectively and without undue impediments.

1987-93, at ¶ 23,189; Orange County Pharmaceutical Soc'y, Inc., No. C-3292 (July 9, 1990); Westchester County Pharmaceutical Soc'y, Inc., No. C-3293 (July 9, 1990); Pharmaceutical Soc'y of the State of New York, Inc., No. C-3294 (July 9, 1990); Long Island Pharmaceutical Soc'y, Inc., No. C-3295 (July 9, 1990); Empire State Pharmaceutical Soc'y, Inc., D. 9238 (Feb. 22, 1991); Capital Area Pharmaceutical Soc'y, Inc., D-9239 (Feb. 22, 1991).

[55] *Peterson Drug Company,* Trade Reg. Rep. (CCH), Complaints and Orders 1987-93, at 22,883.

[56] Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961); United Mine Workers v. Pennington, 381 U.S. 657 (1965). There is a sham exception to the *Noerr-Pennington* doctrine. The Supreme Court has stated that where one uses "the governmental process — as opposed to the outcome of that process — as an anticompetitive weapon," the protection of the *Noerr-Pennington* doctrine may not apply. Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 46, 55 (1993) (quoting Columbia v. Omni Outdoor Advertising, Inc., 499 U.S. 365, 380 (1991)).