

## COLLUSION ON STRUCTURE OF PRESCRIPTION DRUG FORMULARIES WOULD VIOLATE ANTITRUST LAWS

by

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Many prescription drug benefit plans include a drug formulary as part of their cost containment effort. Distinctions in the breadth of these formularies are an important means by which managed care plans compete. Managed care plans balance access to a wide array of prescription drugs and affordable co-payment levels, on the one hand, with premium levels on the other. Consumers should have the benefit of this competition and be free to make choices about what they purchase, rather than having those choices restricted unlawfully by collusion among managed care plans.

Recent press accounts suggest that just such unlawful collusion may be occurring in the design of prescription drug plan formularies. If these reports are accurate, managed care companies may be agreeing among themselves as to the structure of their plan formularies. Conduct of this sort would fit squarely into the category of hardcore anticompetitive practices outlawed by the antitrust laws.

**Background on Managed Care Prescription Drug Formularies.** Prescription drug formularies are an outgrowth of hospital-based formularies, which first became prevalent in the 1950's and 1960's. Formularies are now used by a wide range of managed care organizations outside the hospital setting, particularly pharmaceutical benefit managers.

In simplest terms, a formulary is a list of prescription drugs approved for insurance coverage. A formulary seeks "high-quality medical care, rational prescribing, effective utilization review, and control of costs. . ." U.S. Dep't of Health Education and Welfare, *Task Force on Prescription Drugs: Final Report* at 40 (1969). Formularies vary on a number of criteria, among the more important of which are whether the formulary is:

- Open, closed, or partially closed.** An open formulary is a relatively comprehensive list of drugs with few if any restrictions on providers. A closed formulary is a limited list of drugs chosen by the formulary's Pharmacy and Therapeutics Committee. Only medications on this closed list may be covered.
- Restricted or incentivized.** For example, whether generic drug substitution is required or merely incentivized, or whether the formulary promotes the use of preferred products through economic reward to the physician, the dispenser, or the patient.

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The use of prescription drugs has significantly increased over the course of the last several decades.<sup>1</sup> At the same time, there has been a shift in health care insurance away from traditional fee-for-service reimbursement to a managed care environment. The surge in enrollment in managed care organizations led to the increased use of outpatient drug formularies.

The design of a managed care plan's pharmaceutical benefit is an important driver in consumer acceptance. Studies have shown that elements of drug formulary design — for example, whether the formulary is open or closed, whether generic substitution is mandatory or merely cost-incentivized — are the most important attributes in determining consumer preference for a prescription drug benefit plan.<sup>2</sup> In simplest terms, formularies matter when consumers determine what choices to make in health care.

Similarly, formulary design directly affects the price of any drug benefit. Closed formularies generally offer the greatest potential for cost savings to the managed care organization. In return for greater prescription volumes driven by less choice, plan designers often extract greater discounts from the manufacturers. Cost savings then flow through to reduced premium amounts or co-pay amounts. Consumers trade choice for cost. Conversely, greater drug choice — a completely open formulary, for example, where every conceivable drug choice is equally reimbursable — ordinarily leads to higher premium cost and perhaps higher co-pay amounts.

***Potential Collusion in the Design and Structure of Drug Plan Formularies.*** Because formulary design makes a difference as a matter of consumer choice, health care plans compete to offer more attractive formulary options. Consumers should benefit from competition in the design of their prescription drug formularies and be free to make choices about what they purchase, rather than having those choices restricted unlawfully by collusion among managed care plans.

Recent press accounts suggest that just such unlawful collusion may be occurring in the design of prescription drug plan formularies. In particular, there have been reports that pharmacy officers for some of the country's largest managed care health plans have discussed with one another whether particular medications should be included in drug plans.

For example, the following item was recently reported by a major news source:

Some of the nation's biggest health insurers . . . will likely . . . erect[ ] barriers to rivals of the waning blockbuster allergy drug Claritin once it goes over the counter . . . "These are clearly interchangeable products [referring to Pfizer's ZYRTEC®, Aventis' ALLEGRA®, and Schering-Plough's CLARINEX®]," said William Fleming, chief pharmacy officer at Humana, one of the biggest U.S. health insurers. ***"I've gone out and talked to a lot of our competitors and most folks are looking to put those drugs" into their most pricey drug option.***<sup>3</sup>

There have been similar efforts to keep off of formularies such improved products as Astra Zeneca's

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<sup>1</sup>In large part, this is due to the surge in medications used to prevent serious conditions or reduce the need for more costly treatments, hospitalization, or surgeries. Outpatient prescription drug costs have risen from 4.9% of the total U.S. health care costs in 1980 to 8.2% in 1999, and are projected to be 9.0% of total costs in 2001. Source: Health Care Financing Administration data. *Pharmaceutical Industry Profile 2001* at p. 42.

<sup>2</sup>See, e.g., Drs. David Holdford & Norman V. Carroll, *Consumer Preferences for Types of Cost Containment in Prescription Drug Programs*, 8 J. MANAGED CARE PHARMACY 192, 194-95 (May/June 2002) (describing results of study of 130 consumers asked to evaluate hypothetical managed prescription drug plan profile based on three attributes: access to pharmacy, patient cost-sharing, and formulary restrictiveness).

<sup>3</sup>Kim Dixon, *More U.S. Insurers to Restrict Claritin Rivals*, Reuters News (Sept. 10, 2002) (emphasis supplied). For a sampling of other press accounts that suggest similar problems, see: *Health Insurers Watch Industry Before Committing to Changes on Allergy Drug*, BEST'S INSURANCE NEWS (Sept. 12, 2002); *Insurer News — Claritin: Once OTC, Insurers May Limit Coverage of Rivals*, AMERICAN HEALTH LINE (Sept. 13, 2002).

NEXIUM® (successor to the anti-ulcer medication PRILOSEC®) or Bristol-Myers Squibb’s extended release version of a medication for type II diabetes, GLUCOPHAGE XR®, or products deemed “lifestyle” drugs such as VIAGRA®. Such agreements would make these products unavailable to consumers who are unable or unwilling to pay an artificially inflated co-payment price, or cause consumers who do purchase these drugs on the advice of their physicians to pay a higher price.

***Agreeing on Significant Terms of Trade — Price, Quality, Content — is Illegal.*** One of the most basic precepts in antitrust law is that competitors cannot agree among themselves on significant terms of trade, particularly price or factors that affect price such as product design. Restricting free and open price competition must be avoided because it poses an “actual or potential threat to the central nervous system of the economy.” *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 224-226 n.59 (1940). Arrangements among competitors that affect price are so noxious that they are said to be illegal *per se* — that is, illegal regardless of the alleged merits of the activity, the reasonableness of the fixed price, or the business rationale for the conduct.

In a seminal case, decided early in the history of the Sherman Antitrust Act, the Supreme Court wrote:

The aim and result of every price-fixing agreement, if effective, is the elimination of one form of competition. The power to fix prices, whether reasonably exercised or not, involves power to control the market and to fix arbitrary and unreasonable prices. . . . Agreements which create such potential power may well be held to be in themselves unreasonable or unlawful restraints, without the necessity of minute inquiry whether a particular price is reasonable or unreasonable as fixed . . .

*United States v. Trenton Potteries Co.*, 273 U.S. 392, 397-98 (1927).

It is not a significant extension of the *per se* prohibition on price fixing to condemn agreements among competitors that have an indirect, but nevertheless significant, impact on prices charged to consumers. Collusion among competitors involving product design or the range of product offerings is garden variety unlawful conduct.

For example, in *Nat’l Macaroni Mfrs. Ass’n v. F.T.C.*, 345 F.2d 421, 426 (7<sup>th</sup> Cir. 1965), members of a trade association engaged in *per se* illegal price fixing when they responded to a market shortage of durum wheat by adopting a resolution calling for production of all macaroni with a reduced durum wheat content, an action that affected both the quality of the products offered by the industry as well as the prices paid for durum wheat. The court of appeals held:

[W]here all or the dominant firms in a market combine to fix the composition of their product . . ., they violate the rule against price fixing agreements as it has been laid down by the Supreme Court.

Concluding, the court also wrote:

It makes no difference whether the motives of the participants are good or evil; whether the price fixing is accomplished by express contract or by some more subtle means; whether the participants possess market control; whether the amount of interstate commerce affected is large or small; or whether the effect of the agreement is to raise or to decrease prices.

*Nat’l Macaroni Mfrs.*, 345 F.2d at 427 (quoting *United States v. McKesson & Robbins, Inc.*, 351 U.S. 305, 309-10 (1956)).

Similar efforts by producers of competing products to standardize their products or methods of competing, or to adopt a common approach to product design, have been struck down as well. For example:

1. *In re Detroit Auto Dealers Ass'n*, 955 F.2d 457, 472 (6<sup>th</sup> Cir.), *cert. denied*, 506 U.S. 973 (1992) (action against association of Detroit-area auto dealers who agreed among themselves to close their showrooms all day Saturday and on three weekday evenings). “[W]e do not find error in the Commission’s conclusion that hours of operation in this business is a means of competition, and that such limitation may be an unreasonable restraint of trade.” (footnote omitted).
2. *U.S. v. Motor Vehicle Mfrs. Ass’n*, 643 F.2d 644 (9<sup>th</sup> Cir. 1981) (extending government consent decree negotiated with major U.S. auto manufacturers that terminated a conspiracy among manufacturers to, *inter alia*, delay installation of air pollution control equipment and to not compete in development of new air pollution control solutions).
3. *United States v. Nat’l Ass’n of Broadcasters*, 536 F. Supp. 149, 163 (D. D.C. 1982) (challenge to advertising standards adopted by trade association of television broadcasters; standards sought to limit on the number of minutes per broadcast hour devoted to network or local TV commercials, the number of commercials aired in a given hour, and the number of products that may be advertised on certain types of commercials.) Holding *per se* illegal the NAB’s “multiple product” standard, while reserving for trial judgment on the other standards, the court wrote:

There is no question that the fixing of prices is illegal *per se*. . . . This *per se* rule is not limited to agreements which fix price directly; it extends to any agreement which “interfere[s] with the setting of price by free market forces.” . . . Included under the rubric of *per se* illegality are agreements between competitors which limit the production or supply of a product, the obvious reason being that an artificial limitation on supply normally has a direct effect on price.

*Id.* at 155, quoting *United States v. Container Corp. of America*, 393 U.S. 333, 337 (1969) (other citations omitted).

**Conclusion.** Managed care competitors cannot collude on the shape or nature of their insurance programs or formulary offerings. Limiting or eliminating choice by agreement among competitors is bad for consumers. While managed care cost control is a laudable goal, it should not be achieved by unlawful collusion. Conduct of this nature without justification is condemned absolutely, and without detailed analysis, and is subjected to the harshest penalties under the antitrust laws, because of its “pernicious effect on competition and lack [of] . . . any redeeming virtue,” *Northern Pac. Ry v. United States*, 356 U.S. 1, 5 (1958), and because it is a “naked restraint[ ] of trade with no purpose except stifling of competition.” *White Motor Co. v. United States*, 372 U.S. 253, 263 (1963).