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## **UNITED STATES COURT OF APPEALS**

## FOR THE SIXTH CIRCUIT

J.B.D.L. CORPORATION, MCHUGH PHARMACY WYNNEWOOD, INC. and THE CERTIFIED DIRECT PURCHASER CLASS (05-3988); CVS MERIDIAN, INC. and RITE AID CORPORATION (05-3860), *Plaintiffs-Appellants*,

Nos. 05-3860/3988

v.

WYETH-AYERST LABORATORIES, INC., Defendant-Appellee.

> Appeal from the United States District Court for the Southern District of Ohio at Cincinnati. Nos. 01-00704; 03-00781— Sandra S. Beckwith, Chief District Judge.

> > Argued: November 28, 2006

Decided and Filed: May 10, 2007

Before: DAUGHTREY and GIBBONS, Circuit Judges; EDMUNDS, District Judge.

#### COUNSEL

**ARGUED:** Steve D. Shadowen, HANGLEY, ARONCHICK, SEGAL, & PUDLIN, Harrisburg, Pennsylvania, Eugene A. Spector, SPECTOR, ROSEMAN & KODROFF, Philadelphia, Pennsylvania, for Appellants. Douglas L. Wald, ARNOLD & PORTER, Washington, D.C., for Appellee. **ON BRIEF:** Steve D. Shadowen, HANGLEY, ARONCHICK, SEGAL, & PUDLIN, Harrisburg, Pennsylvania, Eugene A. Spector, Jay S. Cohen, SPECTOR, ROSEMAN & KODROFF, Philadelphia, Pennsylvania, Peter R. Kohn, Eric L. Cramer, BERGER & MONTAGUE, Philadelphia, Pennsylvania, Theresa L. Groh, MURDOCK, GOLDENBERG, SCHNEIDER & GROH, Cincinnati, Ohio, for Appellants. Douglas L. Wald, Asim Varma, David S. Eggert, ARNOLD & PORTER, Washington, D.C., Grant S. Cowan, FROST, BROWN & TODD, Cincinnati, Ohio, Daniel K. Webb, W. Gordon Dobie, Peggy M. Balesteri, WINSTON & STRAWN, Chicago, Illinois, for Appellee.

The Honorable Nancy G. Edmunds, United States District Judge for the Eastern District of Michigan, sitting by designation.

## **OPINION**

JULIA SMITH GIBBONS, Circuit Judge. This litigation arose out of efforts by appellee, Wyeth-Ayerst Laboratories, Inc., to protect its market share in the oral estrogen replacement therapy market through the use of contractual agreements with third-party payer entities. Appellants, wholesale and retail purchasers, brought suit against Wyeth under § 2 of the Sherman Act, alleging that, as a result of Wyeth's allegedly anticompetitive conduct, they were subject to increased prices on one of Wyeth's drugs. On Wyeth's motion, the district court granted summary judgment on appellants' § 2 claim, and this consolidated appeal followed.

For the reasons below, we affirm.

#### I.

Plaintiffs-appellants, J.B.D.L. Corporation ("J.B.D.L.") and McHugh Pharmacy Wynnewood, Inc. ("McHugh"), are the named representatives of a certified class of pharmaceutical wholesalers and retailers that purchased Premarin, an estrogen replacement medication, directly from defendant-appellee Wyeth-Ayerst Laboratories, Inc. ("Wyeth"). Plaintiffs-appellants CVS Meridian, Inc. and Rite Aid Corporation opted out of the class and filed suit separately. On appeal, the class and individual appellants have adopted each other's briefs in their entirety, and we refer to them collectively as "the Purchasers."

Wyeth produces Premarin, a brand-name prescription conjugated estrogen replacement medication.<sup>1</sup> Premarin is a form of estrogen replacement therapy ("ERT") prescribed to treat women who have undergone hysterectomies and whose bodies no longer produce estrogen.<sup>2</sup> Wyeth produces, in addition to Premarin, other hormone therapy drugs, including Premphase and Prempro. Together, the three drugs constitute the "Premarin Family."

Wyeth's dominance in the field of oral ERT drugs is undisputed by the parties. Premarin was approved for marketing in the United States in 1942. Until 1999, Premarin was the only conjugated ERT available and, between 1999 and 2003, prescriptions for Premarin consistently accounted for more than 70 percent of the prescriptions written for oral ERT drugs. In 2000, Wyeth's sales of Premarin generated revenues of nearly \$1 billion.

In March 1999, Duramed Pharmaceuticals, Inc. ("Duramed") won Food and Drug Administration ("FDA") approval for Cenestin, making Cenestin the second branded conjugated ERT drug on the market. Cenestin differs from Premarin in certain notable ways. While Premarin is composed of estrogen extracted from horse urine, Cenestin is made up of nine synthetic estrogen components chemically derived from plant material. Although Cenestin, like Premarin, is approved for the treatment of vasomotor symptoms associated with menopause, it is not approved for long-term use, in the prevention of osteoporosis, for example.

<sup>&</sup>lt;sup>1</sup>The conjugation of estrogen products increases the solubility of the medication in order to increase absorption into the bloodstream.

<sup>&</sup>lt;sup>2</sup>Drugs for post-menopausal women who have not undergone a hysterectomy are hormone replacement therapies ("HRTs"). This case concerns ERTs only.

According to the Purchasers, Wyeth viewed Cenestin's entrance into the oral ERT market<sup>3</sup> as a threat and acted accordingly to limit Cenestin's success. It is undisputed that Wyeth developed the Premarin Preemptive Plan ("Preemptive Plan") upon Cenestin's FDA approval. The overarching aim of the Preemptive Plan was to hold Cenestin to 2 percent of total ERT prescriptions in 1999 by: (1) emphasizing to consumers the differences between Premarin and Cenestin; (2) limiting Cenestin distribution; and (3) limiting Duramed's contracting opportunities in the ERT markets.

In this appeal, the Purchasers focus on the second and third strategies, specifically, Wyeth's attempts to limit Cenestin's distribution through the use of restrictive contractual arrangements with pharmacy benefit managers ("PBMs") and managed care organizations ("MCOs"). MCOs, which include health maintenance organizations and preferred provider organizations, may independently manage their prescription drug benefit program or employ the services of an organization, a PBM, that specializes in pharmacy benefit management. Although the parties provide lengthy discussions of the distinctions between PBMs and MCOs, those distinctions are irrelevant here, and it is sufficient to know that these entities represent a significant part of the third-party payer sector. We treat them identically and refer to them collectively as "MCOs."

As one expert explained, MCOs "are not typically direct purchasers of brand-name pharmaceuticals," but "they influence which products are available to members, and therefore which drugs are purchased" by making decisions about the drugs for which they will pay. Organizational structures known as "formularies" reflect these decisions. Formularies are, generally, a listing of medications for which an MCO provides coverage. They come in a variety of forms. An MCO with an "open formulary" structure will pay for drugs that are not on the formulary. A provider utilizing a "closed formulary," by contrast, will not cover the costs of drugs not included on the formulary. MCOs also use incentive-driven formularies, wherein differing co-payments or other financial consequences associated with particular drugs are meant to influence selection.<sup>4</sup> Because a drug's inclusion on an MCO's formulary can dictate prescription choices for patients covered by MCOs, drug manufacturers seek to secure inclusion on MCO formularies as well as favorable placement within those formularies through financial rewards, including rebates, to MCOs.

Rebates awarded in return for advantageous formulary placement constituted a central part of Wyeth's efforts to maintain Premarin's market position. In 1996 and 1997, prior to Cenestin's approval by the FDA, Wyeth entered into a number of reimbursement agreements with MCOs. Those agreements promised rebates on a number of Wyeth pharmaceuticals, including Premarin and the other members of the Premarin Family, subject to a variety of conditions. In challenging these agreements, the Purchasers take particular issue with Wyeth's use of so-called "sole conjugated estrogen" or "sole CE" clauses, which, as their name suggests, required Premarin's placement on formulary as the only conjugated estrogen drug. For example, the terms of the reimbursement agreement between Wyeth and Advance Paradigm conditioned payment of rebates on the listing of Premarin, Prempro, and Premphase on formulary as "the sole conjugated estrogen-containing products." The rebate agreement between Aetna Health Management, Inc. and Wyeth required that the Premarin Family be the "only preferred hormone replacement therapy product[s]" on formulary. Wyeth's agreement with Medco Containment Services, Inc. required that Medco identify Premarin as the "exclusive branded conjugated estrogen" and the "preferred branded estrogen replacement therapy" on its Plan Formulary. Similarly, OHP Health Plan was entitled to rebates if the Premarin

<sup>&</sup>lt;sup>3</sup>The parties agree that this is the relevant market.

<sup>&</sup>lt;sup>4</sup>For example, certain companies maintain "two-tier" co-payment structures, whereby insureds pay a certain co-payment for generic drugs and a higher co-payment for brand name medications. Other branded pharmaceuticals not included on formulary are not covered. In a "three-tier" structure, a member of a health plan is charged an even higher co-payment for non-formulary drugs, but such a system, unlike a two-tiered plan, does permit some coverage for non-formulary drugs.

Family was listed as the "exclusive conjugated estrogen replacement therapies and the sole preferred estrogen replacement therapies on Formulary." As of January 1, 2000, Wyeth had rebate contracts with 74 MCOs and, of those, 31 contained sole CE clauses preventing the MCO from including in its formulary any other conjugated estrogen therapy.

The agreements also included incentives for MCOs to assist in maintaining Premarin's market share. In its reimbursement agreements, Wyeth consistently tied the size of rebates to the market share of a particular class of drugs, with a sufficiently low market share resulting in the loss of all rebates on particular products. For instance, Wyeth's reimbursement agreement with Coventry promised the award of rebates if the Premarin Family market share did not fall below 72 percent. If the market share held by the Premarin Family fell below 81 percent, Keystone Mercy Health would be entitled to no rebates on those products. Likewise, the size of rebates for OHP Health Plan was directly tied to the maintenance of Wyeth's share in the estrogen replacement market, with OHP receiving no rebates on Premarin Family products if the market share fell below 77 percent.

Another important part of the Preemptive Plan was making MCOs aware of the costs of placing Cenestin on formulary or allowing Cenestin to encroach on Premarin's market share. In other words, Wyeth sought to "[q]uantify the value" of the Wyeth reimbursement agreements. To that end, Wyeth constructed the Cenestin Impact Model to demonstrate the effects of increased Cenestin market share on MCOs' entitlement to Wyeth rebates. For example, using this model, Wyeth determined that Pacificare, a large MCO, would have saved approximately \$100,000 on the lower-priced Cenestin, but would have simultaneously lost nearly \$4 million dollars in rebates from Wyeth if Cenestin obtained between 3 and 4 percent of the national market share.

Wyeth recognized the importance of the MCO market and its contractual arrangements. An internal Wyeth communication reads:

I still encourage our looking at a defense tactic involving our contracted customers – HMOs and PBMs – where we motivate them to block retail substitution. We are the incumbent and small incremental rebates/discounts can have a major financial impact for our customers, moving them to do something to stop Duramed and the Retailers. If we do nothing with our contracts, our customers will not actively work against us, but they won't help us either.

A manager of national accounts at Wyeth e-mailed:

The approval of Cenestin is a significant challenge to our [women's] health care franchise. We must take every opportunity to communicate to our Trade, MCO, GPO, LTC and Federal Government customers accurate clinical information about the Premarin family of products and the associated bundle of benefits. In addition, we must reinforce those managed care contractual arrangements that identify Premarin as the exclusive conjugated estrogen on formulary.

<sup>&</sup>lt;sup>5</sup>One of the parties' few disagreements over the facts concerns whether an MCO stood to lose the rebates on all Wyeth pharmaceuticals if it put Cenestin on formulary or if it forfeited only those rebates on the products in the Premarin Family. Wyeth rejects the Purchasers' claim that Wyeth threatened to deny rebates on all of its products if an MCO violated a sole CE clause. As we read the agreements, where a reimbursement contract included a sole CE clause, an MCO's inclusion of another conjugated estrogen therapy, like Cenestin, would preclude receipt of rebates on any Wyeth pharmaceuticals covered by the reimbursement agreement, not just the Premarin Family. A Wyeth executive confirmed this reading, testifying during his deposition that it was Wyeth's position that an MCO's decision to place Cenestin on its formulary after signing a sole CE clause would constitute a violation of the terms of the entire rebate agreement, entitling Wyeth to refuse to pay rebates on any Wyeth products.

In some instances, where it appeared that an MCO might be considering Cenestin more seriously, Wyeth intervened. An internal e-mail details a meeting with an executive at Express Scripts: "He started out by saying that they had a small but persistent group of clients [who] were insisting on having Cenestin available and he 'needed' to renegotiate the contract. I replied that under no circumstances would we agree to do this and reminded him that they are receiving over \$40 million in rebates per year that would be at risk." In the case of Express Scripts, Wyeth was, apparently, responsible for Duramed's failure to acquire formulary status for Cenestin. Express Scripts notified Duramed by letter in November 1999 that "a pre-existing relationship with Wyeth Ayerst . . . prevents us from entering into a contractual relationship with Duramed at this time." A Wyeth memorandum notified employees of Wyeth's success in blocking Cenestin's access to the Express Scripts formulary.

The Purchasers' Sherman Act claim focuses on Wyeth's use of its relationships with MCOs to maintain its position within the oral ERT market and its aggressive enforcement tactics in ensuring compliance with these agreements. They assert that, at the same time that Wyeth was effectively limiting Cenestin's success, it was increasing the price for Premarin. They claim they paid more for Premarin due to price increases adopted by Wyeth as a result of its successful campaign to limit Cenestin's market share.

On October 12, 2001, J.B.D.L. and McHugh filed suit against Wyeth on behalf of a class of purchasers of Premarin, alleging that Wyeth engaged in unlawful monopolization in violation of § 2 of the Sherman Antitrust Act and that, as a consequence, they overpaid for Premarin. *JBDL Corp. v. Wyeth-Ayerth Labs.*, 01-CV-704-SSB-TSH.<sup>6</sup> CVS and Rite Aid opted out of the class and independently filed suit against Wyeth on November 11, 2003, alleging an identical violation of the federal antitrust statute. *CVS Meridian, Inc. v. Wyeth-Ayerst Labs., Inc.*, 03-CV-781-SSB. The district court consolidated the cases, and the actions proceeded jointly for pretrial and trial purposes. Wyeth filed a motion for summary judgment, asserting that the Purchasers failed to raise a genuine issue of material fact concerning Wyeth's alleged improper monopolization and failed to demonstrate antitrust injury or a causal connection between any alleged injury and Wyeth's actions. On June 13, 2005, the district court issued an order granting Wyeth's motion against all of the Purchasers failed to provide evidence that Wyeth harmed competition rather than a single competitor; (2) the Purchasers did not demonstrate that Wyeth's aggressive marketing campaign violated the strictures of § 2 of the Sherman Act; and (3) there was no evidence of a causal link between Wyeth's alleged anticompetitive conduct and the antitrust injury alleged by the Purchasers.

The Purchasers filed timely notices of appeal, and a panel of this court consolidated the appeals.

### II.

We review the district court's grant of summary judgment *de novo*. *Williams v. Mehra*, 186 F.3d 685, 689 (6th Cir. 1999). Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). A "material" fact is one "that might affect the outcome of the suit." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). This court views the evidence and draws all reasonable inferences in favor of the non-moving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

<sup>&</sup>lt;sup>6</sup>The Purchasers also alleged a violation of § 1 of the Sherman Act, but have abandoned that claim on appeal. Duramed also filed an antitrust suit against Wyeth, which was settled prior to trial.

#### III.

Section 2 of the Sherman Act provides:

Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding \$100,000,000 if a corporation, or, if any other person, \$1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

15 U.S.C. § 2. Section 4 of the Clayton Act permits a private suit for violations of § 2 and the recovery of treble damages to those who succeed on their claims under the Sherman Act. 15 U.S.C. § 15. A successful claim under § 2 of the Sherman Act requires a two-pronged showing: (1) that defendant possessed monopoly power in the relevant market and (2) that defendant engaged in the "willful acquisition, maintenance, or use of that power by anti-competitive or exclusionary means as opposed to 'growth or development resulting from a superior product, business acumen, or historic accident." Conwood Co., L.P. v. U.S. Tobacco Co., 290 F.3d 768, 782 (6th Cir. 2002) (quoting Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 595-96 (1985)). In addition, in this circuit, an antitrust plaintiff must show that (1) the alleged violation tended to reduce competition overall and (2) the plaintiff's injury was a consequence of the resulting diminished competition. Conwood, 290 F.3d at 788-89. The plaintiff "bears the burden of showing that the alleged violation was a material cause of its injury, a substantial factor in the occurrence of damages or that the violation was the proximate cause of the damage." Id. at 788. The defendant's actions need not be the sole proximate cause of any alleged injuries, but "must be proved as a matter of fact and with a fair degree of certainty." Ezzo's Invs., Inc. v. Royal Beauty Supply, Inc., 243 F.3d 980, 990 (6th Cir. 2001).

The Purchasers accuse Wyeth of using the Preemptive Plan to suppress Cenestin's market share and insist that Wyeth increased Premarin's price as a result of the success of those efforts. The district court disagreed, noting the absence of evidence showing that Wyeth's activities in the MCO market caused the increased price injury alleged by the Purchasers. We agree with the district court that the evidence in the record does not create a genuine issue of material fact as to the causal relationship between the Premarin Preemptive Plan and an increase in the price of Premarin and accordingly affirm.

The Purchasers' theory of causation relies on two premises: first, that Wyeth's activities to secure its predominant position in the oral ERT market effectively suppressed competition in the oral ERT market and, second, that Wyeth's success was directly related to an increase in the price of Premarin. We focus our attention on the evidence the Purchasers offer to establish the critical link between Wyeth's actions and the antitrust injury the Purchasers allege, namely, increased prices for Premarin.

The Purchasers argue that Wyeth's success in executing its Preemptive Plan allowed it to increase Premarin's price. They point out that prior to Wyeth's development and execution of the Premarin Preemptive Plan, the average annual increase in the list price for Premarin was 6.7 percent. They assert that in 1999, as it became clear that the Preemptive Plan would be successful, Wyeth began to increase the price of Premarin, beginning with an 11.8 percent increase. Subsequent to the implementation of the Plan, the Purchasers claim, Wyeth increased the list price for Premarin by

<sup>&</sup>lt;sup>7</sup>Because we find an absence of evidence of causation, we need not address whether Wyeth's use of reimbursement agreements was anticompetitive as a matter of law.

15.8 percent on average every year from the year 1999 to 2003. A pricing study prepared for Wyeth by Putnam Associates, Inc., a consulting firm, found that Premarin experienced the greatest price increase for 2001 of the top fifty branded drugs in the market. Wyeth does not deny the accuracy of the Purchasers' claims regarding the increase in Premarin's price but denies any causal relationship between the Preemptive Plan and those increases.

In their attempt to link the purported success of Wyeth's Preemptive Plan to increased prices for Premarin, the Purchasers offer four pieces of evidence: (1) Wyeth documents concerning its pricing practices; (2) expert testimony; (3) a governmental study they claim supports the view that increased competitor market share imposes price restraint in the pharmaceutical market; and (4) "concessions" by Wyeth's experts witnesses.

First, the Purchasers and their experts cite an internal Wyeth "Strategic Options Summary," generated in July 1999. The Strategic Options Summary attempts to predict sales and pricing effects on the Premarin franchise based on a series of assumptions concerning demographics, Wyeth marketing and distribution efforts, and competition in the pharmaceutical market. The Summary posits three scenarios: (1) the base case, where, among other things, Cenestin achieves an 8.8 percent share of the ERT market in 2000, and the Premarin Family experiences a price effect of 6 percent in 2000 and 4 percent in 2001 and 2002; (2) an "upside" scenario, where, among other things, the Premarin franchise experiences a price effect of 12 percent in 2000 and 8 percent in 2001 and 2002; and "a successful ERT campaign" limits Cenestin to a 4.6 percent market share in 2000; and (3) a "downside" case, where the Summary makes no mention of Cenestin or a price effect.

Of interest to the Purchasers is the document's mention of Cenestin within the "Competition" section of the base and upside projections contained in the Summary. They argue that because Cenestin's success is mentioned among the factors anticipated to affect Premarin pricing, a causal relationship exists between these two factors. However, this argument overreads the document. Cenestin's market share is one of various "forecast assumptions" utilized to generate the predictions in the Summary, including the impact on Premarin prices, and the document makes no attempt to quantify the relative weight each factor has in the projections. The Purchasers insist that a jury could infer that Cenestin's market share was the most important factor in the summary's analysis or, at least, a material factor "given its positioning in the document as the first competitive factor identified in each scenario, and in the broader context of other Wyeth documents indicating the importance Wyeth gave to the plan to suppress Cenestin." Cenestin's market share, although listed first among the assumptions about competition, is well towards the end of assumptions for each forecast. Moreover, the Purchasers offer no persuasive reason to attribute Cenestin's placement to anything other than organizational preference on the part of the drafter.

Two of the Purchasers' experts, Keith Leffler, Ph.D., and Jeffrey J. Leitzinger, Ph.D., relied on the Strategic Options Summary to reach their causation conclusions. However, Dr. Leffler conceded during his deposition that the Strategic Options Summary did not prove a connection between Cenestin's market share and Wyeth's intent to increase Premarin price:

Q: But I guess – what it doesn't say, does it, Dr. Leffler, it doesn't say that Wyeth is – it doesn't tie the price increase in terms of whether Wyeth is going to be successful in limiting Cenestin to a 4.6 percent share, does it?

A: I'm not sure what you mean by "tie."

Q: That is, it doesn't say – it doesn't say, We're going to raise our prices 12 percent if we can keep Cenestin to a 4.6 percent share, for example.

A: It doesn't say that, no.

Q: And you don't mean to suggest that that's, in fact, was what Wyeth was doing, right?

A: I mean, it didn't raise it 12 – these percentages were not what it did anyway, so – yes, it did not – this document doesn't even tell me what they, in fact, did.

Q: And the forecast doesn't even make a connection between the size of the Premarin price increase and Cenestin's market share, does it?

A: Not in a –

Q: I mean, there's not a causal relation between the two?

A: No, not in a direct sense at all.

Thus, at least one expert retained by the Purchasers expressly declined to assign the meaning to the Summary that they advance.

The Purchasers also point to internal communications at Wyeth concerning pricing recommendations for Wyeth pharmaceuticals. A proposal to conduct research into Premarin pricesetting states that the market entry of alternatives to Premarin would produce pricing pressure for Wyeth. A presentation on the "Premarin Family Pricing Project" acknowledges that "[d]ominant market share lowers price sensitivity," but contains no mention of Cenestin or Wyeth's efforts to limit Cenestin's market share in the oral ERT market. That Wyeth recognized that its superior market position decreased the necessity of adjusting its own price does not demonstrate that its particular efforts against Cenestin prompted a price increase.

Drs. Leffler and Leitzinger, in their written reports submitted on the Purchasers' behalf, posited a causal connection between Wyeth's use of reimbursement agreements to maintain market control and subsequent Premarin price increases. Dr. Leffler's report states the "basic" economic principle that greater competition decreases a predominant seller's price. It goes on to conclude that Wyeth "[b]y instituting and enforcing a series of contracts with major PBMs that significantly limited the ability of competitors in the ERT market to successfully compete on price with Premarin," Wyeth achieved "substantially greater" price increases than it would have otherwise. In his report, Dr. Leitzinger contends that Wyeth's Preemptive Plan stunted Cenestin's development as a competitor which allowed it to "maintain its hold on customers and [avoid] the need for any defensive pricing reactions."

The experts' conclusions proceed on the assumption that, in the absence of Wyeth's efforts, Cenestin would have experienced such success upon release that it would have effectively constrained Wyeth's market force and created downward pressure on the price of Premarin. The district court identified the flaw in this reasoning as applied to the record before us. Neither of the experts account for the numerous alternative explanations for Cenestin's failure to secure market share, including poor marketing by Duramed, the unavailability of certain dosages of Cenestin, low physician demand, or the clinical and therapeutic differences between Cenestin and Premarin. For that reason, the experts' opinions do not provide a sound evidentiary basis for the Purchasers' theory that Wyeth contributed to Cenestin's failure and consequently created an environment in which it had free reign to increase prices dramatically. In addition, both experts' discussions of the facts implicitly advance the Purchasers' position that the temporal proximity of Cenestin's poor showing in the oral ERT market and Wyeth's price increase proves a causal link. While we find the timing of the events relevant, we deem it insufficient, standing alone, to create a genuine issue of material fact as to causation.

The Purchasers also rely on a report produced by the Congressional Budget Office, which they claim supports the proposition they advance, that is, that the introduction of competitor products acts as a restraint on the pricing practices of a so-called "innovator drugs," like Premarin. Congressional Budget Office, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry (1998), available at http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf. The Purchasers engage in a selective recitation of the findings of that report, however. While citing the report's general conclusion that the introduction of "me-too drugs" "generally keeps the manufacturer of the breakthrough drug from raising its price as quickly as would otherwise be the case," id. at 19, they disregard the report's discussion of empirical evidence on innovator drug pricing. In one of those studies, in four out of five therapeutic classes, the list price for the innovator product continued to increase after the entry of one or more me-too products. Id. at 20. In another study, the average list price of brand name drugs continued to increase, in a manner beyond what could be ascribed to inflationary impact, after the introduction of a me-too competitor. Id. Moreover, although the Purchasers rely on the CBO report, they also criticize the district court's comments about the report as "irrelevant," because they involve an analysis of the effects of a generic drug's approval. In this respect, the Purchasers are generally correct that the CBO report's analysis of the impact of the entry of generic drugs is not of great assistance in this case where Wyeth faced branded competition.

In any event, the report does not create a genuine issue of material fact as to the ability of one branded competitor, Cenestin, to control Premarin's price. At most, the report raises the possibility that Cenestin's presence might have slowed the rate of price increases, but even that claim is a tenuous one based upon the report's findings, as the study confirming this possibility involved innovator drugs with "more brand-name competitors." *Id.* at 20-21.

Finally, the Purchasers rely on the supposed concessions of Wyeth's experts concerning the causal relationship between the Preemptive Plan and Wyeth's subsequent increase in Premarin's price. They cite the report of Wyeth's expert, Janusz A. Ordover, who issued an opinion on the causal relationship between Wyeth's efforts to maintain market share and subsequent price increases. Ordover explained that, in setting the list price of a medication, a drug manufacturer considers a "variety of factors," including "the current state of competition in the marketplace and its expected evolution over time, as well as the competitive positioning of the manufacturer's drug *vis-a-vis* rival offerings." The Purchasers attempt to read Ordover's statement as a concession. This mischaracterizes Ordover's statements, however. Ordover ultimately found the Purchasers' causation theory to be "inconsistent with the evidence and with sound economics . . . ." He attributed Wyeth's price increase to "the belief that Premarin was dramatically underpriced at the prevailing levels."

Similarly, Purchasers claim Wyeth expert Dennis Carlton, Ph.D., admitted that Premarin's pricing might have been different had Cenestin gained a greater market share. In fact, Carlton said that if Cenestin "had been a better product," it would have commanded a larger market share. Dr. Carlton refrained from drawing any connection between Cenestin's having a greater market share and Premarin's being priced at a lower level. The Purchasers also point to the deposition testimony of Christopher James, Ph.D., but Dr. James explicitly declined to identify competitor market share as a determinative factor in the establishment of list price for pharmaceuticals. Thus, the Purchasers' claim that Wyeth experts conceded their causation assertion relies on serious distortions of the experts' analyses.

We conclude that the evidence marshaled by the Purchasers, considered independently or collectively, does not create a genuine issue of material fact as to the causal connection between Wyeth's actions to maintain its market share within the MCO market and its later decision to increase its prices. The district court, therefore, correctly granted summary judgment on this ground.

# IV.

For the foregoing reasons, we affirm the judgment of the district court in favor of Wyeth.