

IN THE UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

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No. 05-3988

No. 05-3860

J.B.D.L. CORPORATION, *et al.*

Plaintiffs – Appellants

CVS MERIDIAN, INC. *et al.*

Plaintiffs-Appellants

v.

WYETH-AYERST LABORATORIES, INC. *et al.*

Defendants-Appellees

On Appeal from the United States District Court
Southern District of Ohio
Western Division

Case Nos. C-1-01-704 and C-1-03-781

BRIEF OF AMICI CURIAE

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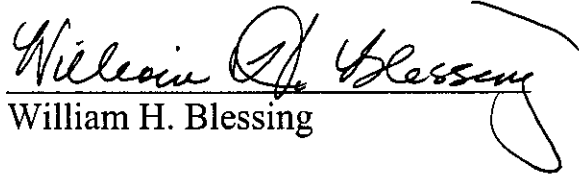
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Plaintiffs – Appellants : :
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: :
v. : :
: :
WYETH-AYERST : :
LABORATORIES, INC., *et al.*, : :
: :
Defendants – Appellees : :

DISCLOSURE OF CORPORATE AFFILIATIONS
AND FINANCIAL INTEREST

Pursuant to 6TH Cir. R. 26.1, *amici* make the following disclosure:

1. Is said party a subsidiary or affiliate of a publicly owned corporation?
No.
2. Is there a publicly owned corporation, not a party to the appeal, that has a financial interest in the outcome? No.


William H. Blessing

November 7, 2005
Date

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BRIEF OF AMICI CURIAE

I. STATEMENT OF THE CASE

The Appellee, Wyeth-Ayerst Laboratories, Inc., et al. ("Wyeth"), is a monopolist in the market for conjugated estrogen, in which its drug, Premarin, carries a 99 percent market share. Plaintiffs are direct purchasers of conjugated estrogen, challenging conduct of Wyeth that perpetuated its monopoly position and thereby preserved its ability to charge Plaintiffs supracompetitive prices for that drug. Since it entered the market in 1942, Premarin has been a well-selling drug that reached annual sales over \$800 million in 2003 and 2004. The drug is also absolutely crucial for the hundreds of thousands of women who rely on it for hormonal therapy, and therefore monopolistic conduct in this market has a direct, adverse impact on those women. *See, e.g.,* Gina-Louise Monari, *Hormone therapy market rallies*, *Med Ad News* (London), Jun. 2005, Vol. 24 Iss. 6, at 4; *Trade Secrets*, *Bus. Tort Rptr* (New York, N.Y.), Apr. 2005, Vol 17 Iss.6, at 187; Leila Abboud, *Health: How Drug Giant Keeps Monopoly on Pill; Barr Falts in Its Bid to Sell Generic Copy of Wyeth's Premarin; the Secrets of Horse Urine*, *Asian Wall St. J.* (New York, N.Y.), Sep. 10, 2004, at M.8.

This case comes at a critical juncture, as United States spending for prescription drugs has quadrupled since 1990, leaping from \$40.3 billion to

\$179.2 billion in 2003. United States Department of Health & Human Services, Centers for Medicare & Medicaid Services, *National Health Expenditures Aggregate Amounts an Average Percentage Change by Type of Expenditure* (Table), <http://www.cms.hhs.gov/statistics/nhe/historical/t2.asp>.

Prescription drug spending is one of the fastest growing components of health care spending, increasing at double-digit rates from 1986 through 2004. Kaiser Family Foundation, *Prescription Drug Trends* (October 2004), available at <http://www.kff.org/rxdrugs/upload/Prescription-Drug-Trends-October-2004-UPDATE.pdf>. In 2002 to 2003, spending on prescription drugs outpaced growth in all other health care services. *Id.* While other factors contribute to increased spending, manufacturer price increases account for 25 percent of the basis for rising prescription drug expenditures. *Id.* Fortunately for consumers several drugs will come off patent in the next few years, leading to the potential for billions of dollars of savings to consumers. Heffler et al., Health Affairs, *Health Spending Projections Through 2013*, Feb. 11, 2004, (Web Exclusive) www.healthaffairs.org (select "Web Exclusives" link, and then "2004").

Unfortunately, however, the exclusionary practices at issue in this case threaten to prevent the entry of lower priced drugs. If the decision below is affirmed, many brand name pharmaceutical manufacturers will be

able to manipulate their monopoly power to delay or prevent generic entry, raise prices, and reduce consumer choice. The conduct challenged in this case, which led to substantial price increases to consumers, is a recipe for higher prices for the pharmaceutical industry, frustrating the efforts of policymakers to control health care costs.

In this case, the district court decided that as a matter of law Wyeth-Ayerst Laboratories (“Wyeth”) did not, as a matter of law, violate Sections 1 or 2 of the Sherman Act, and that the Plaintiffs had failed to show the existence of a triable issue of fact on whether they suffered an antitrust injury. *J.B.D.L. v. Wyeth-Ayerst Labs., Inc.*, Nos. 1:01-cv-704, 1:03-cv-781, 2005 U.S. Dist. LEXIS 11676 (S.D. Ohio June 13, 2005) .

While *amici* strongly disagree with the lower court’s dismissal of Plaintiffs’ Section 1 claims,¹ this brief will focus on the district court’s dismissal of the Section 2 claim and the district court’s ruling that Plaintiffs suffered no antitrust injury. The lower court decision erred in ignoring the clear anticompetitive effects of Wyeth’s conduct, instead choosing to adopt an approach of *per se* legality for above-cost exclusionary conduct. In the

¹ Specifically, *amici* believe that an analysis based on *Microsoft* and employing a rule of reason inquiry is the correct mode of analysis for the exclusionary agreements challenged in this case. Under such an analysis, *amici* believe that summary judgment was improperly granted to Defendants in this case.

interests of brevity, this brief will incorporate by reference the Statement of Facts provided in the Appellants' Briefs on Appeal filed with this Court.

II. STATEMENT OF INTEREST

The AARP and other interested parties named in the above Motion hereby submit this brief as *amici curiae* respectfully asking this Court to overturn the district court's decision. The district court's decision has implications much broader than the case at hand. There are many small, innovative companies in the pharmaceutical and medical device industries that are struggling to bring their products to market against larger, often dominant rivals. As the D.C. Circuit noted in *United States v. Microsoft*, it is "inimical to the purpose of the Sherman Act to allow monopolists free reign to squash nascent, albeit unproven, competitors at will." 253 F.3d 34, 109-10 (D.C. Cir. 2001). When exclusionary conduct prevents these innovative companies from having effective access to the market, consumers lose a vital source of health care competition and pay higher prices as a result. As this case shows, these companies are becoming increasingly reliant upon pharmacy benefit managers (PBMs) as their most important

avenue of access to consumers.² The issue of access to consumers through PBMs is critical as consumers, corporations, and government entities struggle to control the rapidly rising costs of pharmaceuticals.

This case presents the quintessential case of harm to consumers resulting from the exclusionary practices of a dominant company. Hundreds of thousands of women are *dependent upon* conjugated estrogen, the drug at issue in this case. Wyeth's Premarin had a 40-year monopoly in estrogen replacement therapy, which was threatened by Duramed's own conjugated estrogen product.³ After Wyeth's tactics successfully drove Duramed from the market, Wyeth increased prices to consumers nearly 50 percent over 3 years. *J.B.D.L.* at *13. If the district court's decision is allowed to stand, it will encourage precisely those practices that, in this case, were so detrimental to the women who depended upon conjugated estrogen.

² In 2003, PBMs administered prescription benefits for approximately 187 million people. *See*, Direct Purchasers Memorandum of Law in Opposition to Wyeth's Motion for Summary Judgment at 18

³ Price, quality, and choice are all important elements of competition. In this case, consumers may have strongly preferred the excluded drug, Cenestin, since it was not based on pregnant mare's urine and had fewer impurities. *J.B.D.L. Br.* at 17.

III. ARGUMENT

- A. The District Court should not have granted summary judgment on Plaintiffs' Sherman Act Section 2 Claim.

A plaintiff seeking to show illegal monopoly maintenance under Section 2 of the Sherman Act must show that the defendant has engaged in anti-competitive conduct that reasonably appears to be a significant contribution to maintaining monopoly power. *United States v. Dentsply*, 399 F.3d 181, 186-87, 191 (3d Cir. 2005) (citing *United States v. Microsoft*, 253 F.3d at 79).

Defendant Wyeth argued that Plaintiffs' Section 2 claim should be dismissed because it does not fit within the established boundaries of a predatory pricing claim. *Id.* at *33. The district court correctly rejected this argument as simplistic. *Id.* The viability of Section 2 claims that go beyond allegations of predatory pricing is well established. *See Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985); *Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451 (1992); *Conwood Co. v. U.S. Tobacco Company*, 290 F.3d 768, 782 (6th Cir. 2002).

Having rejected the main thrust of the defendant's argument, the district court proceeded to grant summary judgment nonetheless, relying on a misguided reading of the facts and a single opinion from the Eighth Circuit

which runs contrary to the mainstream of Section 2 jurisprudence. *J.B.D.L.* at *49. The dismissal should be overturned.

1. The District Court Neglected to Apply Relevant Precedent

The district court's application of Section 2 precedent was unsatisfactory. While it is true (as the district court insists) that decisions from other circuits such as *LePage's v. 3M*, 324 F.3d 141 (3d Cir. 2003) and *Microsoft*, 253 F.3d 34 and *Dentsply*, 399 F.3d 181, are not binding precedent,⁴ it was unwise for the court to overlook the considerable prior Section 2 jurisprudence. In fact there have been multiple Supreme Court cases on point, and these do constitute binding precedent. *See, e.g., Aspen Skiing Co. v. Aspen Highlands Skiing Corp., supra; Eastman Kodak Co. v. Image Technical Servs., Inc., supra.*

Aspen Skiing and *Kodak* establish a cohesive framework for evaluating the exclusionary conduct of monopolists under the antitrust laws. In *Aspen Skiing*, Aspen Skiing Co. excluded Aspen Highlands, a rival ski hill, from a joint offering agreement for multi-area lift ticket packages.

Aspen Skiing, 472 U.S. at 591. Aspen Highlands brought suit claiming that

⁴ Nor, one might add, is *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039 (8th Cir. 2000), which the court erroneously relies on for much of its opinion.

Aspen Skiing Co.'s conduct constituted unlawful monopolization under Section 2 of the Sherman Act.. *Id.* at 595. In examining Aspen Skiing Co.'s conduct, the Court stated:

The question whether Ski Co.'s conduct may properly be characterized as exclusionary cannot be answered by simply considering its effect on Skiing. In addition, it is relevant to consider its impact on consumers and whether it has impaired competition in an unnecessarily restrictive way. If a firm has been "attempting to exclude rivals on some basis other than efficiency, it is fair to characterize its behavior as predatory.

Id. at 605. The Court's statement suggests a three-part inquiry to determine whether conduct is exclusionary. A court must look at the impact of the alleged conduct on (1) competition, (2) consumers, and (3) the monopolist.

In *Kodak*, the Supreme Court made clear that the *Aspen Skiing* inquiry involved a shifting of burdens. *See, Kodak*, 504 U.S. at 483. In reversing the district court's grant of summary judgment, the Court relied on evidence of harm to competition and consumers, suggesting that Kodak "took exclusionary action to maintain its monopoly." *Id.* Therefore, to avoid liability, Kodak was required to state a valid business justification for its conduct (i.e. impact of the conduct on the monopolist). *Id.* Because factual questions remained as to the validity of Kodak's explanation, the Court concluded that summary judgment was inappropriate. *Id.*

The D.C. Circuit's opinion in *Microsoft* represents the best developed effort to build on the framework established in *Aspen Skiing* and *Kodak* to elaborate a workable monopolization doctrine. The *Microsoft* court likened its approach to that of the "rule of reason" under Sherman Section 1. *Microsoft*, 253 F.3d at 59. *Amici* believe that *Microsoft* establishes a workable framework that strikes the correct balance between the risk of false positives and false negatives in exclusionary conduct cases and urge the court to adopt its "rule of reason" approach.⁵

Under the *Microsoft* test, a plaintiff must prove the first two prongs of the *Aspen Skiing* Court's inquiry in its prima facie case – harm to competition and consumers. *Id.* at 58. This initial inquiry produces a filtering effect, preventing needless litigation. Andrew I. Gavil, *Exclusionary Distribution Strategies by Dominant Firms: Striking a Better Balance*, 72 ANTITRUST L.J. 3, 62 (2004). A plaintiff must put forth sufficient facts to avoid summary judgment. As a result, "most cases will be weeded out before trial for weaknesses related to the plaintiff's assertions with respect to

⁵ A false positive is a ruling that condemns conduct that is procompetitive, while a false negative sanctions conduct that actually is anticompetitive. A balanced antitrust policy that fosters healthy competition and promotes consumer welfare should design rules that minimize the chances of either error occurring. Gavil, *supra* at 30-64 (Section IV, discussing and analyzing the occurrence of false positives and false negatives).

monopoly power or anticompetitive effects.” *Id.* at 77; *see also LePage’s*, 324 F.3d at 158-160, 180 (endorsing and applying the *Microsoft* decision) .

If the plaintiff establishes its prima facie case, however, the burden then shifts to the defendant. The defendant must provide a “procompetitive justification” for its conduct. *Microsoft*, 253 F.3d at 59. The procompetitive justification should relate “directly or indirectly to the enhancement of consumer welfare.” *LePage’s*, 324 F.3d at 163-64. Burden shifting is appropriate because a monopolist is in the best position to discover its own reasons for adopting a particular marketing strategy. *Gavil, supra* at 73. If the defendant cannot show a business justification, courts can feel confident that the marketing strategy was adopted for an exclusionary purpose and may properly condemn the defendant’s actions.

Once the defendant has put forth a business justification, the plaintiff will then have the opportunity to rebut by showing that the defendant’s explanation was pretextual. *Microsoft*, 253 F.3d at 59; *Kodak*, 504 U.S. at 484. If the plaintiff fails to rebut the defendant’s justification, the plaintiff must then “demonstrate that the anticompetitive harm outweighs the procompetitive benefit.” *Microsoft*, 253 F.3d at 58-59. To date, no exclusionary conduct cases have reached the balancing inquiry, and instances of balancing will presumably be rare. *See Gavil, supra* at 79. The

rarity of full scale balancing inquiries reinforces the workability of the *Microsoft* standard for evaluating exclusionary conduct.

In this case, Plaintiffs have met their initial burden. Monopoly power is conceded. Plaintiffs have shown that material facts exist as to whether Wyeth's market-share rebates, product bundling, and exclusive dealing contracts amount to de facto exclusivity. Plaintiffs have also demonstrated that Wyeth intended to exclude competition in order to maintain its market share, rather than engage in competition on the merits. Harm to consumers is present, in the form of increased prices for pharmaceuticals and reduced product choice. Moreover, reasonable triers of fact have found similar marketing strategies to violate Sherman Section 2 because of their anticompetitive effects. *See Dentsply*, 399 F.3d 181 (exclusive dealing agreements); *LePage's*, 324 F.3d at 154-57, 157-59 (product bundling and exclusivity, respectively); *Conwood*, 290 F.3d 768 (exclusive dealing agreements); *Masimo Corp. v. Tyco Health Care Group, L.P.*, Case No. CV 02-4770 MRP, 2004 U.S. Dist. LEXIS 26915 (C.D. Cal., December 15, 2004) (product bundling, exclusive dealing agreements, and market-share agreements).

Rather than analyzing the case according to established Supreme Court precedent, the district court relied on an Eighth Circuit exclusionary

pricing case, *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039 (8th Cir. 2000). The court thus avoided the “waste of time and resources” of a trial when it did not know whether or not it would be overruled. *J.B.D.L* at *47. While *amici* appreciate the court’s attention to judicial economy, this decision is singularly unfair for plaintiffs and, above all, harmful to consumers.

2. *Concord Boat* is Bad Law and Bad Policy

Ignoring the more sophisticated analysis laid out in *Aspen Skiing*, *Kodak*, and *Microsoft*, the district court relied on *Concord Boat* to establish a presumption that Wyeth’s conduct was legal, creating an unreasonably high burden for the Plaintiffs to meet. *Id.* (citing *Concord Boat*, 207 F.3d at 1061). The district court’s reliance on *Concord Boat* was flawed for two reasons. First, the Eighth Circuit emphasized that its *Concord Boat* opinion applied only to single-product rebates, and not bundled rebates such as those offered by Wyeth (or those that were successfully challenged in *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056 (3d Cir. 1978), *Ortho Diagnostic Sys., Inc. v. Abbott Labs., Inc.*, 920 F. Supp. 455 (S.D.N.Y. 1996), and *LePage’s*). See, *Concord Boat*, 207 F.3d at 1062. Thus, even on its own

terms, *Concord Boat* does not apply to the case at bar.⁶ Second, and more fundamentally, the *Concord Boat* presumption of legality does not conform with Supreme Court precedent and has not been accepted by any other Circuits. See *LePage's*, 341 F. 3d at 154-57, *Dentsply*, 399 F.3d 181.

As a matter of policy, *Concord Boat* is a misguided opinion that should not be extended. The critical flaw of *Concord Boat* is that it fails to account for the competitive differences between discount pricing (which is nearly always procompetitive) and exclusionary conduct (which carries less certain competitive effects). Above-cost price cutting can eliminate a rival only when that rival operates less efficiently than the price-cutting firm, and therefore is relatively unlikely to result in consumer harm. For this reason, the law requires plaintiffs to meet the extraordinary burden of showing below-cost pricing in order to state a predatory pricing claim. See *Gavil*, *supra*, at 58-59. Exclusionary bundling, on the other hand, can eliminate a rival regardless of that rival's efficiency, and therefore is more likely to result in increased prices. *Id.* Because exclusionary conduct is more likely than aggressive price-cutting to be anticompetitive, it carries greater risks of

⁶ The facts of *Concord Boat* are distinguishable in other respects. In this case, Wyeth increased prices, had a far more dominant position in the market, and the market for conjugated estrogen had significant barriers to entry. Moreover, due to the dependence of patients on conjugated estrogen, it was clear that a significant segment of the market had inelastic demand. See *CVS Br.* at 12.

false negatives than false positives. *See LePage's*, 324 F.3d at 159-163; Gavil, *Exclusionary Distribution Strategies by Dominant Firms: Striking a Better Balance*, *supra* at 75 (noting that in exclusionary marketing strategy cases “concern for false negatives counsels for a less permissive approach” than in predatory pricing cases); Willard K. Tom, et al., *Anticompetitive Aspects of Market-Share Discounts and Other Incentives to Exclusive Dealing*, 67 ANTITRUST L.J. 615, 624-27 (2000) (describing the anticompetitive effects of exclusionary marketing strategies). For this reason, courts should not adopt *Concord Boat's* presumption of legality for such action.

The harm to competition is real. The common element of all exclusionary marketing strategies is that they raise rivals' costs. *See Einer Elhauge, Defining Better Monopolization Standard*, 56 STAN. L. REV. 253, 320 (2003). Importantly, many of these practices do not even improve the efficiency of the monopolist. *See id.* at 256. Costs may be raised enough to merely slow down rivals' market expansion or, in some instances, eliminate competitors from the market entirely. The most common marketing strategies prevent buyers or distributors from buying from rivals. Product bundling, market-share rebates, and exclusive dealing agreements are all structured in this manner. For example, if a monopolist employs market-

share rebates or product bundling, the buyer may lose discounts on the monopolist's products for making purchases from a rival. *See LePage's*, 324 F.3d at 158 ("The foreclosure of markets through exclusive dealing contracts is of concern under the antitrust laws . . . '[U]nilaterally imposed quantity discounts can foreclose the opportunities of rivals when a dealer can obtain its best discount only by dealing exclusively with the dominant firm.'" (citations omitted)). If, by foreclosing a rival from the most efficient distribution channels,⁷ a monopolist can prevent enough buyers from reaching its rival, the rival may no longer be able to reach or maintain the minimum efficient scale required to compete. *See U.S. v. Dentsply*, 399 F.3d 181, 192 (3d Cir. 2005) (noting that Dentsply's marketing strategy had a "significant effect in preserving Dentsply's monopoly," helping "keep sales of competing teeth below the critical level necessary for any rival to pose a real threat to Dentsply's market share"). When a small firm is prevented from operating at its minimum efficient scale, its costs prevent it from providing the sort of aggressive price competition that benefits consumers, especially consumers of prescription drugs.

⁷ Importantly, a monopolist need not foreclose access to the entire market in order to raise rivals' costs, merely the most efficient channels of distribution. *See Microsoft*, 253 F.3d at 64 ("[A]lthough Microsoft did not bar its rivals from all means of distribution, it did bar them from the cost-efficient ones."); *see also Dentsply*, 399 F.3d at 189-90.

Exclusionary marketing strategies can also deny rivals economies of scale in recouping research investments. *See* Elhauge, *supra* at 320-21. Foreclosure prevents consumers from purchasing new socially desirable technologies. As a result, successful innovations will have a smaller payout than expected, discouraging future research investments, which in turn leads to less future competition. *Id.* This result is especially likely in industries that already possess high barriers to entry, such as the pharmaceuticals industry. It is significant that in the important recent Section 2 cases where plaintiffs have prevailed—*Conwood*, *LePage's* and *Microsoft*—conditions of entry were particularly difficult. Gavil, *Exclusionary Distribution Strategies by Dominant Firms: Striking a Better Balance*, *supra* at 27.

The harm to consumers is also real. In response to these marketing strategies, rivals must charge higher prices to cover higher costs, thereby allowing the monopolist to continue charging the monopoly price and worsening the market options available to consumers. *Id.*; *see also Pool Water Prods. v. Olin Corp.*, 258 F.3d 1024, 1034 (9th Cir. 2001) (acts that raise the price of goods harm consumer welfare); *Full Draw Prods v. Easton Sports, Inc.*, 182 F.3d 745, 755 (10th Cir. 1999) (“limiting consumer choice” is anticompetitive). These significant anticompetitive effects can occur regardless of whether a monopolist’s marketing strategies require complete

exclusivity. *Microsoft*, 253 F.3d at 70 (“[A] monopolist’s use of exclusive contracts, in certain circumstances, may give rise to a § 2 violation even though the contracts foreclose less than the roughly 40 percent or 50 percent share usually required in order to establish a § 1 violation.”).

It is poor policy to establish a presumption that these acts are pro-competitive, because exclusionary marketing strategies often harm competition. *See Kodak*, 504 U.S. at 479 (“We note only that Kodak’s service and parts policy is simply not one that appears always or almost always to enhance competition, and therefore to warrant a legal presumption without any evidence of its actual economic impact.”). A presumption of legality is even more inappropriate considering that a monopolist who wishes to compete on the merits, without fear of antitrust liability, has a substantial safe harbor in aggressive above cost pricing. In light of the balance between false positives and false negatives in exclusionary conduct cases, the court below erred in following *Concord Boat*.

B. Plaintiffs Suffered Antitrust Injury.

The district court's decision to deny antitrust standing has even less support in the antitrust case law, as there is not even a circuit split on this issue. The district court correctly summarized the Supreme Court's two-part antitrust injury test from *Brunswick*—that a direct purchaser must show that (1) it has suffered the type of antitrust injury that antitrust laws were intended to prevent, and (2) that the injury or loss flows from the defendant's unlawful act. *See Brunswick v. Pueblo Bowl-O-Mat*, 429 U.S. 477, 489 (1977). The court's correct analysis ended there, however, as it applied that standard in a manner entirely inconsistent with applicable precedent.

On the first prong of the Supreme Court's *Brunswick* analysis, the Sixth Circuit has recently recognized that forcing direct purchasers to pay higher prices is the quintessential antitrust injury. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 909 (6th Cir. 2003) (forcing direct purchasers to pay more for drugs due to anticompetitive conduct is “the ‘type of injury’ that the antitrust laws were meant to prevent”); *see also Blue Shield of Va. v. McCready*, 457 U.S. 465, 482-83 (1982) (“an increase in price resulting from a dampening of competitive market forces is assuredly one type of injury for which § 4 potentially offers redress”). In concluding that

Plaintiffs' injury was not of the type the antitrust laws were intended to prevent, the district court ignored this binding precedent. To do so, the court necessarily had to reject the "basic economic theory," upon which those precedents are based, namely that, in a competitive market, price increases by one firm induce *more*, not less competition from rivals. Thus, if exclusionary conduct occurred, prices increased and competition was unable to bring prices down, that conduct must necessarily be the root of Plaintiffs' injury.

On the second prong of the *Brunswick* analysis, the district court concluded that Plaintiffs did not present sufficient evidence that Cenestin's low market share was due to its being excluded or downgraded on formularies, as opposed to poor marketing. *J.B.D.L* at *56. This statement of the district court effectively demands that Plaintiffs prove a negative in order to avoid summary judgment. For example, the court faults Plaintiffs' economists for not explaining why estradiol, a competitor in the oral ERT market, experienced market share growth during the period 1998 to 2003. *J.B.D.L* at *54. However, this is entirely irrelevant—the exclusionary practices at issue were not directed at estradiol in any way. Wyeth clearly saw Cenestin as the greatest potential competitive threat to Premarin's continued dominance and effectively nipped that threat in the bud. Even if

the success of estradiol were relevant, the court ignored evidence supporting Plaintiffs' theory of antitrust injury. Despite both parties' arguments and evidence regarding the disputed material facts, the court construed the evidence against the Plaintiff. Such a method was improper, especially in the context of summary judgment.

The district court also disparaged the Plaintiffs' expert economists and the Plaintiffs' assertions that the PBM-HMO sector is critical. As *amici* are keenly aware, PBMs are some of the most powerful players in many prescription drug markets, and promise to grow even more powerful as the Medicare prescription drug benefit is implemented. United States Department of Health & Human Services, Centers For Medicare & Medicaid Services, *Medicare & You 2006*, at 47, available at <http://www.medicare.gov/publications/pubs/pdf/10050.pdf>; United States Department of Health & Human Services, Centers For Medicare & Medicaid Services, *Introducing Medicare's New Coverage for Prescription Drugs*, available at <http://www.medicare.gov/publications/pubs/pdf/11103.pdf>; see also Part D and Me, <http://www.partdandme.com> (last visited Nov. 4, 2005) (PacifiCare's Part D website for consumers, proclaiming, "[The Part D] benefit will be administered through private health-insurance companies that

must bid against one another to ensure the best prices for eligible beneficiaries”).

The Plaintiffs here are direct purchasers, who were deprived of a less expensive product because of the exclusionary agreements Wyeth negotiated with national PBMs. Plaintiffs provide considerable anecdotal, documentary, and economic evidence that Wyeth raised its prices (by nearly 50 percent over three years) only after it ensured through its anticompetitive contracts that there would be no effective competition from Cenestin. *Amici* agree with Plaintiffs that there is ample evidence in the record to support a connection between Wyeth’s exclusionary conduct and these price hikes, sufficient to withstand a summary judgment motion.

In short, the district court seems to be demanding an impossibly high burden of proof from Plaintiffs (especially at the summary judgment level). There is no way Plaintiffs can prove a negative, that Duramed’s small market share could not have possibly been due to poor marketing or any other factor, nor are they required to. Supreme Court precedent requires only that the challenged conduct is a material cause of the Plaintiffs’ loss. *Zenith Radio Corp. v. Hazeltine Research*, 395 U.S. 100, 114 (1969) (stating that a plaintiff need only show that a violation is a “material cause” of the

claimed injury). Moreover, it is not necessary that a plaintiff exhaust all possible alternative sources of injury in fulfilling his burden of proving a compensable injury. *See id.*; *See also Iron Workers Local Union No. 17 v. Philip Morris, Inc.*, 23 F. Supp.2d 771, 793 (N.D. Ohio 1998).

The Sixth Circuit communicates these sentiments exactly in *Conwood* and *Cardizem*. In *Conwood*, this Court rejected an attempt by a defendant to dispose of an antitrust claim as a matter of law on the grounds that “there were other factors in the market [other than the defendant’s anticompetitive conduct], such as retailers’ choices not to display Conwood’s [products], that caused Conwood’s injury.” *Conwood*, 290 F.3d at 788. Based upon the plaintiff’s expert testimony that prices increased because of the defendants’ conduct, the Court properly decided the inferences in favor of the non-moving plaintiff and held that antitrust injury existed.⁸ *Id.* at 790. In *Cardizem*, the plaintiffs were direct purchasers of prescription drugs who alleged that a conspiracy between the defendants to delay the entry of generics into the market increased the prices the plaintiffs were forced to pay for those drugs. 332 F.3d at 899. Similarly to the case at bar, the defendants

⁸ This expert testimony included testimony that, had the plaintiff not been subjected to the defendant’s tactics, it would have increased its market share; that its low market growth was due to the defendant’s behavior; the defendant’s conduct reduced its share of sales; the defendant’s behavior caused an increase in prices, reduced sales, and limited choice; that “but for [defendant’s] actions, the market would have grown more”; and “as a result of [defendant’s] exclusionary conduct, the consumer suffered by having to pay higher prices.” *Conwood*, 290 F.3d at 780, 788-89. The Sixth Circuit ultimately held that these “points were sufficient to show that competition suffered during the relevant period and thus a reasonable jury could have found for the plaintiff on causation.” *Id.* at 790.

attempted to dismiss the case on antitrust injury grounds, arguing that the generic would not have entered the market even absent the allegedly anticompetitive agreement. *Id.* at 911. This Court correctly rejected that argument, however, noting that the defendants were attempting to create an issue of fact on a motion to dismiss. *Id.*

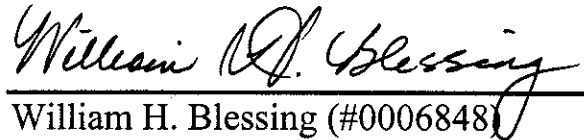
Similar to the testimony of plaintiff's expert in *Conwood*, the direct purchasers' experts offered testimony regarding the effect of Wyeth's anticompetitive agreements on the lack of growth of Cenestin's market share. *J.B.D.L.*, at *51-52. Additionally, Plaintiffs' experts offered testimony regarding the impact of Wyeth's agreements on Premarin's prices, the limited availability of Cenestin, and the diminished availability of other "sole conjugated estrogen" products to direct purchasers. *Id.* at *51-56. Moreover, expert attestation included testimony expressing that but for Wyeth's exclusionary conduct the market would have grown, and as a result of Wyeth's actions direct purchasers of Premarin continue to suffer by having to pay artificially inflated prices. *See id.* We therefore urge the Court to follow its prior jurisprudence in *Conwood* and *Cardizem*, and reverse the district court's conclusion that Plaintiffs did not suffer antitrust injury.

C. Conclusion

If it is allowed to stand, the district court's decision will open the door for other dominant drug manufacturers to engage in exclusionary agreements hampering the ability of lower-priced rivals to enter the market. *See generally* Nat'l Inst. for Health Care Mgmt., *A Primer: Generic Drugs, Patents and the Pharmaceutical Marketplace*, at <http://www.nihcm.org/GenericsPrimer.pdf> (last visited Oct. 4, 2005). The result will be higher prices, lower quality, and less consumer choice, by forcing generics and lesser priced drug options out of the market. *See generally* *Cardizem*, 332 F.3d at 904-905. Additionally, direct purchasers will be left with fewer drugs options to choose from, which as a result, will drastically reduce the available options for consumers. Competition is essential to controlling health care costs, and in order for the principles of competition to function effectively in the prescription drug industry, market power must not be misused to cripple new entrants.

For the reasons stated above, *Amici Curiae* respectfully request that the district court's judgment be reversed.

Respectfully submitted,



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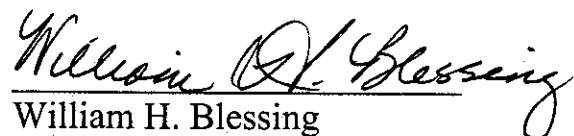
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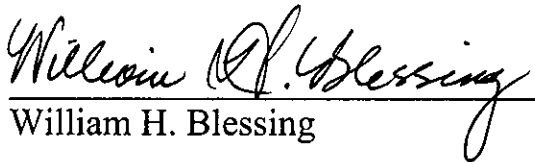

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UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

JBDL CORPORATION, <i>et al.</i> ,	:	Case No 05-3988
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Plaintiffs – Appellants	:	
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CVS MERIDIAN, INC., <i>et al.</i> ,	:	Case No. 05-3860
	:	
Plaintiffs – Appellants	:	
	:	
vii.	:	
	:	
WYETH-AYERST	:	
LABORATORIES, INC., <i>et al.</i> ,	:	
	:	
Defendants – Appellees	:	

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), this brief complies with the type-volume limitation imposed because it contains 6965 words.



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November 7, 2005
Date

