

STATE OF WISCONSIN
COURT OF APPEALS
DISTRICT IV/II
Case No. 2010AP000232-AC

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12-22-2010

**CLERK OF COURT OF APPEALS
OF WISCONSIN**

State of Wisconsin,

Plaintiff-Respondent-Cross-Appellant,

v.

Abbott Laboratories, AstraZeneca LP, AstraZeneca Pharmaceuticals, LP, Aventis Behring, LLC f/k/a ZLB Behring LLC, Aventis Pharmaceuticals, Inc., Ben Venue Laboratories, Inc., Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Roxane, Inc., Bristol-Myers Squibb Co., Dey, Inc., Ivax Corporation, Ivax Pharmaceuticals, Inc., Janssen LP f/k/a Janssen Pharmaceutical Products, LP, Johnson & Johnson, Inc., McNeil-PPC, Inc., Merck & Co. f/k/a Schering-Plough Corporation, Merck Sharp & Dohme Corp. f/k/a Merck & Company, Inc., Mylan Pharmaceuticals, Inc., Mylan, Inc. f/k/a Mylan Laboratories, Inc., Novartis Pharmaceuticals Corp., Ortho Biotech Products, LP, Ortho-McNeil Pharmaceutical, Inc., Pfizer Inc., Roxane Laboratories, Inc., Sandoz, Inc. f/k/a Geneva Pharmaceuticals, Inc., Sicor, Inc. f/k/a Gensia Sicor Pharmaceuticals, Inc., SmithKline Beecham Corp. d/b/a GlaxoSmithKline, Inc., TAP Pharmaceutical Products Inc., Teva Pharmaceuticals USA, Inc., Warrick Pharmaceuticals Corporation, Watson Pharma, Inc. f/k/a Schein Pharmaceuticals, Inc. and Watson Pharmaceuticals, Inc.,

Defendants,

Pharmacia Corporation,
Defendant-Appellant-Cross-Respondent.

**THE STATE OF WISCONSIN'S RESPONSE TO THE
AMICUS BRIEFS OF THE BRAND AND GENERIC
DEFENDANTS AND APPENDIX**

ON APPEAL FROM THE
CIRCUIT COURT FOR DANE COUNTY,
JUDGE RICHARD G. NIESS, CIRCUIT JUDGE, PRESIDING
Circuit Court Case No. 04-CV-1709

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ARGUMENT

Three aspects of the amici's briefs stand out. First, they obtained leave to file by promising to explain the "context" of AWP practices. Yet one reads the drug manufacturers' briefs in vain for an explanation of what keeps them from reporting real AWPs, rather than numbers inflated by up to 1,000%. The jury never heard such an explanation either.

Second, the amici's enthusiasm for the keystone of Pharmacia's brief—its "nonjusticiability" arguments based on the legislature's supposed intent to use AWPs to inflate "Estimated Acquisition Cost" to pay profits to pharmacies—is unmistakably tepid. The amici visit the "justiciability" issue only in discussing the causation issue, and as will be seen, that discussion *weakens* Pharmacia's argument.

Third, the brand amici have failed to heed this Court's order of November 10, 2010, warning them not to discuss "issues from the trial that [Pharmacia] has not addressed in its brief." *Id.* at 4. Both groups of amici mainly offer arguments Pharmacia has not made on appeal or at trial. As this Response shows, Pharmacia was right not to make them.

I. The Amici Only Weaken Pharmacia's Justiciability Arguments.

The centerpiece of Pharmacia's appeal was its argument that by passing budget bills, the legislature intended to set Medicaid drug reimbursement at levels that provided a profit to pharmacies by setting

“Estimated Acquisition Cost” (EAC) at levels higher than the federal definition. Hence, Pharmacia argued, allowing the judiciary to *consider* this case violates the separation-of-powers doctrine by permitting a court to overrule the legislature’s choice of proper reimbursement. *See* Pharmacia’s Brief of Appellant (henceforth “PB”) at 16-19.

Wisconsin responded that Pharmacia’s argument depends on an untenable assertion about the legislature’s intent in passing budget bills. The bills themselves say nothing about profits to pharmacies, and no committee report or floor statement about the bills mentions profits. The reports discussing the effect of discount levels from AWP on pharmacy profits were criticized by the pharmacy lobby and were contradicted by other reports. In this situation, the failure of the legislature to agree to increases in the AWP discount shows nothing about a legislative “intent to pay profits” by inflating EAC. Wisconsin’s Brief (henceforth “WB”) at 19-25. Wisconsin also showed that two presumptions affirmatively argue against any such intent. First, the legislature is presumed to follow the law and that it cannot be presumed to have deliberately intended EAC to be set at a level that is higher than the federal definition of EAC. Second, there is a presumption against implied repeal of a statute. That presumption argues against Pharmacia’s argument that the legislature, by approving budget bills, intended to repeal the applicability of §§100.18

and 49.49(4m)(a)2 to false statements of AWP. WB at 25-27.

Wisconsin concluded by showing that since Pharmacia's assertion about the legislature's "intent to pay profits" through inflating EAC is untenable, its separation-of-powers argument has no merit. Holding Pharmacia liable for damages does not intrude on any "core legislative function," since it does not contradict any legislative judgment the legislature made. WB at 28-31.

The amici's limited discussion of the justiciability issue only weakens an already unpersuasive argument.

A. The "causation" variation

The brand amici try to repackage Pharmacia's separation-of-powers argument in "causation" garb. They argue that Wisconsin's causation argument "assumes that if the Legislature knew a drug's actual acquisition cost, it would have directed Wisconsin Medicaid to pay pharmacists no more than that amount with no profit margin." Brand Amici Brief ("BAB") at 26. According to the amici, this determination requires the judicial branch to determine what decision the legislative branch would have made when setting the reimbursement rate, in violation of the separation-of-powers doctrine. *Id.*

This version of the argument depends on the same assertion about legislative intent that Pharmacia's depends on. To support that version of

the legislature's intent, the amici cite a report of a 2006 Governor's Commission for the proposition that Wisconsin set its formula for brands' EAC with the purpose of having pharmacists earn a profit margin on the EAC component of reimbursement. BAB at 19.

The amici chose a terrible example. This report compels the opposite conclusion: that Wisconsin's goal was to *avoid* inflating EAC to pay pharmacists a profit. As the jury found, profits earned by pharmacies on EAC were the result of Wisconsin lacking accurate AWP's and consequently having to play a game of blind-man's-buff in fixing the right discount to comply with the federal requirement to establish EAC at real, not inflated, acquisition levels. On the very page of the Report cited by the *amici*, the Commission identified five broad principles and goals that guided its discussions and recommendations. Principle No. 4 read: "Payment to pharmacists should cover the reasonable operational cost of the services they provide, *with ingredient costs reimbursed as close to actual costs as can reasonably be determined.*" BAB Appendix at 83 (emphasis added). In short, the brand amici only undermine the main premise of Pharmacia's appeal—that Wisconsin intentionally used inflated AWP's to set EAC to generate profits to pharmacies.¹

¹ This document suggests that if it were necessary for pharmacies to earn profits on Medicaid reimbursements, it would be done through the "dispensing fee."

B. The “political question” arguments

The brand amici’s “political question” discussion repeats Pharmacia’s, except that the amici invoke only three of the *Baker v. Carr* factors rather than the five invoked by Pharmacia. *Baker v. Carr*, 369 U.S. 186 (1962). *Cf.* BAB at 27-28 with PB at 23. As Wisconsin has shown, the correct number of applicable factors is zero. WB at 32-34. The political question exception to justiciability is reserved for rare and profound issues of governance. Whether drug companies have been causing overpayments on drugs is not one of those issues.

II. The Amici’s “Falsity” Arguments Are Unpersuasive.

Pharmacia has disclaimed arguing the “sufficiency of the evidence.” *See* WB at 18. As to the falsity of Pharmacia’s AWP, that disclaimer was a foregone conclusion. The trial evidence showed that key industry players (including First DataBank, which published the AWP) *defined* AWP to mean what their name said, that Pharmacia could have published accurate AWP but did not, and that a jury could find that Pharmacia itself regarded AWP as *untrue*. *Id.* at 8-12.

Faced with such evidence, Pharmacia argued only that because Wisconsin knew published AWP exceeded actual average wholesale prices and needed discounting, a jury could not find them false, misleading or deceptive under Wis. Stat. §§100.18 or 49.49(4m)(a)2.

Pharmacia Brief (“PB”) at 24-25. Wisconsin responded that far from understanding AWP to mean something other than its name conveyed, Wisconsin Medicaid and the legislature at most understood that prices that intended to convey real information were inaccurate and needed to be discounted. So viewed, Pharmacia’s AWPs were nothing more than false statements that do not cease being false just because a listener thinks them inaccurate. *Id.* at 34-38.

The brand amici offer two “falsity” arguments that Pharmacia elected not to make. Neither holds water.

A. The “term of art” argument

The brand amici assert that because Wisconsin statutes and regulations do not define “Average Wholesale Price,” its meaning “derives from the common understanding of the parties using the term.” BAB at 7. To the contrary, in the first instance, a term with a descriptive name derives its meaning from the plain meaning of that name. *In re Pharm. Indus. AWP Litig.* 460 F.Supp.2d 277, 285 (D.Mass. 2006).

The plain meaning might be displaced if all of the parties have a common understanding that the term means something different than that meaning and hence has become a “term of art.” Pharmacia did not make this argument, and for good reason. To be a “term of art,” the term “must have an established and settled meaning in the industry.” *Id.* at

285. Affirming a judgment against one of the amici, the First Circuit held the trial court did not err in holding that AWP had not met this necessary criterion for a “term of art.” *In re Pharm. Indus. AWP Litig.*, 582 F.3d 156, 170 (1st Cir. 2009). As discussed above, the trial evidence here supports the same conclusion.

The brand amici seem to say that AWPs became a term of art because over the years the federal government published reports declaring that AWPs are higher than actual average wholesale prices and recommending that states discount them. BAB at 9. These reports did not make Pharmacia’s false statements true, much less create an understanding between Wisconsin and Pharmacia about what Average Wholesale Price “really” means.

The brand amici suggest that the “understanding” of Wisconsin’s Department of Agriculture, Trade and Consumer Protection (DATCP) was that AWP is a manufacturer’s “suggested selling price for wholesalers to use,” and that wholesalers “start their price negotiations with retailers at AWP.” BAB at 9, *quoting* R135/Ex. 36/21. Beside the fact that the relevance of *DATCP’s* understanding is dubious, the understanding is simply wrong.

The trial evidence—especially of Pharmacia’s “marketing the spread”—showed that charging AWP to pharmacies was exactly what

Pharmacia wanted wholesalers *not* to do. If wholesalers actually charged AWP, they would eliminate the “spread” on Pharmacia’s drugs (the difference between what pharmacies pay to acquire them and what they are reimbursed upon dispensing them. The existence of a spread) and one bigger than Pharmacia’s competitors—appears to be the *raison d’être* for Pharmacia’s inflated AWP. See Wisconsin’s Brief of Cross-Appellant (henceforth “WBCA”) at 6-13.

Similarly, far from showing that wholesalers use AWP as a basis to negotiate prices, testimony showed that in selling to pharmacies, wholesalers discount their prices not from AWP but from *Wholesale Acquisition Cost* (WAC), which was always significantly *below* AWP. R305, Video Dep. of Neil Warren played at trial at 263:12-270:15 (S.App. 23-26).

AWP is not comparable, as the amici claim, to terms of art like “World Series,” “two by four,” or “Big Ten.” BAB at 10-11. Everyone agrees what “the World Series” means, but the evidence revealed no agreement between Wisconsin and Pharmacia, much less agreement throughout the industry, that AWP is intended to mean something different than its name. The amici’s specter of Wisconsin seeking millions in forfeitures against sellers of tickets for “Big Ten” games (BAB at 11) is vacuous. First, the Big Ten publicly lists its number of

members, but Pharmacia provided no such candor as to the “real” meaning of AWP. Second, the Wisconsin legislature has enacted no specific law regulating how college athletic conferences name themselves. It *has* enacted §100.18(10)(b) to emphasize that the words “wholesale price” used in trade means what it says.

B. The “formulaic mark-up” argument

The brand amici argue that published AWPs for brands were calculated as a “formulaic 20 or 25% mark-up from the manufacturer’s WAC [wholesale acquisition cost] price” and hence “[t]here is nothing false or ‘wrong’ about the number, which the State concedes is simply the product of a standard mathematical calculation.” BAB at 11.

This argument, which Pharmacia’s briefs do not make, has no merit. The fact that brand defendants calculated published AWPs by a formula does not negate their falsity, particularly since there was no evidence that Wisconsin was told by Pharmacia or anyone else that published AWPs were derived from a “formulaic markup” from WACs until that information was pried out of them by this litigation. (The “concession” claimed by amici was an answer by Wisconsin’s damages expert on cross-examination when asked to confirm the percentage differences between WACs and AWPs on his computer spreadsheets.) First DataBank, which published the AWPs, defined them as actual

averages of real wholesale prices, not as “WAC + 20%,” “WAC + 25%,” or WAC plus some other arbitrary percentage.²

III. The Brand Amici’s New Arguments Under §100.18(1) Are Improper and Lack Merit in any Event.

In the guise of supporting Pharmacia’s arguments that its AWP’s were not “false,” the brand amici offer two arguments that have nothing to do with the issue of falsity. First, they argue that causing AWP’s to be published by First DataBank did not produce a representation “to the public,” as required by Wis. Stat. §100.18(1), because the AWP’s Wisconsin uses are received from First DataBank on computer tapes which are supplied under contract (BAB at 13-14). According to the brand amici, “when a buyer enters into a contract with a seller, the buyer is no longer a member of the public.” *Id.*, citing *K&S Tool & Die Corp. v. Perfection Mach. Sales, Inc.*, 2007 WI 70, ¶26, 301 Wis.2d 109, 732 N.W. 792. BAB at 14-15. Second, the amici argue that §100.18(1) contains an implied requirement of proving that the publication was made to “promote the sale of a product.” BAB at 14, citing *State v. Automatic Merchs. of America, Inc.*, 64 Wis.2d 659, 663, 221 N.W.2d 683 (1974). According to the amici, Wisconsin did not prove this “element,” because “AWP’s are themselves a product owned by First

² Although the amici filed their briefs to provide “context,” they provide false context on this issue. They claim the term AWP “has never referred to an actual average of the prices retailers pay to wholesalers for drugs.” BAB at 1. To the contrary, according to Pharmacia’s own documents, historically, AWP’s were accurate. R304/PX-641 (S.App. at 125).

DataBank that First DataBank conveys, via confidential contract to EDS [Wisconsin’s agent for administering Medicaid payments].” BAB at 14.

This Court should strike these “First DataBank contract” arguments. Pharmacia did not argue this issue below or on appeal and hence amici have violated this Court’s order of November 10, 2010.

Pharmacia skipped these arguments for good reason.³ As to the first argument, a representation to Wisconsin, as the payer of drugs on behalf of Medicaid recipients, is *per se* a representation to “the public.” The State is the *embodiment* of the public. Through Medicaid, it buys drugs on behalf of nearly a million people. The amici cite no case implying that the State is not “the public” within §100.18. And even if the State were not *per se* the “public,” it is a member of the “public” under the circumstances of this case. A statement made even to *a single listener* can be made to the “public” under §100.18. *Bonn v. Haubrich*, 123 Wis.2d 168, 174, 366 N.W.2d 503 (Ct.App. 1985) (sustaining claim under §100.18(1) where the statement was made by telephone to a single consumer). “A plaintiff remains a member of ‘the public’ unless a

³ In the circuit court, nearly all the amici skipped them too. The consolidated defendants’ 102-page summary judgment brief never mentioned them. R135. Three defendants made them in individual briefs. R132 (Novartis) at 51-55; R131 (AstraZeneca) at 40; R139 (Schering/ Warrick) at 19-22. To camouflage their violation of this Court’s order, the amici place these arguments under a caption declaring that §100.18(10)(b)—the ban on calling a price “wholesale” if it is “more than the price which retailers regularly pay for the merchandise”—did not apply, despite its plain language. BAB at 12. Pharmacia did make the §100.18(10)(b) argument, but it has nothing to do with the amici’s new arguments.

particular relationship exists between him or her *and the defendant.*”
K & S Tool & Die, ¶27 (emphasis added). Wisconsin has a contractual relationship with First DataBank, but First DataBank is not a defendant. Contractual relationships between Wisconsin and EDS, and between EDS and First DataBank, are irrelevant. They merely provide the pipeline through which Pharmacia’s false AWP’s are relayed to Wisconsin. If the amici’s “to the public” argument were right, a manufacturer could publish false advertising on cable television, and then argue that the contracts between listeners and the cable company created a “particular relationship” between the listener and the manufacturer, protecting the manufacturer from §100.18 liability.

As for the second argument, Pharmacia not only did not raise it, but as discussed above, disclaimed a “sufficiency of the evidence” argument on any element of §100.18 liability. The evidence was sufficient for the jury to conclude that Pharmacia deemed the providing of AWP’s to First DataBank as an essential link in promoting the sale of its drugs, given evidence that most of Pharmacia’s drugs are ultimately paid for by third party payers and that those payers will not pay unless they have AWP’s they can use to determine reimbursement. Particularly damning was the evidence that Pharmacia used inflated AWP’s to “market the spread” on its drugs. *See* WB at 11-12 and WBCA at 6-12.

IV. The Amici’s “Causation” Arguments Have No Merit.

A. The amici offer nothing new on the “reliance” argument.

Pharmacia’s brief asserted that to show causation, Wisconsin had to prove it relied on the assumption that AWP’s were actual averages of wholesale prices, and that because it admitted knowing the AWP’s needed discounting, it could not establish this reliance. PB 28-29. In response, Wisconsin showed that *Novell v. Migliaccio*, 2008 WI 44, 309 Wis.2d 132, 749 N.W.2d 544, held that while reasonable reliance “may be relevant” to causation, it is unnecessary to make out a case under §100.18. In this case, Wisconsin, for practical reasons, had to rely on reported AWP’s for reimbursement. While Wisconsin Medicaid and the legislature knew that reported AWP’s needed discounting, they did not know what real acquisition costs were. In this situation, with Wisconsin relying on AWP to arrive at the estimated acquisition cost for drugs and lacking a practical alternative, untrue AWP’s caused harm by increasing reimbursements. It was Pharmacia who failed to persuade the jury that reimbursements would have been the same if true AWP’s had been reported. WB at 44-45.

The amici fail to improve on Pharmacia’s “reliance” argument. Like Pharmacia, the brand amici invoke *AstraZeneca LP v. Alabama*, 41 So.3d 15 (Ala. 2009), which overturned jury verdicts for Alabama in two

AWP trials on the ground that Alabama’s sole claim—for common law fraud—failed for inability to prove the “reasonable reliance” element. BAB at 21. The rejoinder remains the same: “reasonable reliance” is not required under §100.18, which, like most state consumer protection laws, uses a broader concept of causation than common-law fraud uses. This difference was decisive in Pennsylvania’s AWP case against Bristol-Myers Squibb. A jury rejected Pennsylvania’s common-law fraud claims, which required proof of reasonable reliance, but the trial judge decided *for* Pennsylvania on its statutory consumer protection claim, which did not require such reliance, and awarded large damages. *Comm. of Penn. v. Bristol-Myers Squibb Co.*, No. 212 M.D. 2004 (Commonwealth Ct. Sept. 10, 2010), reprinted in the Appendix to this Response (henceforth “Am.Resp.App.”) (attached hereto), at 1 & n.1.

B. The brand amici’s “causation” variation on Pharmacia’s “no duty” argument lacks merit.

Pharmacia argued that no statute or regulation required it to report AWP, so that at worst, it merely failed to report accurate AWP, and thus the case involves mere “nondisclosure,” which is nonactionable under §100.18. PB 30-32, *citing Tietsworth v. Harley-Davidson, Inc.*, 2004 WI 32, ¶40, 270 Wis.2d 146, 677 N.W.2d 233. In response, Wisconsin showed this is not a “nondisclosure” case. Whether Pharmacia had a duty to report AWP, it reported them; they were false;

and Pharmacia must pay for the damage they caused. WB at 45.

The brand amici offer a complicated variation on Pharmacia's "no duty" argument, under the rubric of causation. According to them, Wisconsin complains about Pharmacia's *failure to disclose the meaning* of its AWP's, not about its causing the publication of false prices. Hence, they say, to establish causation, Wisconsin had to compare what it actually paid versus what it would have paid had defendants caused the *same* numbers to be published by First DataBank "accompanied by a description the State views as accurate." BAB at 22. Instead, they argue, Wisconsin proved causation by showing what it would have done "if the numbers had been changed to 'correctly' fit the State's redefinition of what AWP should mean." *Id.* This, they say, is a mere "failure to disclose information," nonactionable under *Tietsworth*. *Id.*

This rewrite of Pharmacia's "no duty" argument does not cure the original. The amici provide no reason why the jury or court had to view this case as involving a failure to disclose an explanation about the meaning of Pharmacia's numbers, rather than involving affirmative false statements about prices. Pharmacia did not report disembodied numbers with no explanation of what they stood for. It reported numbers along with *the explanation inherent in the name*—and caused the numbers to be published by First DataBank, which explained that the numbers

meant what their name said they were.

In short, the evidence supported the jury in viewing this as a case of false statements, not as a case of failure to disclose what raw numbers really meant. Where a case involves affirmative untruths, the causation question is not, “What happened compared to what would have happened if the defendant had said nothing at all?” Wisconsin’s claim against Pharmacia is not that Pharmacia spoke when it should have remained silent, but that it spoke untruthfully. Under causation instructions Pharmacia agreed to, the jury could find that it caused damage to Wisconsin by reporting false average wholesale prices.

C. The brand amici’s “causation” argument based on the federal regulation has no merit.

The jury accepted Wisconsin’s argument that false AWP’s caused Wisconsin to set EAC at inflated levels rather than at the federally defined level—the State’s “best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers.” 42 C.F.R. §447.502. As discussed above, Wisconsin showed there is no basis for Pharmacia’s argument that the legislature intended to reimburse at inflated levels, and hence that the result would have been the same had Pharmacia’s AWP’s been true. One of many reasons to reject Pharmacia’s argument is that the legislature is

presumed to follow the law. The legislature presumably did not intend Wisconsin Medicaid to use EACs deliberately inflated far above the binding federal definition of EAC. *See* WB at 19-27. *See* WB at 19-27.

The amici argue, however, that setting systematically inflated EACs *is* consistent with the federal regulations. They say that while the regulations define EAC as the state's best estimate of actual acquisition costs, the regulations set a ceiling on *aggregate* reimbursement for single-source drugs—the sum of EAC plus reasonable dispensing fees for all drugs—rather than setting a ceiling on EAC reimbursement across all drugs. 42 C.F.R. §447.512(b). Thus, they argue, Wisconsin can comply with the regulation by deliberately setting EAC at inflated levels that over-reimburse acquisition costs, as long as it counterbalances that excess by paying unreasonably *low* dispensing fees. They claim that a board within the Department of Health and Human Services (HHS) so held in 1992. BAB at 24, *citing Pennsylvania Dep't of Public Welfare*, DAB No. 1315 (HHS Departmental Appeals Board, 1992) (BAB Appendix at 228-229). Hence, the amici conclude, Pharmacia does not have the burden of rebutting the presumption that Wisconsin would have reimbursed drugs at no more than the actual EAC if Pharmacia's prices had been accurate. BAB at 23-25; *see also* Generic Amici Brief (henceforth "GAB") at 23-29.

Pharmacia has not made this argument on appeal. Its only argument on the regulations' definition of EAC is a suggestion in its reply brief that the language of the definition of EAC is trumped by the regulations' requirement that rates be set high enough to maintain access. Pharmacia Reply Brief at 6-7. But that just suggests that to incentivize pharmacies to participate in Medicaid *overall* reimbursement must be adequate, not that Wisconsin needs to inflate ingredient cost reimbursement and underpay on the dispensing fee.

The amici's "two wrongs make a right" interpretation does not make sense, and the history of the regulations does not support it. As the generic amici point out, in the late 1980s, HCFA (the Health Care Finance Authority, predecessor of today's CMS, the Centers for Medicare and Medicaid Services) revised the regulations to place drug expenditure ceilings on an aggregate rather than a prescription-by-prescription basis. That revision freed the states from having to review each of hundreds of thousands of reimbursements to assure that the exact acquisition cost was reimbursed each time. *See* GAB 23-24. But the amici cite no evidence, and there is none, that HCFA contemplated states *intentionally* setting EACs at inflated levels and then counterbalancing that inflation by *intentionally* setting dispensing fees at unreasonably low levels.

Moreover, a state that did set EACs at greatly inflated levels and counterbalanced that inflation with unreasonably low dispensing fees would have to disclose what it was doing to the federal government and obtain its approval to operate in this exceptional manner. This is the real (and only) implication of the *Pennsylvania Department of Public Welfare* decision, a decision Pharmacia does not mention on appeal. That decision involved multisource drugs, for which the aggregate reimbursement limits set by the federal regulations do not directly depend on the drugs' EAC but on federally-set ceilings called "Federal Upper Limits" (FULs). *See* WB at 4.

In *Pennsylvania* decision, HCFA had disallowed federal funds because Pennsylvania had exceeded the federal aggregate upper limit by paying for ingredients in excess of the FULs. Appealing from the disallowance, Pennsylvania argued that under federal regulations, HCFA should have calculated the amount of the upper limit using a dispensing fee Pennsylvania had proposed that was higher than the fee Pennsylvania had actually paid. Using the higher fee for the calculation would have had the effect of raising the aggregate upper limit. Pennsylvania would have come in under this higher limit despite the ingredient costs paid *above* the FULs because the excess payments would have been offset by the lower dispensing fee actually paid.

The board rejected Pennsylvania’s justification because Pennsylvania had not proved to the satisfaction of HCFA that the higher dispensing fee it argued it *could* have used was the “reasonable” fee required by the regulations. BAB Appendix at 226-227. The decision reaffirmed that a state must “separately examine these components to determine what is the appropriate amount of . . . [ingredient costs] for which payments may be made and what is a reasonable dispensing fee for any period.” *Id.* at 226 (brackets in original, *quoting* Ruling on Request for Reconsideration in case no. DAB No. 1271 (February 6, 1992) at p. 4.)

Although *Pennsylvania Dep’t of Public Welfare* did not involve EACs, it implies that *unless* a state documents the reasonableness of a dispensing fee higher than what was paid and receives approval from HCFA to use that amount in calculating its aggregate upper limit, overpaying on ingredient costs violates federal law. There is no allegation that Wisconsin ever documented a higher fee or sought its approval. Nor was there any reason to do so. A Medicaid director testified that Wisconsin never intended to underpay “the dispensing fee by overpaying on the ingredient cost.” R438/24:8-10. And Wisconsin’s dispensing fee was over twice the dispensing fees private insurers paid. *See* R437/218:9-219:22; R438/26:4-7; R439/242:8-243:8 (S.App. 373-

74). Thus, all that the amici have shown is that although there may be an exception to the federal prohibition on overpaying EAC, that exception has no application to this case.

Finally, the brand amici assert that “federal Medicaid” has “approved” an Idaho regulation that “expressly *requires* that state’s Medicaid agency to pay pharmacists a dispensing fee plus ‘the net cost of the drug *and a reasonable operating margin.*’” BAB at 25 (emphasis in original). This false statement shows why this Court cautioned the amici against raising new issues Pharmacia never raised. The brand amici give no citation for federal “approval” of this Idaho regulation. Had Pharmacia raised this argument below, Wisconsin would have offered evidence that CMS *disapproved* this scheme, because it appeared to allow building a profit into EAC. CMS refused to approve the proposed amendment to Idaho’s state Medicaid plan until Idaho had removed the “reasonable operating margin” language from the plan.⁴ This episode shows, if anything, that CMS supports *Wisconsin’s* interpretation of the federal regulations.

⁴ The correspondence between CMS and Idaho is not in the record, since in the circuit court no defendant mentioned this argument or the Idaho regulations on which it rests. But the correspondence is public record, filed in *State of Idaho v. Alpharma USPD, et al.*, Case No. CVOC07-01847 (Dist. Ct. 4th Judic. Dist.), as Exhibits 5, 6, and 7 to the State of Idaho’s Response (filed November 12, 2010) to Defendants’ Joint Motion for Summary Judgment. (Am.Resp.App. 4-21). Having improperly raised this argument that they never raised below, the amici cannot complain of Wisconsin requesting this Court to take judicial notice of the public-record documents that refute it. See *State v. Ramel*, 306 Wis.2d 654, ¶24 n.9, 743 N.W.2d 502 (Ct. App. 2007).

D. The use of MACs for generics did not negate causation.

Pharmacia spent two sentences arguing that Wisconsin could not prove causation with respect to generic drugs, because “they were reimbursed based on MACs, which were set without regard to AWP or any other published prices.” PB 30. In response, Wisconsin pointed out that the jury heard evidence that (1) if a generic drug’s true AWP had been lower than the MAC Wisconsin set for it, pharmacies would have been reimbursed for the drug based on AWP, and (2) true AWP would have rendered MACs unnecessary for Pharmacia’s drugs. WB at 12, *citing* R436/60:22-61:15 (S.App. 282-283), 185:4-10 (S.App. 310).

In the twelve pages they spend amplifying Pharmacia’s two-sentence argument (GAB at 7-19), the generic amici add nothing of substance to it, and do not discuss Wisconsin’s simple rejoinder.

For starters, this argument against causation does not apply at all to the generic drugs for which Wisconsin has not set MACs. Wisconsin reimburses such drugs under the same AWP-based formula it uses for most brand drugs. R436/36:25-37:24 (Am.Resp.App. 26-27). Moreover, for generic drugs with a “MAC,” it takes time to establish that MAC. R436/37:25-38:13 (Am.Resp.App. 27-28). In the meantime, the drugs are paid under the AWP-based formula. R436/60:5-21 (S.App. 282). The generic amici never mention these facts.

As to generics for which MACs were established, the evidence supported the jury's finding of causation of damage by false AWP. As the generic amici state, neither the federal regulations nor the Wisconsin legislature told Wisconsin to set MACs for generic drugs. Wisconsin Medicaid set them in order to save money by paying less than the federal reimbursement ceilings on multi-source drug reimbursement. GAB at 15-16. Wisconsin could have used the AWP formula to reimburse generics, and its chief MAC official testified that Wisconsin would not have needed a MAC program if generic AWP had been true. *See* WB at 42; S.App. 282-283. And even with the MAC program in place, another Wisconsin official testified that if the AWP formula had produced a lower estimated acquisition cost for a drug than that drug's MAC, Wisconsin would have used the formula, not the MAC. S.App. 310.

Given this evidence, the jury rightly rejected the assertion that AWP "played [no] role in reimbursing pharmacies and other providers for dispensing the vast majority of generic drugs." GAB 16. Instead, the jury could conclude that the only reason that the AWP did not determine such reimbursements was that they were inflated to levels that caused the drugs' estimated acquisition cost to exceed the drugs' MACs.

Like Pharmacia, the generic defendants never address this evidence. Instead, they argue that Wisconsin Medicaid set MAC prices

“on the basis of actual market prices.” They accuse Wisconsin of the “nonsensical” argument that “Wisconsin Medicaid would not have needed to use market prices as a basis for reimbursement if only it had access [to] market prices to use as a basis of reimbursement.” GAB 17.

Even as amplified by amici, this argument has no merit. The evidence supported a finding that Wisconsin’s effort to get “market” prices was hindered by false AWP’s. Ted Collins, who sets MACs for Wisconsin, testified to the difficulty in getting accurate and current information on actual prices, including having to sometimes use veterinary prices. R436/41:23-44:24 (S.App. 272-75). The missing link was truthful AWP’s. The false AWP’s for generic drugs provided had no predictable relationship to real average wholesale prices. R305, Video Deposition of James Cannon played in court, 79:15-80:10 (Amici.Resp. App. 30).

The generic amici tout how “aggressive” Wisconsin’s MAC program was. GAB 15. This fact cuts *against* Pharmacia. It shows Wisconsin was uninterested in paying systematic profits to pharmacies by inflating generic drug acquisition-cost reimbursements. That fact provides further support for a jury finding that truthful AWP’s would have allowed Wisconsin to save money on generic reimbursement.

The generic amici also argue that causation of damage on generic

drugs was negated by the fact that Ted Collins, in setting MACs, would mark up the lowest price he could find in the market by a percentage to ensure that pharmacists would continue to participate in the program. BAB at 18. As explained by Mr. Collins, the MACs with the mark-up were set to “arrive at the lowest price that’s uniformly available,” not to “pay profits.” R436/32:22-25 (S.App. 270). Collins marked up the “lowest price [he] can find,” in order to “accommodate whatever differences there may be in other source prices [he didn’t] have access to.” R436/35:19-36:16 (Am.Resp.App. 25-26), 67:9-11. Collins was thus not marking up what he believed was a true *average*. He marked up the *lowest* price—the outlier. The jury could reasonably credit Collins’ explanation that this procedure was necessary to compensate for the scattered and uncertain nature of the price evidence he was forced to rely on in the absence of true AWP’s.

E. The 1987 amendments to federal regulations on multiple-source drug reimbursements are irrelevant.

The generic amici assert that amendments to the federal regulations in 1987 could allow pharmacies to earn a profit on the ingredient-cost component of reimbursement for multiple-source drugs. GAB at 28-39. The provisions in question have nothing to do with single-source drugs reimbursed based on EAC. They apply, rather, to multiple-source drugs for which a “federal upper limit” (FUL) had been

set, and impose a ceiling on the aggregate of the drugs' FULs and reasonable dispensing fees. (These regulations now appear at 42 C.F.R. §447.512(a) and §447.514.) Because one FUL covers multiple manufacturers' versions of a drug and thus might be higher than a particular drug's acquisition cost, FULs allowed a possible profit to pharmacies able to purchase the lowest-priced version of the drug.

However, even for the multi-source drugs covered by these regulations, this possibility of profit on the ingredient-cost component is irrelevant in Wisconsin—which explains why Pharmacia has not mentioned this subject on appeal. Those regulations merely provided a *ceiling* (the aggregate sum of drug FULs) on multiple-source drug reimbursement. But the Wisconsin Medicaid program chose to pay *less* than FULs for these drugs. It set its own “Maximum Allowable Cost” figures (MACs) for these drugs, and it used those MACs, not the FULs, for reimbursement. R436/34:21-25 (Amici.Supp.App. 24). Thus, whatever the federal regulations on multi-source drugs allowed Wisconsin to do, the jury could find Wisconsin used MACs to *avoid* providing profits to pharmacies through the ingredient-cost component of reimbursement of those drugs. The testimony was, again, that the MACs were set to “arrive at the lowest price that’s uniformly available,” not to “pay profits.” R436/32:22-25 (S.App. 270). And as discussed

above, the jury could conclude that if AWP for these multi-source drugs had been truthfully reported, the drugs would have been reimbursed at the even lower AWP-based rates.

V. The Generic Amici’s Discussion of Amps Is Irrelevant.

The generic amici conclude their brief with a long discussion of how drug manufacturers are required by the rebate provisions of 42 U.S.C. §1396r-8 to report figures to HCFA (now CMS) called “Average Manufacturers’ Price” (AMP). AMP is an average unit price paid to the manufacturer by wholesalers. CMS is required to keep these prices confidential from the states, as the amici admit. GAB at 32-33. CMS uses these AMPs to calculate rebates owed by the manufacturers to states. The generic amici argue that states could work backwards from these rebates to deduce what the AMPs were. *Id.* at 33.

This “reverse engineering” argument, which Pharmacia has not made on appeal, leads nowhere. AMPs are not wholesalers’ prices to pharmacies (*i.e.*, the AWP that Wisconsin is trying to estimate and pay), but rather manufacturers’ prices to wholesalers.⁵

The closest the amici come to explaining the relevance of AMPs is a murky argument to the effect that because the AMP statutory

⁵ Ted Collins testified that on a few occasions, he tried to use “Unit Rebate Amounts” to help him establish what wholesalers’ actual prices to pharmacies were, but that it was “never really useful in terms of arriving at a price that [he] was comfortable using.” R.436/49:11-17 (S.App. 280), 76:23-78:4.

provisions required the manufacturers to report net discounted prices, HCFA had no “expectation that AWP’s reflect prices actually paid in the marketplace.” GAB 34. If the amici are asserting that the federal government gave its *imprimatur* to the reporting of false AWP’s, a sufficient answer is the “OIG Guidance” (PX-828, A.Ap. at 534-546), which warned manufacturers of the importance of AWP in Medicaid reimbursement and said the government expected *accurate* price reporting. *See* WB at 66-67.

VI. The Brand Amici’s Jury Trial Arguments Have No Merit.

A. The amici’s new §100.18 argument is unpersuasive.

To carry a constitutional right to a jury trial, a statutory cause of action must be “essentially the counterpart” of a cause of action, whether criminal or civil, existing in 1848 and recognized then as “at law.” *Village Food & Liquor Mart v. H & S Petroleum, Inc.*, 2002 WI 92, ¶11, 254 Wis.2d 478, 647 N.W.2d 177. Two causes of action must share a “similar purpose” to be essential counterparts. *Harvot v. Solo Cup Co.*, 2009 WI 85, ¶72, 320 Wis.2d 1, 768 N.W.2d 176.

The circuit court, whose decision preceded *Solo Cup*, found that Wisconsin’s claim under §100.18 had an essential counterpart in the pre-statehood cause of action for cheating, which, as the amici note, included “the modern tort of misrepresentation.” BAB at 32. Pharmacia in this

Court chose not to discuss this reasoning. It never addressed the “cheating” cause of action, or tried to show it was not an essential counterpart of §100.18 under *Village Foods* and *Solo Cup*’s “similar purpose” test. Instead, Pharmacia offered a single paragraph arguing that (1) in *State v. Ameritech Corp.*, 185 Wis.2d 686, 517 N.W.2d 705 (Ct.App. 1994), *aff’d by an equally divided Court*, 193 Wis.2d 150, 532 N.W.2d 449, this Court held there is no constitutional jury-trial right under §100.18, and (2) *Ameritech* was “cited with approval” in *Solo Cup*, and therefore its constitutional holding still controls. PB 41-42.

In response, Wisconsin showed that *Solo Cup*’s citation of *Ameritech* was limited to whether the legislature’s failure expressly to prescribe a jury trial for a statutory cause of action prevents a court from finding that the legislature intended such a right by implication. On the constitutional question, *Ameritech*’s “codification” framework of analysis was specifically rejected in *Village Food*, and has never been reinstated. Thus, as the circuit court held, the §100.18 issue demands *de novo* consideration under *Village Food* and its successors. WB at 52-53.

The brand amici do not argue that *Solo Cup*’s citation of *Ameritech* controls the constitutional issue. Instead, they try to fill the analytic void left by Pharmacia, arguing that “cheating” and §100.18 do not share a “similar purpose” for purposes of *Solo Cup*. BAB at 31-33.

The amici barely describe what cheating consisted of at statehood. Blackstone lists “cheating” as one of eleven felonious offenses “against public trade.” R197 (Chapter 12 attachment) (4 William Blackstone Commentaries on the Law of England (1769), at 154, 157) (Am.Resp.App. 31, 34). (The amici rely on an 1897 edition of Blackstone that post-dates Wisconsin statehood, and they cite to material that is not included in the 1769 pre-statehood version.) This particular offense deals with “prevent[ing] deceit” in public trade. *Id.* at 157 (Am.Resp.App. 34). Blackstone’s discussion of cheating begins by emphasizing that public trade “cannot be carried on without a punctilious regard to common honesty, and faith between man and man.” *Id.* He then points out that there are a “prodigious multitude of statutes, which are made to prevent deceits in particular trades,” because the legislature “thoroughly abhors all indirect practices.” *Id.*

Cheating, as used in 1848, was clearly synonymous with “deceiving” or deviousness in trade practices. Even today, a dictionary definition of “cheating” includes “to deceive; influence by fraud: *He cheated us into believing him a hero.*” Random House Dictionary (2009), <http://dictionary.reference.com/browse/cheat>. Thus, under the offense of “cheating” “any deceitful practices, in cozening another by artful means ... in matters of trade” were tried to a jury. R197/158

(Am.Resp.App. 35) (“Cozen” means “to cheat, deceive, or trick.” Random House Dictionary (2009), <http://dictionary.reference.com/browse/cozen>.) Also tried to a jury was a claim of “defraud[ing] another of any valuable chattels by colour of any ... false pretense.” R197/158 (Am.Resp.App. 35)

In short, “cheating” concentrated on trade practices, as §100.18 does today, and within that area of concentration, proscribed a broad range of deceptive practices, as does §100.18 today. Nonetheless, the amici claim, unpersuasively, that the two have different “purposes.”

1. The amici argue that under *State v. Schweda*, 2007 WI 100, 303 Wis.2d 353, 736 N.W.2d 49, courts must “narrowly construe” the statutory causes of action analogized to pre-1848 common law claims, lest they “render the *Village Food* test a nullity.” BAB at 31-32, quoting *Schweda*, 2007 WI 100 at ¶¶34, 40. What *Schweda* actually remarked was:

The breadth of [the cause of action for] nuisance is so great that we must narrowly construe the actions that we analogize to nuisance, lest we render the *Village Food* test a nullity because “present causes of action of all sorts assessed under this test will only have to be compared generally ... in order to invoke the constitutional protection to a trial by jury.”

Schweda, 2007 WI 100 at ¶40, quoting *Village Food*, 2002 WI 92 at ¶ 46 (Wilcox, J., concurring and dissenting). As the majority noted,

“Historically, ‘nuisance’ has been a term so broad that it could encompass a vast array of causes of action. It included everything from an alarming advertisement to a cockroach baked in a pie.” *Schweda*, 2007 WI 100 at ¶32. The cause of action for cheating did not share this unbounded, amorphous quality. Like §100.18, it focused on deceptive trade practices, and within that focus, like §100.18, swept broadly.

2. To cast §100.18 as narrower than “cheating,” the amici call §100.18 a mere “cause of action for false advertising.” BAB at 32. It is far more than that. Its text covers any “advertisement, announcement, statement or representation of any kind to the public relating to such purchase, sale, hire, use or lease.” §100.18(1). It proscribes misrepresentations in trade in “real estate, merchandise, securities, employment, or service.” It covers not only those who make statements but those who “cause [them], directly or indirectly, to be made.” (*Id.*) It covers not only intent to sell, but intent to “distribute, increase the consumption of, or in any wise dispose of . . . anything offered . . . to the public.” (*Id.*)

In contrast, in *Schweda* and *Solo Cup*, the 1848 causes of action and their claimed modern statutory counterparts worked in different ways. In *Schweda*, the environmental statutes and regulations invoked by Wisconsin worked by imposing specific regulatory requirements. In

distinguishing these provisions from the “nuisance” cause of action, *Schweda* analyzed, claim by claim, the pinpointed nature of these obligations—such as “violations of the limits on concentrations of pollutants in discharges incorporated into [defendant’s] pretreatment permit.” *Schweda*, 2007 WI 100, ¶¶37, 38. In contrast, the cause of action for nuisance is amorphous, contains no specific affirmative requirements, and “has meant all things to all people.” *Id.*, quoting Prosser and Keeton on the Law of Torts, §86 at 616-617 (5th ed. 1984).

The same distinction was obvious in *Solo Cup*. The statutory cause of action—the Wisconsin FMLA—imposes affirmative obligations on employers, defined in quantitative terms, to give family and medical leave to employees, regardless of any employment agreement, and to hold their jobs open with no reduction in seniority when the leave ends. The supposed 1848 “counterpart” was a statute preventing cruelty to apprentices. *Solo Cup*, 2009 WI 85, ¶¶82-83.

3. The amici argue that “cheating” and §100.18 have different purposes because cheating, among other things, proscribed “unsavory activity” such as using false weights and measures and putting sawdust in bread. BAB at 32. But a seller who used false weights and measures to state the quantity for which it was charging, or who represented sawdust-stuffed bread to be “bread,” would court §100.18 liability.

4. The amici argue that §100.18 “is not simply a codification of common law misrepresentation” (BAB at 32), and claim, without citation, that cheating, unlike §100.18, contains a *scienter* requirement (*id.* at 33). But *Village Food* rejected the “codification” test, and *Schweda* confirmed that rejection. *Schweda*, 2007 WI 100, ¶¶20, 21.

B. The amici offer nothing new as to the right to a jury under §49.49.

With respect to §49.49, the amici track Pharmacia’s main argument—that because §49.49 bans fraud in a government program that did not exist in 1848, the “purpose” of §49.49 is different than the purpose of common-law fraud. According to them, *Solo Cup* instructs that courts “should not look to the broad purpose of a modern statute” but should “instead focus on the specific purpose of the statute in the historical context in which it was enacted.” BAB at 33, *citing Solo Cup*, 2009 WI 85, ¶¶79-80. One searches these paragraphs, and the entire opinion, in vain for this statement. Nothing in *Solo Cup* or *Schweda* supports the assertion that the “purpose” of an antifraud statute is different—in a constitutional jury-trial analysis—than the purpose of common law fraud simply because the statute covers a subset of the situations that common-law fraud covers, or simply because the program that is the subject of the antifraud statute did not exist in 1848.

The amici’s proposed rule would be dangerous. As the author of

Solo Cup pointed out in *Schweda*, the right to a civil jury trial is a “highly valued attribute of American government” and was regarded by the founders as an essential bulwark of civil liberty. *Schweda*, 2007 WI 100, ¶89 (Prosser, J., concurring and dissenting). The amici do not want a jury trial, but in many cases defendants do. Denying trial by jury as to a statutory claim denies such a trial to both plaintiffs and defendants. This erosion of constitutional protection is particularly serious when the State is plaintiff. Defendants accused of civil fraud have had the right to trial by jury since statehood. But in the amici’s view, when the alleged fraud concerns a modern government program, the legislature can eliminate this protection by enacting a statutory fraud remedy limited to that program. Neither *Schweda* nor *Solo Cup* intended this result.

CONCLUSION

Except as to the issues raised by Wisconsin’s cross-appeal, the judgment of the circuit court should be affirmed.

Respectfully submitted,

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CERTIFICATION

I hereby certify that the foregoing brief conforms to the Court's order of August 19, 2010, granting leave to Wisconsin to file a response to the amici briefs not exceeding 35 pages.

Dated this 22d day of December 2010.

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CERTIFICATION

In accordance with §809.19(12)(f), Wis. Stats., I hereby certify that the text of the electronic copy of the Respondent's Brief is identical to the text of the paper copy of the Respondent's Brief.

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