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STATE OF WISCONSIN
SUPREME COURT

Case No. 2010AP000232-AC from District IV/II

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., Sisor, Inc. f/k/a Gensia Sisor 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 NON-PHARMACIA
BRAND AND GENERIC DEFENDANTS**

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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The *amici curiae* are defendants in this lawsuit who did not participate in the opening trial against Pharmacia Corporation. After Wisconsin filed its response brief (“WB”) in this Court, these defendants moved to file *amicus* briefs. Wisconsin then sought leave to file this Response, which answers arguments that Pharmacia did not make in this Court.

I. THE FORMULAIC RELATIONSHIP BETWEEN AWP & WAC REVEALS NOTHING ABOUT ACTUAL ACQUISITION COSTS.

The brand *amici* argue that for brand drugs, “AWPs have always represented a formulaic markup, typically either 20 or 25%, over the drug’s wholesale acquisition cost (WAC), which is the invoice price manufacturers charge to wholesalers.” Brand Amicus Brief (“BAB”) at 1. Hence, they conclude, “the numbers published as AWP’s have a predictable, mathematical relationship to the marketplace prices for brand drugs.” *Id.* at 1-2. These assertions incorrectly suggest that Wisconsin could have used AWP’s to know what real prices were, but chose not to.

First, this argument is far beyond the scope of the “speculation of damages” issue accepted for review by this Court. Any suggestion by the

amici that the jury’s finding that Pharmacia’s AWP’s were deceptive and false should nonetheless be called into question is contradicted by the clear language of the statute governing liability for deceptive wholesale prices—
“It is deceptive to represent the price of any merchandise as a ...
wholesaler’s price, or a price equal thereto, unless the price is not more than
the price which retailers regularly pay for the merchandise.” Wis. Stats.
§ 100.18(10)(b).

Second, the argument is wrong. The formulaic relationship between AWP and WAC reveals nothing about actual acquisition costs. WAC is the *manufacturer’s* published price to *wholesalers*. WACs do not reveal what *wholesalers* charge when they resell to retail pharmacies, which is the amount Wisconsin needs to know for reimbursement purposes. Wisconsin needs to know the *actual* markups from WACs that wholesalers use. Publishing AWP’s based on false, formulaic markups from WACs produces false, formulaic AWP’s that fill the data sources Wisconsin needs to rely on with misinformation.

To compound the problem, because of discounts, most wholesalers buy from manufacturers at less than WAC. Supp.Ap. 90, 173-74. For this reason, several jurisdictions that base reimbursement on WAC rather than

AWP have successfully sued generic drug manufacturers for causing false WACs to be published by First DataBank. *See In re Pharm. Indus. AWP Litig.*, 672 F.Supp. 211, 215 (D.Mass. 2009) (finding WACs deceptive under Massachusetts law because they were not actual prices to wholesalers); *In re Pharm. Indus. AWP Litig.*, 685 F.Supp. 186, 202-10 (D.Mass. 2010) (same under New York law).

II. SINCE WISCONSIN DID NOT “CROSS-SUBSIDIZE,” IT IS PURE SPECULATION THAT IT WOULD HAVE DONE SO IF IT HAD HAD ACCURATE PRICES.

Pharmacia’s opening brief depended on the assertion that the legislature intended to set the “Estimated Acquisition Cost” component of reimbursement at a level which would provide profits to pharmacies. PB 3, 29, 35-36, 51. Wisconsin responded that this assertion is baseless. WB 23, 25. Remarkably, the brand *amici* side with Wisconsin, effectively demolishing Pharmacia’s attempt to deduce legislative intent through trial evidence. BAB at 8-10. They rightly conclude: “Here, all the legislature did was appropriate an amount of money it was told would enable the Medicaid program to reimburse pharmacists at a specified formula level.” *Id.* at 9. They rightly add that “*why* the legislature chose to enact a law, as

opposed to what it *said* in that law – is not a simple historical fact analogous to the intent of contracting parties.” *Id.*

But the brand *amici* then jump the track by concluding that the jury could not determine what would have happened had Wisconsin been given true rather than false AWP. Not only did the jury have evidence of what Wisconsin actually *did* with accurate AWP (see WB 15-17, 21), but it had the benefit of—and was instructed on—the legal rule that public officials, including legislative bodies, are presumed to follow the law. *Bohn v. Sauk County*, 268 Wis. 213, 219, 67 N.W.2d 288 (1954). Wisconsin showed, and the *amici* do not dispute, that (1) federal law binding on Wisconsin defines EAC as a State’s best estimate of the *actual* prices to pharmacies (WB 26-27); and (2) Wisconsin told the federal government that Wisconsin’s EAC formula was its best estimate of *actual* acquisition costs. WB 14; Supp.Ap. 149.

Hence, it was not “speculation” for the jury to presume that the legislature, in approving Medicaid budgets, intended to comply with the requirement of setting EAC at real, not inflated levels. WB 26-32. Nor was it “speculation” for the jury to find that if Wisconsin had received accurate information about acquisition costs—which it would have had if

defendants had not falsified their published AWP—Medicaid officials would have used those lower prices, as they did in the past, to reimburse at actual average acquisition costs with no interference from the legislature. WB 15-17, 21.

The brand *amici* do not dispute that the legislature is presumed to comply with the law. Thus, they are forced to argue that federal regulations allow the deliberate inflation of EAC, even though the regulations *define* EAC as an estimate of *actual* acquisition cost. BAB 13-16.

But in so arguing, the *amici* once again part ways with Pharmacia. Pharmacia argued that federal regulations forbid the “dispensing fee” from including a profit to pharmacies, and that hence they *must* permit EAC to be inflated to provide such profits, notwithstanding the definition of EAC; otherwise no pharmacy would participate in the Medicaid program. PB 8, 33-35. But as Wisconsin showed, the plain language of the regulations, the legislative history of the rule, the publicly declared position of the federal Center for Medicare and Medicaid Services (CMS), and the only federal case directly to examine the issue all confirm that the rules mean what they say: a State must set its EACs at its best estimate of *actual* costs. If a State deems it necessary to include a profit to pharmacies on Medicaid business,

it can do so through the dispensing fee. WB 5-6, *citing* HHS Office of Inspector General, *Replacing Average Wholesale Price: Medicaid Drug Payment Policy*, July 18, 2011 (<http://oig.hhs.gov/oei/reports/oei-03-11-00060.asp>); WB 26-29.

The *amici* say not a word in support of Pharmacia’s rationale for reading the EAC regulations to mean something irreconcilable with what they say. And the *amici* disagree with Pharmacia and agree with Wisconsin that a State may include a profit to pharmacies in the dispensing fee. BAB 14 (*citing* the same HHS report Wisconsin cited).

But the *amici* then argue that Wisconsin did just the reverse. They argue that Wisconsin deliberately set its dispensing fee at an unreasonably low level that made pharmacies *lose* money on every prescription—and then deliberately inflated its EAC payments above real acquisition-cost levels to make up for that unreasonably low fee. They argue that the federal regulations permit this so-called “cross-subsidization” of an inadequate dispensing fee with an inflated EAC. BAB 12-16; *Generic Amici Brief* (“GAB”), 11.

Specifically, the federal regulations provide that a State’s total *aggregate* reimbursement on brand drugs (and generics without “Federal

Upper Limits”) must not exceed the sum of EACs plus reasonable dispensing fees. 42 C.F.R. §447.512(b). The *amici* seize on the “aggregate” language, arguing that it lets States (1) set unreasonably low dispensing fees and then (2) offset that unreasonably low fee by deliberately inflating EACs. BAB 14, *citing Pa. Dept. of Public Welfare*, D.A.B. No. 1315 (HHS Department Administrative Board, March 18, 1992) (hereafter “*PDPW I*,” reprinted at <http://www.hhs.gov/dab/decisions/dab1315.html>); GAB 10-11. The case relied on by the *amici* was re-opened in *Pennsylvania Dept. of Pub. Welfare*, DAB No. 1557 (Jan. 26, 1996) (“*PDPW II*”), reprinted at <http://www.hhs.gov/dab/decisions/dab1557.html>, although the *amici* do not mention it.

PDPW I involved a dispute between Pennsylvania’s Medicaid agency and HCFA, the predecessor to CMS. In calculating the “federal share” of Pennsylvania’s Medicaid drug expenditures, HCFA found that Pennsylvania’s total of ingredient cost reimbursements and dispensing fee payments on multisource drugs had exceeded the relevant aggregate limit set by the federal regulations. Pennsylvania appealed the resulting “disallowance” of federal reimbursement to the HHS Department

Administrative Board. Pennsylvania admitted overspending on ingredient cost reimbursements, but asserted that the overpayment compensated for the unreasonably low dispensing fee it had paid. Hence, Pennsylvania argued, HCFA should calculate a *higher* aggregate spending limit for Pennsylvania by using a *higher* “reasonable dispensing fee” than it had actually paid.

Under the Board’s two decisions, Pennsylvania ultimately lost \$3.6 million in “federal share” matching funds. *PDPWI* assumed that the federal regulations allowed Pennsylvania to defend against the federal government’s recoupment effort by showing that its admitted overpayments on ingredient costs were offset by the unreasonably low dispensing fee that it paid providers—but only because specific pre-conditions were met.

In its annual “assurances” to CMS, Pennsylvania had, as required, assured HCFA that it would not spend more than the aggregate ingredient costs of the drugs dispensed plus a “reasonable dispensing fee.” *See* 42 C.F.R. §§447.518, .514(b) (2006). In those assurances, Pennsylvania specified a “reasonable dispensing fee” that was higher than the actual dispensing fee that it subsequently paid to pharmacists. The Board agreed with Pennsylvania that it was acceptable to use the higher dispensing fee,

rather than the actual fee, to determine the upper payment limit, but only because the higher figure had been previously specified in its assurances. *Id.* at 11 n.8. *See also PDPW II* at 6 (the higher dispensing fee could be used to calculate a higher limit “only because” Pennsylvania had established it “in advance”). The Board remanded requiring Pennsylvania to prove that the higher dispensing fee was, in fact, “reasonable.” *PDPW I* at 10.

Four years later, the dispute came before the Board again because even using the higher dispensing fee to calculate the upper payment limit, Pennsylvania’s expenditures exceeded the limit. *PDPW II* at 1-2. In *PDPW II*, Pennsylvania argued that an amount *even higher* than that specified in its assurances would be reasonable in calculating Pennsylvania’s upper payment limit. The Board rejected Pennsylvania’s position, holding that “the applicable regulations required Pennsylvania to establish a reasonable dispensing fee prior to or at the time of providing its assurances, ... and that it is irrelevant that a greater amount might also have been considered reasonable.” *PDPW II* at 1-2. The Board affirmed HCFA’s \$3.6 million disallowance of federal Medicaid contributions to Pennsylvania. *Id.*

Thus, in this pair of decisions, the Board took the position that if a State wishes to show that excessive EAC payments are offset by inadequate dispensing fees, (1) the State must *prove* what a “reasonable” dispensing fee would have been based on an analysis of data that include pharmacy overhead costs and profits, *PDPW I* at 3, and (2) the State must make this showing “prior to or at the time” it submits its original assurances to CMS that it is complying with the aggregate limits. *PDPW II* at 6.

The procedural requirements these decisions imposed are crushing to the position of the *amici* and Pharmacia—that Wisconsin intended to overpay providers for ingredient costs, that HCFA/CMS allowed it, and that Wisconsin therefore would have done so even if it had known actual acquisition costs. There was no trial evidence to support the notion that Wisconsin provided in its assurances to CMS a higher “reasonable dispensing fee” than the dispensing fee that was actually paid.¹ Without a higher “reasonable dispensing fee” set out “in advance,” Wisconsin’s

¹ Indeed, the only evidence the *amici* cite of the supposed inadequacy of the dispensing fee is complaints from industry groups representing *pharmacies*. See BAB 8. “Undocumented complaints from the beneficiaries of overpayments show nothing, while Wisconsin showed through credible evidence that the fee paid was reasonable. WB 17-18.

spending was limited to *actual* ingredient costs plus the *actual* dispensing fee paid. Moreover, Wisconsin certified to HCFA/CMS that its AWP-based formula for determining EAC was its best estimate of *actual* acquisition costs. WB 14; Supp.Ap. 149. If Wisconsin nonetheless had knowingly paid millions of dollars in inflated ingredient costs, it risked HCFA/CMS withholding the multi-million-dollar federal share of those of inflated payments. There was no evidence that Wisconsin did so, and the jury was instructed the Wisconsin officials acted in accordance with the law absent evidence to the contrary. Since Wisconsin did not cross-subsidize, it is pure speculation that it would have done so if it had had accurate prices.

The brand *amici* take the “cross-subsidization” argument to bizarre lengths by citing Alabama’s 2010 announcement that it had discontinued using AWPs to set EACs in favor of a system of surveying actual acquisition costs, that it was increasing the dispensing fee in connection with this change, and that CMS had approved these changes. *See* BAB 15-16, citing an Alabama Medicaid Agency press release. According to the brand *amici*, the fact that CMS approved this change illustrates “CMS’s recognition that Alabama’s previous inadequate dispensing fee had been cross-subsidized by its AWP-based drug reimbursement.” BAB 15. They

then assert that Wisconsin’s current dispensing fee is only 32% of the fee adopted by Alabama. *Id.*

This argument is improper because it depends on material that is clearly outside the record—a press release, no less. It is also worthless, because it proves nothing about the issues before this Court. Alabama is not Wisconsin, and 2010 is not 1994 through 2006, the damages period in this case. Moreover, there is no evidence that Alabama ever told CMS that its previous dispensing fee was inadequate or that it had deliberately inflated its estimate of acquisition costs, much less that CMS approved those earlier plans knowing the State “cross-subsidized.” If CMS’s approval of Alabama’s changes permits any inference at all, it is that CMS approved of Alabama’s finding a way to avoid the distortions that the use of AWP produces in estimating *accurate* EACs, as the law requires.

III. THE GENERIC AMICI’S NEW ARGUMENTS HAVE NO MERIT

The generic *amici* offer two new “speculation” arguments that Pharmacia’s brief did not make.

A. For many generic drugs, Wisconsin set EACs not by reference to AWPs but by assigning them “Maximum Allowable Costs”

(MACs). Under that program, a consultant, Ted Collins, tried to research the price at which pharmacies could buy these drugs. He then took the *lowest* price he could find and marked it up by a modest percentage to set the MAC, and he did not intend to pay a profit. Collins testified to the difficulties of gathering price information in the absence of accurate AWP for these drugs, sometimes having to rely on veterinarians for pricing data. He testified that if he had had AWP reflecting actual average wholesale prices, he would have used those AWP to set the MACs. *See* WB 16-17, *citing* Supp.Ap. 219-29, 231-32. On that basis, Wisconsin asked the jury to calculate damages on these drugs in the same fashion as it did for other drugs—the difference between the reimbursement that would have resulted from setting ingredient cost reimbursement at real AWP and the inflated amounts that Wisconsin actually paid.

The generic *amici* assert that Collins set the MACs at “a 10-25% markup over actual market prices” plus the dispensing fee, and that hence Wisconsin was asking the jury to “speculate that Wisconsin would not have adopted the MAC program that it did, and that it would have reached a different decision regarding providing a mark-up to pharmacies if it had used AWP as a reflection of market prices rather than the data-analysis

results that it did use.” GAB 7-8. This argument falsely describes what Collins did. He did *not* base his MACs on a “markup over actual market prices.” He based them on marking up the *lowest price he could find in the marketplace*. The problem with the technique, as Collins testified, was that it was hard to get systematic data on what pharmacies were really paying on average. That is why he said that if he had had accurate AWP—*i.e.*, reliable *average* wholesale prices—he would have used them as the drugs’ ingredient cost, rather than setting a MAC by marking up the lowest price he could find.

The generic *amici* do not argue that the legislature would have overruled Collins in using accurate AWPs to set EACs on these drugs, and no evidence supports such a notion. As opposed to the formula for EAC for brand drugs and generic drugs without FULs, where the legislature was asked to approve budget requests based on particular formulas, the legislature delegated the authority to set MACs to the Medicaid program.

B. The generic *amici* spend six pages arguing something Wisconsin agrees with: the federal regulations provide a separate aggregate limit on reimbursement applicable to those generic drugs that have been given a “Federal Upper Limit” (FUL), and this special limit allows

pharmacists who acquire drugs at prices below the FUL to retain the difference as profit. Hence, they say, the argument that applies to brand drugs and to non-FUL generics—that federal law required Wisconsin to set reimbursement at its best estimate of actual cost levels—does not apply to drugs with FULs. GAB 8-13.

Wisconsin noted this fact in its response brief. WB 27 n.2. The fact has no significance to the “speculation” issue. On this subset of drugs, Wisconsin reimbursed with MACs. The damages calculations, therefore, relied not on the limits set by federal law, but on credible (and unrebutted) evidence, discussed above, that Ted Collins would have simply set the MACs for these drugs at their AWP if he had had accurate AWP. It also relied on credible evidence that even as to drugs with MACs, if the AWP-based formula for any such drug had produced a lower figure than the MAC, Wisconsin would have paid the lower figure. R436/61:11-15, 185:4-10.

CONCLUSION

The *amici*'s efforts to provide tenable “speculation” arguments in place of those Pharmacia chose to offer are without merit. Wisconsin

respectfully requests that this Court rule that the jury did not impermissibly
“speculate” in determining damages.

Dated: October 14, 2011

Respectfully submitted,

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CERTIFICATION

I hereby certify that the foregoing State of Wisconsin's Response to the *Amicus* Briefs of the Non-Pharmacia Brand and Generic Defendants conforms to the rules contained in § 809.19(8)(b) and (c), Wis. Stats., for a brief and appendix produced with a proportional serif font. The length of this brief is 2,997 words.

Dated this 14th day of October, 2011.

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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 State of Wisconsin's Response to the *Amicus* Briefs of the Non-Pharmacia Brand and Generic Defendants is identical to the text of the paper copy of the Brief of Cross-Appellant.

Dated this 14th day of October, 2011.

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