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OF WISCONSIN**

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

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., Sicom, Inc. f/k/a Gensia Sicom 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 REPLY
IN SUPPORT OF ITS CROSS-APPEAL 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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I. Pharmacia’s “Misrepresentation” Accusations Have No Basis.

Pharmacia begins its argument with unfounded accusations of “factual misrepresentations” by Wisconsin. Pharmacia’s Brief of Cross-Appellee (“PBCA”) at 16-22. For example:

A. Wisconsin did not misrepresent Pharmacia’s “Wholesale Acquisition Cost” figures (WACs) as inaccurate. Wisconsin asserted, accurately, that WACs did not reveal *real* “wholesale acquisition costs,” since they were discounted, often drastically. Wisconsin’s Brief of Appellee (“WB”) at 3; Wisconsin’s Brief of Cross-Appellant (“WBCA”) at 12. While accuracy of WACs themselves was not a liability issue, it was Pharmacia who insisted on their close connection with actual AWP. *See, e.g.*, PB 13. Thus there was nothing “inconsistent” (PBCA 21) in Wisconsin requesting an injunction that would require Pharmacia to report discounted WACs.

B. Wisconsin did not misrepresent that Pharmacia stopped sending AWPs to First DataBank on “advice of counsel.” A Pharmacia

executive so testified. R305(Kennally)/117:17-118:11 (S.App.¹ 10).

Wisconsin did not misrepresent that Pharmacia verified AWP's for First DataBank. A Pharmacia executive testified to such verification, then tried to repudiate that testimony at trial. S.App. 355-57.

C. Wisconsin accurately stated that generics were sometimes reimbursed based on Pharmacia's false AWP's. (Wisconsin's Amici Response Brief at 22.)

D. Wisconsin never stated that Wisconsin Medicaid had no authority to use correct AWP's when they were supplied. Wisconsin accurately stated that when Medicaid "received information demonstrating what retail pharmacies actually paid on average, [it] used this information to lower reimbursement." S.App. 156-73, 198, 306-07.

E. Wisconsin had no need to (and did not) represent that the *current* version of its automated claims process was operational before 1999. In fact, whether Pharmacia caused a false representation to be made for each claim does not depend on whether the AWP for that claim was

¹ In its Cross-Appeal, Wisconsin inadvertently used "R.Ap." to refer to "S.App."

supplied by computer or manually. Wisconsin accurately stated that its automated system “filled in” the AWP’s. *See* R435/137:22-138:18; R436/61:6-15, 185:4-10 (reprinted in attached appendix (“C.Reply.App.”) at 2-7); *see also* PBCA 24.

F. Wisconsin made no misrepresentation by calling the practice of marketing the spread “improper.” A Pharmacia executive conceded it was unethical. R438/195:6-196:14 (S.App. 361-62). It is irrelevant that Wisconsin did not claim that “marketing the spread” was a *per se* violation of the statutes. The circuit court could take unethical behavior into account in determining per-violation forfeiture amounts.

G. It was not “inconsistent” for Wisconsin to argue that Medicaid employees could not testify regarding reimbursement decisions “made by the legislature,” but have Medicaid witnesses testify to their understanding of federal regulations and Wisconsin’s AWP-discount formula. *No one* can testify as to legislators’ intent in passing legislation, but Medicaid officials can offer their understanding of the law that is relevant to carrying out their duties in administering the Medicaid program.

II. The Circuit Court Erroneously Vacated the Verdict on the Number of False Representations.

Wisconsin argued that (1) under §49.49(4m)(a)2's plain language, Pharmacia caused a false representation of material fact to be made for use in determining a Medicaid payment each time a false representation of AWP was generated to determine a claim, and (2) the circuit court's interpretation of §49.49(4m)(a)2 to bar this counting method lacks legal support. WBCA 20-29.

Pharmacia asserts that the forfeiture statute is penal and must be construed strictly against Wisconsin. PB 25. However, the Wisconsin Supreme Court has "long recognized that the rule of strict construction of penal statutes is not a rule of general or universal application Sometimes a strict and sometimes a liberal construction is required, even in respect to a penal law, because the dominating purpose of all construction is to carry out the legislative purpose." *State v. Kittilstad*, 231 Wis.2d 245, 262, 603 N.W.2d 732 (1999).

This Court has rejected overly-narrow constructions of forfeiture statutes. For example, in *State v. Schmitt*, 145 Wis.2d 724, 429 N.W.2d 518 (Ct.App. 1988), the Court refused to construe the phrase "[e]ach day of continued violation is a separate offense" to limit violations to only one per

day because “expos[ing] persons who violate more than one ... law on any given day to liability for more than one violation per day” “would be more consistent with the purposes” of the statute. 145 Wis.2d at 737-38.

A. Each AWP generated to determine a claim was a “representation” under §49.49(4m)(a)2.

Pharmacia does not dispute that every Medicaid drug claim generated a representation of that drug’s AWP and that the representation determined the outcome of each particular claim. Pharmacia acknowledges that the original electronic transmission of AWP’s into Wisconsin’s database are “representations,” but argues that subsequent representations of those AWP’s through populating the AWP field on each claim are only “uses” of the original representations, not representations themselves. PBCA 26-28.

Pharmacia offers neither authority nor good reason for this limitation. As a matter of physical fact, a “representation” of AWP is made in connection with each claim. A blank price-field is filled with the AWP applicable to the particular drug at that particular time, and these representations determine how each claim is paid.

B. Pharmacia “caused” false representations to be made each time a claim was processed.

Pharmacia argues that even if a “false representation” was made each time a claim was paid, Pharmacia violated the statute only if it “caused” a representation where otherwise none would be made, and that simply causing that representation to be false does not give rise to a violation. In support, Pharmacia argues that Wisconsin itself “caused” providers to submit claims and “caused” its agent to compute reimbursement based on AWP, and Pharmacia did not know the details of Medicaid processing. PBCA 30.

This is an unreasonable interpretation of §49.49(4m)(a)2. What was wrongful, and harmful, about Pharmacia’s conduct was causing representations of AWP to be made that it knew were *false*. This is the import of *State v. Williams*, 179 Wis.2d 80, 505 N.W.2d 468 (Ct.App. 1993), which construed the criminal prohibition in §49.49 and held that in the prohibition of “intentionally” making or causing to be made a false statement, “intentionally” modifies only “false.” 179 Wis.2d at 89. *Williams*’ holding disproves Pharmacia’s notion that “knowingly” in §49.49 modifies “cause” instead of “false.”

This reasoning also disposes of Pharmacia’s related argument that the legislature did not include the term “directly or indirectly” in §49.49(4m)(a)2. There was nothing “indirect” about Pharmacia’s contribution to the falsity of the AWP’s that were generated for each claim.

Pharmacia also argues that §49.49(4m) was “intended to address [only] statements made by providers.” PBCA 31. Its plain language states otherwise. While some sub-sections apply “only to . . . fraudulent activity by a recipient or by a provider,”—*e.g.*, §49.49(5)—§49.49(4m) applies to all “persons.” While some subsections cover only statements by providers or recipients in an “application”—*e.g.*, §49.49(4m)(a)(1)—§49.49(4m)(a)2 applies to *any* representation made “for use in determining” a Medicaid payment.

C. The verdict correctly measured *Pharmacia’s* conduct.

Pharmacia argues that the jury’s verdict failed to focus on “the acts of the defendant, not on subsequent acts by others,” and that §49.49(4m)(b) imposes a forfeiture “for each . . . representation,” not for “each subsequent use of a representation.” PBCA 33. This merely repeats the argument, answered above, that the generation of false AWP’s for each claim were only “uses” of representations, not representations themselves.

Pharmacia asserts that *State v. Menard, Inc.*, 121 Wis.2d 199, 358 N.W.2d 813 (Ct.App. 1984), supports its position because “the Court focused solely on the defendant's conduct in seeking eight advertisements” and “awarded eight forfeitures.” PBCA 33-34. To the contrary, the Court *reversed* a holding that Mendard was liable for only eight forfeitures and counted as additional violations the re-publication of the same advertisements in subsequent editions. 121 Wis.2d at 202.

Pharmacia argues that the verdict conflicts with penalty cases under the False Claims Act, particularly *U.S. v. Bornstein*, 423 U.S. 303 (1976). PBCA 34-36. However, while the FCA has similarities to §49.49(4m), it does not impose a forfeiture “for each statement” as does §49.49(4m)(b), and is not controlling. Regardless, in other FCA cases and AWP litigation, courts have disagreed with Pharmacia’s application of *Bornstein*.

In *U.S. v. Ehrlich*, 643 F.2d 634 (9th Cir. 1981), the Ninth Circuit affirmed assessment of a separate penalty for each inflated voucher a contractor caused an innocent mortgagee to submit. The court rejected the argument, based on *Bornstein*, that the contractor “did but one act”— inflating his costs. *Id.* at 637-38. It said that the contractor “knew a false claim would be submitted each month” by the mortgagee, “could have

prevented the filing of additional false claims,” but instead, “did nothing and gained a continuing benefit from the inflated interest subsidies.” *Id.* at 638. “[I]t would defeat the purposes of the Act, given [defendant’s] knowledge and control of the situation, to limit his liability to one forfeiture.” *Id.*

Here, where Pharmacia knew (and intended) that its false AWP would inflate every claim reimbursed based on AWP, it equally defeats the purposes of §49.49 to limit liability for forfeitures to the number of times First DataBank reported Pharmacia’s AWP to Wisconsin. In fact, the trial court in the Hawaii AWP litigation held (in denying a directed verdict) that *the number of claims* reimbursed based on AWP would go to the jury to determine penalties under the Hawaii’s FCA. *State of Hawaii v. Abbott Laboratories, Inc.*, No. 06-1-0720-4, 188-95 (Sept. 21, 2010) (C.Reply.App.10-17).

Similarly, in the AWP Multidistrict Litigation, Judge Saris held (in the context of a statute-of-limitations issue) that a new violation accrued “each time a false claim was presented” for reimbursement. *In re Pharm. Industry AWP Litig.*, 498 F.Supp.2d 389, 400 (D.Mass. 2007). She reasoned:

[A manufacturer's] publication of false price data, which involves the regular quarterly republication of false AWP figures with knowledge that these figures would be used to set reimbursement figures for subsequent claims, is distinguishable from the case in *Bornstein*, where the submission of multiple claims 'was, so far as [defendant] was concerned, wholly irrelevant, completely fortuitous and beyond [defendant's] knowledge or control.'

Id.

In short, the jury correctly concluded that *Pharmacia* was responsible for each false representation made in processing reimbursement claims.

D. Pharmacia's "discretion" argument against remand is mistaken.

Citing §49.49(4m)(b)'s use of "may," not "shall," Pharmacia argues that even if the verdict correctly measured the number of violations, the Court should nonetheless affirm the vacatur because the circuit court had discretion to limit forfeitures to "those statements for which it believed Pharmacia was responsible." PBCA 36-38. First, if the jury's count was correct, then the circuit court's forfeiture award was based on an erroneous view of the law and cannot stand. Second, the issue of whether forfeitures are discretionary or mandatory, R315/15-23 (C.Reply.App.20-28), was not addressed by the circuit court, which can decide on remand whether it has

discretion and if so, whether it wishes use its discretion to impose forfeiture for fewer than all of the false statements Pharmacia caused.²

III. The Circuit Court’s Alternative Calculation Was Based on a Mistaken View of “Materiality.”

Wisconsin argued that the circuit court’s alternative method of counting, which construed a “material” representation as one that was *actually used* to make a payment, was wrong as a matter of law. WB 29-34.

A. Merits arguments.

Wisconsin showed that the §49.49’s plain language requires a false statement made “for use” in determining a payment, not that it “was used” in determining a payment. WBCA 30. Pharmacia does not reply to this argument.

Wisconsin explained that the circuit court’s construction was contradicted by the statement in *State v. Williams*, 179 Wis.2d 80, 505 N.W.2d 468 (Ct.App. 1993), that “[§49.49] does *not* require the state to

² It is irrelevant to the §49.49 forfeitures issue that Wisconsin withdrew its request for forfeitures under §100.18 (PBCA 10). Section 100.18, which cover representations “to the public,” would have utilized a different method of counting violations than §49.49(4m)(a)2, which has no such requirement.

prove that anyone actually received a medical assistance benefit or payment.” WBCA 32-34, *citing* 179 Wis.2d at 89 (emphasis added). Pharmacia’s only response is to rewrite the Court’s statement—replacing the lack of requirement that “anyone” received payment with the lack of requirement that “defendants themselves” received payment. PBCA 40.

Wisconsin also showed, and Pharmacia does not dispute, that the circuit court’s interpretation of *Williams* produces a more stringent definition of “materiality” than the construction of the same term by the U.S. Supreme Court and this Court under other statutes (*e.g.*, §946.31(1) prohibiting perjury) and even common-law fraud. WBCA 31. Pharmacia’s response—that Wisconsin “never explains why these tests are more germane than the test in *Williams*” (PBCA 41)—is an evasion. The legislature would have no reason to make fraud on Wisconsin Medicaid harder to prove than any other fraud.

Wisconsin showed the circuit court’s interpretation has unacceptable implications for the prosecution of persons who try but fail to defraud Medicaid. WB 31-32. Pharmacia brushes aside this objection, stating that the legislature can fix this problem if it wants. PBCA 42. Nothing needs

fixing. The statute as written does not require that a false representation actually affected a payment.

Finally, Pharmacia's argument that Wisconsin is not entitled to "yet another opportunity" to get this matter right (PBCA 43) repeats the same argument at PB 38-40; see Wisconsin's answer, WB 50-51. There is no merit to the additional suggestion (PBCA 44) that remand would violate double jeopardy. *See Schmitt*, 145 Wis.2d at 739.

B. Waiver arguments.

Pharmacia argues that waiver occurred when Wisconsin failed to object to the instruction that a "material fact" is one that "actually affected" the amount of a payment. (C.Resp. 39.) However, the instruction did not use "actually" or "affected" in the past tense. It stated: "a 'material fact' is one that affects the amount of a payment." (C.Resp.Ap. 18.) The instruction is consistent with Wisconsin's position (and the law) that a representation is material if it has the capacity to affect a payment. Representations of AWP are material because they "affect" Medicaid payments. Conversely, the "dates of service" in *Williams* were not material because dates could not affect payments.

Contrary to Pharmacia's assertion, Wisconsin argued below that materiality does not require an "actual impact on transactions." PBCA 40. Wisconsin opposed Pharmacia's "materiality" argument below and quoted an earlier holding that whether a "false AWP constitutes a violation is *not* dependent on whether 'someone looked at it, or even relied on it.'" R343/6 (C.Reply.App.30) *citing* R331/4 (A.Ap.161).

Pharmacia's judicial estoppel arguments (PBCA 40-41) fail because Wisconsin's arguments were not inconsistent, much less "clearly inconsistent," nor has Pharmacia alleged that any such arguments were "adopted" by any court, as required. *Mrozek v. Intra Financial Corp.*, 2005 WI 73, ¶22, 281 Wis.2d 448, 699 N.W.2d 54.

IV. The Circuit Court Considered Improper Factors in Setting the Amount Per Violation.

A. The “pass-on” rationale.

Pharmacia’s only defense of the circuit court’s reducing forfeitures based on Pharmacia’s assumed ability to “pass them on” to its customers is that Wisconsin should have sought reconsideration of this ground. PBCA 45, *citing* Wis. Stat. §806.07 and *Young v. Young*, 124 Wis.2d 306, 316, 369 N.W.2d 178 (Ct.App. 1985). Neither the statute nor *Young* requires a party to move for reconsideration before appealing.

B. The “government knowledge” rationale.

Wisconsin argued *its* knowledge and decisions regarding AWP—absent any allegation that Pharmacia relied them—should not have been considered by the circuit court to “mitigate” Pharmacia’s behavior. WBCA 39-40. Pharmacia’s only substantive response is to assert that Wisconsin “never suggested the issue was irrelevant” to forfeitures. *Id.* at 46. Not true. The argument was made below. R315/10 (C.Reply.App.19).

IV. The Circuit Court Erroneously Refused to Enter Effective Injunctive Relief.

Wisconsin argued that at least six of the circuit court’s reasons for refusing to enter a specific injunction, R449, were erroneous. WB 44-48. In disputing these points (PBCA 50-52), Pharmacia relies on a picture of

the evidence and arguments that the jury rejected: that First DataBank, not itself, determines AWP (PBCA 51); that it did not know what wholesalers' real prices were (*id.* 47); that since the legislature has not mandated the reporting of AWPs, it is acceptable for Pharmacia to cause false ones to be reported (*id.* 50); *et cetera*. Pharmacia had a fair chance to persuade the jury of these positions. It lost. While it rightly upheld the jury's verdict, the circuit court erroneously denied a meaningful injunction on the basis of a view the jury rejected.

Pharmacia also argues that the Dormant Commerce Clause prohibits the requested injunctive relief. PBCA 54. The circuit court rightly did not invoke this constitutional ground. State action is prohibited by the Dormant Commerce Clause only if it excessively burdens interstate commerce. *See Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). No case suggests that the Commerce Clause deprives a state of the power to prevent deceptive practices against its own government programs simply because those measures may cause problems for a private defendant's business practices in other states.

Finally, Pharmacia argues the court could take into account that Wisconsin has settled with some defendants for money damages only,

without imposing injunctive requirements. PBCA 47. First, the settlements did not waive any right to seek injunctive relief if the illegal conduct continued. Second, Pharmacia's rationale threatens public policy encouraging settlement. *Radlein v. Industrial Fire & Cas. Ins. Co.*, 117 Wis.2d 605, 622, 345 N.W.2d 874 (1984). Wisconsin, other states, and the United States have sued major drug manufacturers for their AWP practices. The parties to these lawsuits are increasingly settling them. (The United States announced on December 21, 2010 that settlements that month alone in this area totaled over \$700 million. C.Reply.App.31.³) It frequently makes sense in a settlement to give up demands for injunctive relief in return for adequate monetary relief. But it will discourage settlements of *any* kind if governments know that settling for money only will decrease their chance of getting injunctive relief against defendants who exercise their right to fight on.

³ See <http://www.justice.gov/opa/pr/2010/December/10-civ-1464.html>

CONCLUSION

Wisconsin respectfully repeats its request for relief as stated in its opening brief (WBCA 49-50).

Respectfully submitted,

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Dated: December 29, 2010

CERTIFICATION

I hereby certify that the foregoing brief conforms to the rules contained in §809.19(8)(b) and (c)2, Wis. Stats., for a brief and appendix produced with a proportional serif font. The length of this brief is 2,998 words.

Dated this 29th 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 State of Wisconsin's Reply in Support of its Cross-Appeal and Appendix identical to the text of the paper copy of The State of Wisconsin's Reply in Support of its Cross-Appeal and Appendix.

Dated this 29th day of December 2010.

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