



STATE OF WISCONSIN

CIRCUIT COURT  
Branch 9

DANE COUNTY

STATE OF WISCONSIN,

Plaintiff,

v.

Case No. 04-CV-1709

ABBOTT LABORATORIES, *et al.*,

Defendants.

**RECEIVED**

OCT - 3 2014

**TEVA'S TRIAL MEMORANDUM**

DANE COUNTY CIRCUIT COURT

The State of Wisconsin (the “State”) claims that, during the 1995 to 2008 case period, the publication of “false” and “deceptive” Average Wholesale Prices (or “AWPs”) caused Wisconsin Medicaid to make \$8.7 million in “overpayments” for Teva’s prescription drugs. But this case differs in an important way from the Pharmacia AWP case tried in 2009. In contrast to that case, where most of the pharmacy claims at issue were reimbursed based on AWP, more than 97 percent of claims at issue here were reimbursed based on **something other than AWP**. Most of these claims were reimbursed at Maximum Allowable Cost (“MAC”) – a metric Wisconsin Medicaid set based on its own survey of actual market prices. AWP’s played no role in these reimbursements: the State’s designee testified that if Wisconsin Medicaid set a MAC for a generic drug, then MAC would have been the basis for reimbursement **regardless of the AWP**. (Dep. of K. Smithers (Aug. 15, 2007) (“Q. So in other words, if there’s a MAC price that’s been set, then it’s the MAC price that’s used as the basis for reimbursement? A. Correct. Q. Regardless of whether it’s higher or lower than, say, AWP minus 10 percent? A. Correct.”).) Thus, for most of the claims at issue, AWP’s were not “material” or “for use in determining rights to a benefit or payment” (both necessary to prove liability under Wis. Stat. § 49.49) and did not cause the State’s alleged injury.

For the small number of claims reimbursed based on AWP, the State caused all of the “overpayments” it now claims as damages by choosing a reimbursement formula that it knew would pay pharmacies more than their acquisition costs. The State’s knowledge that AWP were inflated and not real prices dates back several decades. Despite this knowledge, the State continued using AWP in its reimbursement formula and set AWP discounts it knew were less than the discounts should be if the goal was to limit reimbursements to pharmacy acquisition costs. “False” and “deceptive” AWP played no role in these decisions. The State’s knowledge and choices foreclose it from proving that AWP are “false” (necessary to prove liability under Wis. Stat. § 49.49), “deceptive” (necessary to prove liability under Wis. Stat. § 100.18), or that Teva caused the State’s alleged injury.

Despite the concessions it made in negotiations with pharmacy groups over AWP discounts, the State actually **underpaid** for most of the drugs at issue in this case. The State’s MACs were extremely “aggressive” and, combined with the State’s low dispensing fees, resulted in pharmacies taking a loss on most claims for Teva’s drugs. The State’s damages expert failed to account for pharmacy dispensing costs in his analysis. Had he done so, the State’s alleged damages would be only \$1.1 million.

In sum, the State was not defrauded by Teva and the State did not use or rely on “false” and “deceptive” AWP when it reimbursed pharmacies for Teva’s drugs.

**I. Summary of the State’s Legal Claims and Teva’s Defenses**

The State brought five counts against Teva and other manufacturers. On September 18, 2014, the State and Teva filed a stipulation to dismiss two counts with prejudice: the Wisconsin Trust and Monopolies Act claim (Count III) and the unjust enrichment claim (Count V). The State’s remaining counts are as follows:

**A. Counts I and II: Wis. Stat. § 100.18(1) and (10)(b) (Deceptive Trade Practices Act)<sup>1</sup>**

To prevail on this claim, “[the State] must prove three elements. First, that with the intent to induce an obligation, [Teva] made a representation to ‘the public.’ Second, that the representation was untrue, deceptive or misleading. Third, that the representation caused [the State] a pecuniary loss.”<sup>2</sup> *K&S Tool & Die Corp. v. Perfection Mach. Sales, Inc.*, 2007 WI 70, ¶ 19, 301 Wis. 2d 109, 121-22, 732 N.W.2d 792, 798 (Wis. 2007) (citations omitted).

The State cannot prevail on this claim for at least three reasons. First, there is no “untrue, deceptive, or misleading” representation. As the State knew, “AWP” was not a real price, but a benchmark used for reimbursement. And Suggested Wholesale Price (or “SWP”) – which Teva began using after 2001 – is not “deceptive” because it did not purport to reflect pharmacy acquisition costs. Second, the AWP and SWPs for Teva’s drugs were not represented to “the public” – they were published in subscription-based industry compendia, whose main users knew that AWP were not actual prices. Third, the State cannot prove causation. The evidence will

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<sup>1</sup> Although the State brought two counts under Wis. Stat. § 100.18, the Court has ruled that they are not separate claims; thus, Counts I and II are addressed here together. (*See Order on Pls.’ Mots. for Partial Summ. J. Against Defs. Novartis, AstraZeneca, Sandoz, and Johnson & Johnson at 4 (May 20, 2008).*)

<sup>2</sup> The State seeks damages for Teva’s alleged violation of Wis. Stat. § 100.18(1). (Third Am. Compl. ¶ 82(D) (seeking “damages pursuant to Wis. Stat. § 100.18(11)(b)2 and § 100.263”).) An award of damages under Wis. Stat. § 100.18(1) requires proof of causation. *See, e.g., K&S Tool & Die Corp.*, 2007 WI 70, ¶ 19, 301 Wis. 2d at 122, 732 N.W.2d at 798.

show that the State’s conscious choices determined its reimbursements to pharmacies, not any alleged conduct by Teva.

**B. Count IV: Wis. Stat. § 49.49(4m)(a)(2) (Medical Assistance Fraud Act)**

To prevail on its Wis. Stat. § 49.49(4m)(a)(2) claim, the State must prove that: (1) Teva “[k]nowingly ma[d]e or cause[d] to be made any false statement or representation,” (2) the false statement was “of a material fact,” and (3) the false statement was “for use in determining rights to a benefit or payment.” Wis. Stat. § 49.49(4m)(a)(2); *see also State v. Williams*, 179 Wis. 2d 80, 87, 505 N.W.2d 468, 470 (Ct. App. 1993).

The State cannot prevail on this claim for at least three reasons. First, there is no “false” statement or representation. As noted, “AWP” is a reimbursement benchmark and the State knew this. And SWP did not purport to reflect pharmacy acquisition costs. Second, the AWP and SWPs for Teva’s drugs were not “material” or “for use in determining rights to a benefit or payment” given that the majority of claims for Teva’s drugs were reimbursed based on something other than AWP. Third, the State cannot prove that Teva acted “knowingly.”

**II. Summary of the Evidence the Teva Defendants Expect to Offer at Trial**

**A. The Medicaid Program**

Like most states, Wisconsin provides prescription drug coverage as a part of its Medicaid program. Federal regulations give Wisconsin and other states significant flexibility in determining how to reimburse for prescription drugs. For drugs other than those for which the federal government has set a Federal Upper Limit (“FUL”), reimbursement “must not exceed, in the aggregate, payment levels that the [state Medicaid] agency has determined by applying the lower of the – (1) [Estimated Acquisition Cost] plus reasonable dispensing fees established by the state agency; or (2) Providers’ usual and customary charges to the general public.” 42 C.F.R. §

447.512(b) (formerly 42 C.F.R. § 447.331(b)). While some states have defined Estimated Acquisition Cost as AWP minus a percentage discount picked by the state, Wisconsin, for at least the last two decades, has reimbursed the vast majority of generic drugs at state-determined MACs.

#### **B. Maximum Allowable Cost**

During the 1995 to 2008 case period, Wisconsin reimbursed more than 78 percent of pharmacy claims for Teva drugs at MAC. MAC is a reimbursement metric that Wisconsin set based on actual market prices obtained from various sources, including wholesalers and pharmacy buying groups. After reviewing these sources and locating the lowest available price for a drug, Wisconsin took that price and added a mark-up of 10 to 25 percent to determine the MAC. But even with this mark-up, Wisconsin's MACs were considered "aggressive" and often did not cover pharmacies' costs.

Notably, Wisconsin did not use AWP to set MAC. Nor did AWP play any role in determining reimbursement for drugs with a MAC. If Wisconsin set a MAC for a generic drug, the MAC was the basis for reimbursement even if discounted-AWP resulted in a lower reimbursement.

#### **C. Wisconsin's Knowledge and Choices**

Wisconsin created its MAC program decades ago in response to widespread knowledge that AWPs were greater than the pharmacy acquisition costs. For generic drugs, which entered the market in large numbers following the 1984 Hatch-Waxman Act, the MAC program was Wisconsin's solution to the well-known problem that AWPs were not real prices and did not reflect the amounts pharmacies actually paid. By 1989, about half of the drugs covered by Wisconsin Medicaid were reimbursed at MAC or (for selected manufacturers) Direct Price. By 2008, the vast majority of generic drugs were reimbursed at MAC.

## **D. Damages**

Wisconsin Medicaid's reimbursements for most Teva drugs consisted of two components: an "aggressive" MAC and a dispensing fee. In theory, the dispensing fee should cover a pharmacy's dispensing costs. But throughout the case period, Wisconsin Medicaid's dispensing fee never came close to covering pharmacy costs. For example, Wisconsin Medicaid commissioned a study of dispensing costs, which found the average cost in 2000 to be \$7.01 – compared with the dispensing fee of \$4.38. An updated version of this study projected the average cost in 2007 to be \$9.94 – compared with the dispensing fee, unchanged at \$4.38.

The evidence will show that Wisconsin pharmacists considered their total Medicaid reimbursement in determining whether to participate in Medicaid. The State's damages expert erred in considering only one component of reimbursement: the ingredient cost. Adjusting his analysis to account for dispensing costs reduces the State's alleged damages from \$8.7 million to \$1.1 million.

## **III. Summary of Pre-Trial Issues Pending Before the Court**

### **A. Motions for Summary Judgment**

On August 19, 2014, Teva and the State filed motions for partial summary judgment. Both parties filed their respective oppositions on September 18, 2014, and replies are due on October 8, 2014. The Court will hear argument on the motions on October 23, 2014.

(1) Teva's motion for partial summary judgment. Teva seeks summary judgment on the following issues:

- The Court should grant Teva summary judgment on the State's Wis. Stat. § 49.49 count for all claims not reimbursed based on AWP. To set out a Wis. Stat. § 49.49 violation, the State must prove that an AWP was "material" to Wisconsin Medicaid's reimbursement decision and that it was "for use in determining rights to a benefit or payment." But, as the State's own expert concedes, over 97 percent of claims for Teva's drugs were reimbursed based on something other than AWP. For these claims, the State simply cannot prove liability under Wis. Stat. § 49.49.

- The Court should grant Teva summary judgment on the State’s Wis. Stat. § 49.49 and Wis. Stat. § 100.18 counts for claims arising after 2001, when Teva began reporting SWP. SWPs are not “false” under § Wis. Stat. 49.49 nor are they “untrue, deceptive or misleading” under Wis. Stat. § 100.18. As the plain meaning of “suggested” indicates, SWP never purported to reflect pharmacy acquisition costs. This plain meaning was reinforced by explicit disclaimers that accompanied Teva’s SWPs, which stated that “[s]uggested wholesale prices do not reflect the actual cost to the pharmacy or charge to the customer.” Thus, for any claim arising after 2001, the State cannot prove liability under either Wis. Stat. § 49.49 or Wis. Stat. § 100.18.

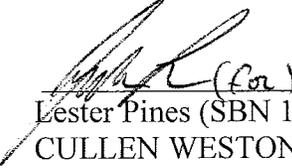
(2) The State’s motion for partial summary judgment. The State claims that Teva’s AWP are deceptive as a matter of law under Wis. Stat. § 100.18(10)(b) because Teva represented AWP as “wholesaler’s price[s]” that were “more than the price which retailers regularly pay.” The State also claims that Teva committed 58,779 violations of Wis. Stat. § 100.18(1). This is wrong as a matter of law. The State has failed to prove that AWP are “deceptive” given the substantial evidence of a common understanding that AWP were not actual prices and that state Medicaid programs were not permitted to AWP absent a substantial discount of the state’s choosing. Moreover, the State’s count of 58,779 violations is vastly inflated because the State wrongly equates the number of times Wisconsin Medicaid **received** AWP for Teva’s drugs with the number of times it actually **relied** on them for reimbursement. *See State v. Abbott Labs.*, 2012 WI 62, ¶ 86, 341 Wis. 2d 510, 573, 816 N.W.2d 145, 171 (2012) (holding that this Court correctly determined the number of violations “by searching the record for the number of times that FDB conveyed to Medicaid [ ] a false AWP for a Pharmacia product that Medicaid then used, at least once, in the reimbursement of a pharmacy.”). The State is, in effect, asking this Court to overturn the Wisconsin Supreme Court’s ruling on this precise subject.

**B. Motions *in Limine***

The parties have also filed motions *in limine* to exclude certain testimony and evidence. Responses are due on October 16, 2014. The Court will hear argument on the parties’ motions on October 23, 2014.

Among other issues raised by Teva's motions *in limine*, Teva seeks to exclude expert testimony and analysis concerning the number of alleged violations of Wis. Stat. § 49.49, which Teva expects the State will offer in evidence as a basis for the jury to calculate forfeitures. This Court, of course, has already outlined the appropriate methodology for calculating forfeitures, holding that a "false" AWP must have been "material" to a Wisconsin Medicaid reimbursement – that is, used at least once in paying a pharmacy claim. The State's damages expert did not follow this directive and therefore should not be permitted to present this evidence to the jury.

Dated: October 3, 2014

  
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