

Medicaid Rebate Agreement with each drug manufacturer whose drugs are reimbursed by Medicaid. The very existence of this Medicaid Rebate Agreement, which affects the amounts states ultimately pay in reimbursement, removes the State from the realm of “the public” as is contemplated in the Deceptive Trade Practices Act (the “DTPA”). Second, the State does not deny that it is seeking damages in this litigation. Since the State is seeking damages, it legally follows that the State needs to show that actions by the defendants caused the State harm. The State cannot make that showing. Finally, the State does not dispute that Wisconsin Medicaid reimbursed multi-source claims on the basis of a Maximum Allowable Cost (or “MAC”) that it set through a survey of actual market prices. Because Wisconsin Medicaid reimbursed these claims without reference to any price reported by any drug manufacturer or published by any drug pricing compendium – including average wholesale price (“AWP”) or wholesale acquisition cost (“WAC”) – but instead relied on actual market prices, the State cannot prove, as to these claims, that Schering or Warrick caused it any harm.²

ARGUMENT

I. WISCONSIN MEDICAID IS NOT A MEMBER OF THE “PUBLIC” AND THEREFORE HAS NO CLAIM UNDER THE DPTA.

Plaintiff is not a member of the “public” and therefore cannot establish any violation of Section 100.18. The benefits and obligations flowing between Schering and Warrick and the State as a result of their Medicaid Rebate Agreements create a “particular relationship” between the parties and preclude the application of Section 100.18 to Schering and Warrick.

The State’s bald assertion that any statement made to Wisconsin Medicaid is a *per se* statement to the public enjoys no support in the law and is counter to the obvious purpose of the

² In addition to the arguments set forth in their Motion for Summary Judgment, Schering-Plough and Warrick incorporate by reference and adopt fully all of the facts and arguments advanced in Defendants’ Joint Cross-Motion for Summary Judgment and Supporting Memorandum and the cross-motions for summary judgment filed by other defendants to the extent that those motions further entitle them to the entry of summary judgment in their favor.

DPTA. Wisconsin courts have long held that a statement is not made to the “public,” as required for a finding of a violation of Section 100.18, if it is made between parties who enjoy a “particular relationship.” See Wis. Stat. § 100.18(1); *State v. Automatic Merch. of Am., Inc.*, 64 Wis. 2d 659, 664, 221 N.W.2d 683, 686 (1974) (citing *Cawker v. Meyer*, 147 Wis. 320, 326, 133 N.W. 157 (1911)). Courts have further explained: “The important factor is whether there is some particular relationship between the parties . . . which would distinguish the prospective purchasers from ‘the public’ which the legislature intended to protect.” *Automatic Merch. of Am.*, 64 Wis. 2d at 664.

The State does not dispute that, since 1991, Wisconsin Medicaid has received benefits through the Medicaid Rebate Agreements executed by Schering and Warrick, as required by the Federal Center for Medicare and Medicaid Services (“CMS”) (formerly the Health Care Finance Administration). See Mot. for Summary Judgment, PUF, at ¶¶ 16-22, p. 20; Plaintiff’s Opposition, at 38-39. The State instead argues that because the Rebate Agreements do not specifically regulate the use of AWP, they are irrelevant to whether or not the State is a member of the public for the purposes of Section 100.18. See Plaintiff’s Opposition, at 39. However, the State construes both the agreements and the relationship between the parties far too narrowly.

As is plain on the face of these agreements, the Rebate Agreements entered into by CMS on behalf of the states are designed to affect, and do affect, the overall reimbursement framework as it exists between the states, the federal government, and manufacturers. See PUF, at ¶ 22. If Schering and Warrick did not enter into Rebate Agreements, their products would not qualify for reimbursement through the Medicaid program. See PUF, at ¶ 16. Similarly, absent these agreements, Schering and Warrick undoubtedly would not have rebated tens of millions of dollars to the Wisconsin Medicaid program over the last seventeen years. The Rebate

Agreements signed by Schering and Warrick directly impact Wisconsin Medicaid's pharmaceutical reimbursement budget, which is at the heart of the present litigation.

Furthermore, in determining who is a member of the public, Wisconsin courts have scrutinized the relationship between the parties – not the specifics of the contract at issue. In fact, a contract is not even necessary to establish that a “particular relationship” exists. A contract between two parties is only one type of “particular relationship” which will remove a plaintiff from the public realm for purposes of the DTPA. *See Uniek, Inc. v. Dollar Gen. Corp.*, 474 F. Supp. 2d 1034, 1039 (W.D. Wis. 2007) (“If the Wisconsin courts had intended to exclude from the law only contracting parties, it could have stated the rule as whether the parties had a ‘contracting relationship,’ but [the courts] have employed the more general language, ‘particular relationship.’”); *K & S Tool & Die Corp. v. Perfection Mach. Sales, Inc.*, 301 Wis. 2d 109, 732 N.W.2d 792 (2007). Wisconsin courts have found that plaintiffs were not “the public” for purposes of Section 100.18 because of “particular” relationships that did not constitute contracts. *See Uniek*, 474 F. Supp. 2d at 1039 (finding that despite the lack of a contract, “long-term, established” dealings created the type of “particular relationship” that precluded plaintiff from claiming a violation under Section 100.18). In light of this fact, Plaintiff's hair-splitting as to the content of the Rebate Agreements is irrelevant to defendants' liability under Section 100.18.

The State further argues that it does not share a particular relationship with manufacturers because there were no “direct dealings relevant to this case between the State and defendants.” *See Plaintiff's Opposition*, at 40. However, the text of the Rebate Agreements specifically shows that there were, in fact, direct dealings between the State and the manufacturers. As outlined in the Rebate Agreements, four times per year, the State submits an invoice directly to the manufacturers and the manufacturers, in turn, send a check to the State. *See Medicaid Drug*

Rebate Agreement, Schering Corporation (1991), at ¶¶ II(b), (g).³ Given these contracts between the State and manufacturers, “if this relationship does not ‘distinguish’ plaintiff from ‘the public,’ then virtually nothing would.” *See Uniek*, 474 F. Supp. 2d at 1039. Here, where the State and manufacturers have been obligated to one another under the provisions of a Rebate Agreement for seventeen years, there can be no question that their relationship is distinguishable from one with the public.⁴ On this basis alone, Schering and Warrick are entitled to summary judgment.

II. CAUSATION IS REQUIRED TO RECOVER DAMAGES UNDER THE DTPA AND PLAINTIFF CANNOT SHOW THE REQUIRED CAUSATION.

The State’s assertion that it need not make a showing of causation to avoid summary judgment on its Section 100.18 claim misconstrues both the language and the purpose of the DTPA. The State spends numerous pages arguing that Section 100.18 allows for injunctive relief without a showing of causation. Those arguments simply do not matter here. The State requests damages in this case, and recovering damages, as a matter of law, requires a showing of actual loss caused by a defendant’s actions. *See* DAN B. DOBBS, LAW OF REMEDIES, § 9.2(6), at 699-700 (2d ed. 1993). The State does not and has never disputed the fact that it seeks damages, and it cannot avoid the requested partial summary judgment ruling by claiming it possesses facts

³ Exhibit 30 to the Declaration of Janna J. Hansen Transmitting Documents Relied Upon in Defendants Schering-Plough Corporation and Warrick Pharmaceuticals Corporation’s Reply Memorandum in Support of Their Motion for Partial Summary Judgment on Counts I and II of the Complaint (hereinafter the “Hansen Decl.”), Filed Under Seal; *see also* Medicaid Drug Rebate Agreement, Warrick Pharmaceuticals Corporation (1993) (Exhibit 9 to the Declaration of Earl H. Munson Transmitting Documents Relied Upon in the Defendants Schering-Plough Corporation and Warrick Pharmaceuticals Corporation’s Motion for Partial Summary Judgment in their Favor on Counts I and II of the Complaint and Supporting Memorandum of Law, Filed Under Seal).

⁴ Moreover, in addition to the relationship arising out of the Rebate Agreements CMS entered into on behalf of the states, the State of Wisconsin has another direct contractual relationship with Schering. Wisconsin Medicaid and Schering have entered into a Supplemental Rebate Agreement wherein Schering provides the State with additional rebates in exchange for inclusion of its drugs on a Preferred Drug List. This contract between the parties provides further evidence of the State’s “particular relationship” with Schering that precludes the State from bringing its claim under the DTPA. *See* Supplemental Rebate Agreement, Schering Corporation (2004) (Exhibit 31 to the Hansen Decl., Filed Under Seal); *see also* Deposition of Michael Boushon 11/5/07, at 204:22–208:2 (Exhibit 32 to the Hansen Decl.).

supporting an equitable remedy when it requests a legal one. It cannot substitute the elements required for one type of relief when it actually desires another. Recovery of damages under Section 100.18 requires a showing of causation. The State has not and cannot make this showing, and partial summary judgment in Schering-Plough and Warrick's favor on Counts I and II of the Complaint is, therefore, warranted.

Section 100.18(11)(d), under which the State purports to proceed, affords monetary relief to "any person suffering pecuniary loss **because of** the acts or practices" that violate Section 100.18. *See* Wis. Stat. § 100.18 (emphasis added). Wisconsin case law has definitively interpreted this "because of" language as requiring "a causal connection between the untrue, deceptive or misleading representation and the pecuniary loss." *K & S Tool*, 301 Wis. 2d at 129; *see also Tim Torres Enter., Inc. v. Lindscott*, 142 Wis. 2d 56, 70, 416 N.W.2d 670, 675 (Ct. App. 1987) (interpreting Section 100.18 "as requiring a causal connection between the practices found illegal and the pecuniary losses suffered"). The Wisconsin Supreme Court has further held that, "because the purpose of the DTPA includes protecting Wisconsin residents from untrue, deceptive, or misleading representation made to induce action, proving causation in the context of § 100.18(1) requires a showing of material inducement." *K&S Tool*, 301 Wis. 2d at 129. Put another way, Wisconsin courts make clear that a plaintiff seeking recovery of damages under Section 100.18 must show that it actually relied on the statement at issue, that this reliance substantially affected purchasing decisions, and that those decisions led to pecuniary loss. *Id.* at 129-30 (explaining that reliance, both reasonable and actual, can be used in determining whether a representation "materially induced the plaintiff's pecuniary loss").

The above-cited cases interpret the "because of" language in the context of Section 100.18(11)(b)(2), but these interpretations are equally applicable to actions brought under

Section 100.18(11)(d) by the Wisconsin Attorney General. Section 100.18(11)(d) contains the same “because of” language when the relief sought is monetary damages. *See* Wis. Stat. § 100.18(11)(d) (“The court may in its discretion . . . make such orders or judgments as may be necessary to restore to any person any pecuniary loss suffered **because of** the acts or practices involved in the action, provided proof thereof is submitted to the satisfaction of the court.”) (emphasis added). Simply put, both sections of the DTPA set out requirements for the recovery of monetary damages using the exact same words. It is a basic principle of statutory construction that a court will “attribute the same definition to a word both times it is used in the same statute or administrative rule.” *DaimlerChrysler v. Labor and Industry Review Comm’n*, 299 Wis. 2d 1, 24, 727 N.W.2d 311, 322 (2007); *see also Wilson v. Waukesha County*, 157 Wis. 2d 790, 797, 460 N.W.2d 830, 833 (1990) (“We will reject an interpretation which ascribes different meanings to the same word as it variously appears in a statute unless the context clearly requires such an approach.”). Thus, it is clear that law interpreting the causation element required for recovery under Section 100.18(11)(b)(2) applies with equal force to the identical language found in Section 100.18(11)(d).

The only Wisconsin case cited by the State for its claim that it need not show causation fails to support the State’s position. In *State v. American T.V. and Appliance of Madison, Inc.*, the State brought an action in its enforcement capacity to prohibit additional publication of what it believed to be a disingenuous and potentially harmful advertising campaign.⁵ *See State v. Am. T.V. and Appliance of Madison, Inc.*, 140 Wis. 2d 353, 355-60, 410 N.W.2d 596, 597-98 (Ct. App. 1987) (describing relief requested), *overruled by State v. Am. T.V. and Appliance of Madison, Inc.*, 146 Wis. 2d 292, 430 N.W.2d 709 (1988). Enjoining behavior potentially

⁵ In *American T.V.*, the State also sought civil forfeiture penalties, which were determined to be unavailable because the conduct at issue was not deemed to be misleading. *Id.*

harmful to consumers is a far cry from what the State attempts to do in this suit. Here, the State is acting like a private plaintiff, seeking damages for itself. Thus, the State must make a showing as to all of the elements required to recover damages.

In a case such as this one, where the State is seeking damage recovery on its own behalf, the State cannot avoid a summary judgment ruling by invoking the elements of a statutory section affording only equitable relief. At the most fundamental of levels, to prevail in an action at law where compensatory relief is sought, one must show harm or loss, and that loss must bear some relation to the defendant's conduct. *See* DAN B. DOBBS, LAW OF REMEDIES, § 9.2(6), at 699-700 (2d ed. 1993). The State cannot avoid summary judgment by ignoring a very basic element of its claim that is required for it to obtain the relief it has requested. *See Transp. Ins. Co. v. Hunzinger Constr. Co.*, 179 Wis. 2d 281, 291-92, 507 N.W.2d 136 (Ct. App. 1993) (“[O]nce sufficient time for discovery has passed, it is the burden of the party asserting a claim on which it bears the burden of proof at trial ‘to make a showing sufficient to establish the existence of an element essential to that party’s case.’”). In other words, even if Plaintiff could establish the first two elements of its DTPA claim (and we believe it cannot), three elements are required to obtain the damages the State requests. *See K&S Tool*, 301 Wis. 2d at 121-122 (“K & S claims [defendant] violated § 100.18(1). To prevail on such a claim, the plaintiff must prove three elements. First, that with the intent to induce an obligation, the defendant made a representation to ‘the public.’ Second, that the representation was untrue, deceptive or misleading. Third, that the representation caused the plaintiff a pecuniary loss.”). It would be an exercise in futility to allow the State to proceed to trial on the issue of whether the defendants’ actions may have violated Section 100.18 when it is undisputed that there has been no causation and, thus, no damages.

Undisputed facts prove that the State cannot show the requisite causation for compensatory relief under Section 100.18. The State claims that it was the allegedly inflated AWP and WACs that the manufacturers purportedly reported to First DataBank that caused it to over-reimburse providers, but it does not dispute that, for most multi-source drugs, it reimbursed on the basis of MACs set through research into market prices. *See* PUF, at ¶¶ 34-45. In its Opposition, the State includes an affidavit from Ted Collins, a consultant responsible for the MAC program. *See* Plaintiff's Opposition, at Ex. 4. Collins makes various statements in his affidavit regarding the Wisconsin MAC program, many of which are in tension with Collins' extensive deposition testimony. As an initial matter, under Wisconsin law, an affidavit in support of summary judgment that contradicts prior deposition testimony does not create a disputed issue of fact. *Yahnke v. Carson*, 236 Wis. 2d 257, 270, 613 N.W.2d 102, 109 (2000) (adopting the "sham affidavit" rule, and stating that "for purposes of evaluating motions for summary judgment . . . an affidavit that directly contradicts prior deposition testimony is generally insufficient to create a genuine issue of fact for trial"). In any event, the Collins affidavit is insufficient to avoid summary judgment because in no place does it refute the fact that Wisconsin reimbursed the vast majority of multi-source drugs on the basis of MACs that were set through a survey of market prices. *See* PUF, at ¶¶ 39-45. Given that Wisconsin's MACs were undisputedly based on actual market prices, and not on any measure the defendants allegedly reported to the pricing compendia, the State cannot meet its burden of proving causation.⁶

⁶ In fact, even a cursory review of Plaintiff's Response to Schering-Plough and Warrick's Statement of Undisputed Facts shows that the State does not dispute *the* critical paragraph in Schering-Plough and Warrick's Statement of Undisputed Facts. To the contrary, the State acknowledges the facts set forth in Paragraph 44 are undisputed – that, "in setting the MAC, [Mr. Collins] searched for the lowest price for the drug that was readily available in the marketplace" and "then added a 10-25% mark-up to that price to ensure that pharmacies serving Medicaid patients in Wisconsin would be able to acquire the drug for a price at or below the established MAC." *See* PUF, at ¶ 44.

The argument that, “if the manufacturers had reported lower AWP’s, we would have set lower MACs” fails for a very simple reason. Wisconsin’s MACs were set based on the prices available in the market. *See* PUF, at ¶¶41-42. Pharmacy providers could not be expected to take a loss on each prescription filled for a Medicaid beneficiary. Participation in Medicaid is voluntary. If MAC prices had been set at a level lower than the level at which they were set – that is, at a level just high enough to ensure sufficient availability of the drug at prices below the MAC rate – then pharmacies would simply have withdrawn from the Medicaid program. *See* PUF, at ¶¶44, 46.⁷ It is, therefore, entirely unsurprising that the State cannot meet its burden of proof on the causation element as it relates to multi-source drugs reimbursed on the basis of Wisconsin’s MACs. Wisconsin’s MACs were as low and efficient as possible, and did not depend on published prices. Reporting of lower prices by the defendant drug manufacturers could not have done anything to change these facts or reduce the MAC rates. Thus, whether characterized as causation, “material inducement,” actual reliance, or “pecuniary loss because of a violation,” the State simply cannot produce evidence in support of the third and necessary element of its claim for damages – at least as it relates to multi-source drugs subject to a MAC. Warrick is, therefore, entitled to summary judgment on Counts I and II of the Complaint.⁸

⁷ Mr. Collins’ affidavit concedes effectively this much. In Paragraph 10, Mr. Collins concludes his affidavit by posing a hypothetical. In relevant part, he avers, “*If* defendants had reported a true AWP, and that AWP was lower than my MAC price, then I would have used the true AWP as the MAC price (*assuming* that the drug was then currently and readily available to all pharmacies)” – at that price – an assumption for which there is no factual support in the record and one that is hard to believe. *See* Plaintiff’s Opposition, at Ex. 4 (emphasis added). It is only under these hypothetical circumstances, unsupported by resort to the factual record, that Mr. Collins posits Wisconsin’s MAC program would be adversely impacted. As the case law makes plain, rank speculation and unsupported hypotheticals are not sufficient to defeat summary judgment. *See Helland v. Kurtis A. Froedtert Memorial Lutheran Hosp.*, 229 Wis. 2d 751, 756, 601 N.W.2d 318, 321 (Ct. App. 1999).

⁸ Plaintiff appears to concede, in its Response brief, that Wis. Stat. § 100.18(10)(b) does not create a cause of action separate from its Section 100.18(1) claim. *See* Plaintiff’s Opposition, at 40 and Defendants’ Reply in Support of Their Joint Cross-Motion for Summary Judgment, at n.21. Accordingly, there is no separate dispute about whether causation is a necessary element of a claim brought under Section 100.18(10)(b).

III. ISSUE PRECLUSION DOES NOT APPLY TO SCHERING-PLOUGH, SCHERING, OR WARRICK.

Neither Schering-Plough, Schering, nor Warrick were held liable for any damages in the multi-district litigation AWP fraud trial (the “MDL”). *See In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 70-74 (D. Mass. 2007); *In re Pharm. Indus. Average Wholesale Price Litig.*, C.A. No. 01-12257-PBS, 2007 WL 3235418, at *4 (D. Mass. Nov. 2, 2007). Nonetheless, the State asserts, in a passing reference at the end of its brief, that issue preclusion should apply in regard to the MDL proceeding. The State’s claim fails for at least two separate reasons. First, issue preclusion only applies to findings that are “essential to the judgment.” *See Michelle T. v. Crozier*, 173 Wis. 2d 681, 685, 495 N.W.2d 327, 329 (1993). Schering-Plough, Schering, and Warrick were not held liable for any damages in the MDL. Thus, any findings in the MDL which were essential to the judgment can only favor Schering-Plough, Schering, and Warrick. Second, the State does not analyze at least three important substantive differences between the Massachusetts statute at issue in the MDL and Wisconsin’s DTPA, each of which makes the DTPA more restrictive. Under the DTPA, the State is responsible for proving that it is a member of “the public,” the causation element of Section 100.18, and that defendants represented untrue, deceptive, or misleading WACs or AWPs to the public with an intent to induce drug purchases. The State’s brief assertion as to issue preclusion does not provide a defense to Schering-Plough and Warrick’s motion for summary judgment, particularly as it relates to these necessary elements of a DTPA claim. Any assertion of issue preclusion fails for this reason as well.

RELIEF SOUGHT

Schering-Plough and Warrick respectfully request that this Court grant partial summary judgment in their favor and dismiss Counts I and II of the Complaint as they relate to the Schering and Warrick drugs at issue.

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Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that on April 28, 2008, a true and correct copy of the foregoing document was served upon all counsel of record via Lexis-Nexis File and Serve.



Keri Laidlaw