



STATE OF WISCONSIN

CIRCUIT COURT
Branch 9

DANE COUNTY

STATE OF WISCONSIN,)	
)	
Plaintiff,)	
)	
v.)	Case No. 04-CV-1709
)	Unclassified – Civil: 30703
ABBOTT LABORATORIES, et al.,)	
)	
Defendants.)	
)	

**PLAINTIFF'S TRIAL BRIEF
AGAINST TEVA**

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In this brief, the State will set forth the elements of its claims and provide examples of evidence that fulfill each of those elements. The State will also set forth the relief to which it believes it is entitled.

I. Elements of the State's Claims.

A. Counts I & II: Deceptive Trade Practices Act, Wis. Stat. § 100.18(1) & 10(b).

There are two elements of an enforcement action under the Deceptive Trade Practices Act (“DTPA”), Wis. Stat. § 100.18: (1) a representation to the public with the intent to induce an obligation; (2) the representation was untrue, deceptive, or misleading. *Novell v. Migliaccio*, 2008 WI 44, ¶ 49, 309 Wis.2d 132, 151-152, 749 N.W.2d, 544, 553. It is not necessary to prove that Teva caused any harm to establish a violation of § 100.18. As this Court held, “the whole purpose for an enforcement action is to *forestall* any harm caused by the targeted conduct.” (Decision and Order on Certain Defense Cross-Motions for Summary Judgment, July 29, 2008, at 4) (emphasis in original).

The statute also specifically provides that “[i]t 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.” § 100.18(10)(b).

B. Count IV: Medical Assistance Fraud statute, § 49.49(4m)(a)2.

The elements of a claim under the Medicaid fraud statute, Wis. Stat. § 49.49(4m)(a)2, are as follows: (1) knowingly making or causing to be made; (2) a false statement or representation of material fact; (3) for use in determining rights to a benefit or payment in connection with medical assistance. Wis. Stat. § 49.49(4m)(a)2; *State v. Abbott Labs., et al.*, 2012 WI 62, ¶ 52, 341 Wis. 2d 510, 542, 816 N.W.2d 145, 161. Similarly, it is not necessary to prove that Teva caused any harm to establish a violation of § 49.49(4m), but only that Wisconsin Medicaid used an AWP in the reimbursement process.

II. The State's evidence satisfies all elements of its claims.

A. "Publication" Element:

Both statutes require that Teva¹ either made or caused to be made a statement. Section 100.18 provides that Teva shall not "make, publish, disseminate, circulate, or place before the public, *or cause, directly or indirectly*, to be made, published, disseminated, circulated, or placed before the public" any statement. Wis. Stat. § 100.18(1) (emphasis added). Similarly, § 49.49(4m) provides that Teva shall not "make or *cause to be made* any false statement." Thus, both statutes provide for liability for the direct action of making statements or the indirect action of causing statements to be made.

The State's evidence establishes (although it is unnecessary to establish both) that Teva both made *and* caused to be made statements, *i.e.*, their false AWP's. For example, Teva directly provided its AWP's in letters sent to state Medicaid agencies, including Wisconsin Medicaid. Further, Teva caused AWP's to be published in pricing compendia, such as Red Book and First DataBank ("FDB").

Testimony and documents from Teva overwhelmingly establish this. Teva established an AWP for each of its drugs² and published those AWP's through various industry pricing publishers, including FDB and Red Book.³ During a period of time after their AWP-related practices came under scrutiny, Teva Pharmaceuticals USA used the term "suggested wholesale

¹ The Teva defendants (collectively referred to as "Teva") are comprised of several drug manufacturers who are currently owned by Teva Pharmaceutical Industries, Ltd. These defendants are Teva Pharmaceuticals USA, Inc., IVAX Corporation, and IVAX Pharmaceuticals, Inc. Although originally named as a defendant, the State is not pursuing claims against the Teva subsidiary, Sicor, Inc.

² **TEVA**: Marth Dep. (3/1/11), 65:19-66:8 (agreeing that Teva "set its average wholesale price" and "sent that price to the price reporting services"); Cioschi Dep. (7/11/08), 282:7-9 ("Q. Now, Teva is solely responsible for setting and publishing its own AWP/SWP? A. Yes."); **IVAX**: Hogan Dep. (6/17/08), 89:13-22; Sarfas Dep. (3/19/2009), 35:20-22.

³ **TEVA**: Marth Dep. (3/1/11), 65:19-66:8; **IVAX**: Hogan Dep. (6/17/08), 108:18-21.

price” (or “SWP”) interchangeably with the term “AWP.”⁴ Even where they reported prices under the name “SWP,” those prices were published by FDB and Red Book as AWP.

When Teva reported AWP’s to the pricing compendia, it intended that they would publish those identical AWP’s.⁵ Teva purchased FDB’s pricing database, which contained the AWP’s for its drugs,⁶ and knew that FDB published the identical AWP’s that Teva submitted.⁷ Teva also monitored the AWP’s published by FDB and, if it found any error, requested that FDB correct it and FDB did so.⁸ Additionally, FDB and the other pricing publishers asked Teva to verify the AWP’s for Teva’s drugs, and it did so.⁹ In sum, Teva caused the publication of its AWP’s through the pricing compendia.¹⁰

Although the Supreme Court in *K & S Tool & Die Corp. v. Perfection Machinery Sales, Inc.*, 301 Wis. 2d 109, 122, 732 N.W.2d 792, 799 (Wis. 2007), stated that the defendant’s intent

⁴ **TEVA:** Marth Dep. (5/28/08), 154:11-155:17; 156:14-157:1 (Teva began referring to AWP as “SWP” at some point in 2000s); Marth Dep. (3/1/11), 91:19-92:6 (SWP was established in the same way as AWP); Cioschi Dep. (2/12/08), 73:9-20 (SWP refers to same price as AWP).

⁵ **TEVA:** Marth Dep. (3/1/11), 215:15-20 (“We would want them to publish the AWP we gave them.”); **IVAX:** Hogan Dep. (2/6/08), 72:8-12 (agreeing that the purpose of sending prices to the publishers was “so that it would be published to the industry”).

⁶ **TEVA:** Marth Dep. (3/1/11), 72:13-14; **IVAX:** Sarfas Dep. (8/22/2007), 256:9-257.

⁷ **TEVA:** Marth Dep. (3/1/11), 82:4-19; **IVAX:** Sarfas Dep. (3/19/2009), 195:12-196:2.

⁸ **TEVA:** Cioschi Dep. (7/11/08), 106:13-18; 108:12-21; **IVAX:** Sarfas Dep. (3/19/2009), 195:12-19 (“If you’re saying when they sent me out a verification or if, let’s say, somebody brought to my attention, hey you’re [sic] prices may not be right, I would have done a verification, said update -- FDB, update to this correct price.”).

⁹ **TEVA:** Cioschi Dep. (7/11/08), 108:12-21 (agreeing that Teva would fill out a verification sheets sent by First DataBank); **IVAX:** Hogan Dep. (6/17/08), 188:10-21; Sarfas Dep. (8/22/2007), 255:2-256:7; *see also*, PX-1002; PX-1008; PX-1011; PX-1079 (emails between First DataBank and Teva defendant officials regarding First DataBank’s Product Update Reports).

¹⁰ *See, e.g.*, **TEVA:** Marth Dep. (3/1/2011), 82:4-19; **IVAX:** Sarfas Dep. (3/19/2009), 35:20-22 (“Q. Did IVAX control the AWP’s that were published on its drugs? A. I mean, yes, we -- we established them.”); 37:18-20 (“Q. IVAX controlled the AWP’s, correct? A. Correct. We set our AWP’s.”).

to induce an obligation was not a distinct element of § 100.18, the statute requires that the representation was made with the “intent to sell, distribute, increase the consumption of or in any wise dispose of ... any merchandise ..., directly or indirectly, to the public for ... use ... or with intent to induce the public in any manner to enter into any contract or obligation relating to the purchase, sale, hire, use or lease of any ... merchandise.” Teva’s publication of its AWP’s in the pricing compendia was clearly done with the intent to “sell, distribute, increase the consumption of or in [some way] dispose of” its drugs.

Teva published AWP’s through the pricing compendia because it was necessary to ensure that its customers received reimbursement from third-party payers, including state Medicaid programs.¹¹ Teva knew that state Medicaid programs such as Wisconsin used the AWP’s to determine reimbursement to Medicaid providers such as retail pharmacies.¹² According to Teva, AWP’s “often must be included in certain fields in the electronic systems of Teva’s customers, as well as in those of FDB, so that Teva’s customers can be assured that, should they choose to purchase Teva’s products and dispense those products to needy Medicaid recipients, they will be

¹¹ **TEVA:** Marth Dep. (3/1/11), 67:10-14 (“Q. Why do you send pricing information and, in particular, the average wholesale prices to the pricing publications? A. Because you can't sell your products if you don't.”); 70:15-71:6 (agreeing that states use average wholesale prices in their reimbursement formulas and that Teva sent average wholesale prices to price reporting services so that its drugs could be reimbursed); **IVAX:** Hogan Dep. (6/17/08), 120:14-121:8 (“AWP was reported for reimbursement”); Sarfas Dep. (3/19/09), 38:9-25 (stating that Ivax must report AWP in WAC to the compendia, “Otherwise my product doesn't get set up [meaning eligible for reimbursement] and then I'm at a disadvantage”).

¹² **TEVA:** Cioschi Dep. (7/11/08), 181:4-10 (“Q. [W]e know the state Medicaid agencies get from First DataBank the published suggested wholesale price and wholesale acquisition cost, but they do not get the actual contract price. Is that correct? A. Yes.”); DeNicola Dep. (7/31/09), 204:10-20 (“Q. And TEVA is aware that states go to that information at First DataBank and base their reimbursement upon that information, correct? A. Correct.”); **IVAX:** Bloom Dep. (2/4/09), 156:6-20 (IVAX knew that the AWP’s it sent to the compendia were being used for Medicaid reimbursement).

reimbursed by state Medicaid agencies ... for dispensing those Teva products.”¹³ Teva was also aware that an increase in the published AWP resulted in a potential increase in the amount of reimbursement paid by a state Medicaid program that used AWP as part of its reimbursement formula.¹⁴

B. The “Untrue, Deceptive, or Misleading,” or “False” Element:

Section 100.18 requires an “untrue, deceptive, or misleading” statement. Similarly, § 49.49(4m) requires a “false” statement. Through § 100.18(10)(b), the Legislature has established that *as a matter of law*, it is deceptive to publish a wholesale price that is more than the price which retailers regularly pay. Nothing and no one—except a change in the law—can make this behavior *not* deceptive. *See* Motion for Partial Summary Judgment Against the Teva Defendants on the Deceptive Wholesale Price Provision of § 100.18, August 19, 2014. Thus, in addition to being untrue and misleading, Teva’s AWP’s are deceptive as a matter of law.

The prices are also “false” under the Medicaid Fraud statute. Where a term is undefined, Wisconsin courts turn to the dictionary and apply the plain meaning of the term. *Jauquet Lumber Co. v. Kolbe & Kolbe Millwork Co.*, 164 Wis.2d 689, 698 (Wis. App. 1991). By publishing “average wholesale prices,” Teva represented that they were *prices*; that they were an *average* of prices; and that they were an average of prices at the *wholesale level*. Teva’s AWP’s are false: Teva’s AWP’s were not prices at all; they were not averages of anything; and they represented no reality at the wholesale level.

¹³ PX-1400 (Teva Pharmaceuticals USA, ’s Responses and Objections to Plaintiff’s Second Set of Interrogatories to All Defendants, Response to Interrogatory No. 11, March 13, 2008; *see also*, PX-1401 (Ivax Response to Interrogatory No. 11, March 13, 2008).

¹⁴ **IVAX:** Bloom Dep. (2/4/09), 99:8-12 (“Q. Well, would the increase in AWP prices on this drug have the effect of increasing reimbursement to your customers that were reimbursed based off of AWP? A. Yes, it would.”).

1. The State's evidence that Teva's prices were deceptive/false is overwhelming.

According to the testimony of Teva's own witnesses, its published AWP's were not averages of prices at which wholesalers sold the Teva drugs to retailers.¹⁵ Nor were they averages of prices at which Teva sold drugs directly to retail pharmacies.¹⁶ Nor were they prices which any retail pharmacy ever paid to acquire the drugs.¹⁷ The description of AWP by Teva's own officials as a "fictitious price,"¹⁸ an "arbitrary published price for a drug that no customer actually pays,"¹⁹ and a "paper price ... not really a price, price"²⁰ leave no doubt that its published AWP's were inflated above the actual average of prices charged by wholesalers.

In fact, the difference between Teva's published AWP's and actual average wholesale prices was substantial, as demonstrated by the State's expert witness, Thomas DiPrete, Ph.D. Dr. DiPrete calculated for each relevant NDC the difference between the published AWP and the actual average wholesale price (based on data subpoenaed from two national wholesalers)

¹⁵ **TEVA:** Cioschi Dep. (7/11/08), 84:11-16 (stating that SWP is "not a wholesale price"); **IVAX:** Hogan Dep. (6/17/08), 112:6-22; Shanks Dep. (2/22/08), 47:11-20 (AWP is "not an average wholesale price, which one would think it is.").

¹⁶ **TEVA:** Cioschi Dep. (7/11/08), 86:2-87:20 (agreeing that "SWP is not a calculated price based on actual sales data"); **IVAX:** Hogan Dep. (6/17/08), 87:14-88:9 ("AWP had nothing to do with our pricing"); Sarfas Dep. (8/22/07), 179:16-180:1; 190:5-8 (agreeing that "none of your customers pay you AWP").

¹⁷ **TEVA:** Cioschi Dep. (7/11/08), 71:2-5 ("Q. At a minimum, the average wholesale price was not a price at which you believe anybody was actually paying. Is that correct? A. That's right."); 122:6-11 ("Q. You know that the average wholesale price that was being published by First DataBank in connection with Teva was not the price that pharmacies were paying. Is that correct? A. Right."); **IVAX:** Sarfas Dep. (3/19/09), 35:4-8 (agreeing that "the AWP's were often much higher than the prices that IVAX knew pharmacies were actually paying").

¹⁸ Cioschi Dep. (7/11/08), 65:18-66:17.

¹⁹ PX-1411 ("Answer Key" to Ivax Laboratories – aero pharmaceuticals Basic Training Quiz).

²⁰ Cioschi Dep. (2/12/08), 40:22-41:15; 73:9-20.

expressed as a percentage of the actual average wholesale price. For Ivax drugs, the spreads between published AWP and the actual average wholesale prices based on sales to Wisconsin pharmacies averaged 525% (meaning the published AWP were 6.25 times the actual average wholesale prices). For Teva Pharmaceuticals USA, the spreads averaged 1019%.²¹ Teva has not offered any evidence to challenge or dispute these calculations.

Dr. DiPrete's analysis also demonstrates that the percentage difference between Teva's published AWP and the actual average prices charged by wholesalers was highly variable, ranging from 20% higher to 5000% higher.²² Thus, there was no consistent percentage relationship between Teva's published AWP and the prices actually charged by wholesalers to providers. Consequently, as Teva's officials conceded, it was not possible to accurately predict providers' average acquisition costs for a generic drug based upon the drug's published AWP.²³

2. Teva's assertion that AWP is simply a "list price" is legally incorrect.

As a matter of law, Teva cannot avoid liability by arguing that its AWP were merely "list prices" and therefore were not "false" or "untrue, deceptive, or misleading." As numerous courts have held, the "list price" argument is not a valid defense since a so-called "list price" is lawful only if "substantial sales" were made at the price. *Giant Food, Inc. v. FTC*, 322 F.2d 977, 981-982 (D.C. Cir. 1963); *In re George's Radio & Television Co., Inc.*, 60 F.T.C. 179 (1962) (advertising "manufacturer's suggested list prices" where no substantial sales were made at that

²¹ Expert Report of Thomas DiPrete, 4/01/14, at 22-23.

²² PX-0205; PX-0223.

²³ **TEVA**: DeNicola Dep. (7/31/09), 186:20-187:2 ("Q: Can you look at the AWP price for a particular NDC at any time and gain any insight into either the contract or net price to any customer or any class of trade? ...A: Not that I am aware of."); **IVAX**: Bloom Dep. (2/04/09), 156:24-157:2 ("Q: In other words, can you look at an AWP or WAC on any given drug and gain any insight into the actual cost of the drug to anyone? A: No.).

price was unlawful); *Regina Corp. v. FTC*, 322 F.2d 765, 767-68 (3d Cir. 1963) (manufacturer's "suggested list price" was deceptive where it exceeded retailers' customary selling price); *In re Pharm. Indus. AWP Litig.*, 586 F.Supp.2d 186, 202 (D.Mass. 2010) (applying substantial sales test to WACs of Teva and Ivax, among other drug companies, and holding that they were not "true list prices"); *The People of the State of Illinois v. Abbott Labs.*, No. 05-CH-2474, Circuit Court of Cook County, Illinois, Transcript of March 20, 2012 Hearing, pp. 42-43, (applying substantial sales test to generic AWP and rejecting "list price" defense).

Where, as here, *no* sales of Teva drugs were made at AWP, much less "substantial sales," the "list price" defense is unavailable. See Plaintiff's Motion *in Limine* No. 6: To Bar Improper Arguments Based Upon Legally Unavailable Defenses, at 6-9. Likewise, Teva's AWP were not a "benchmark price" since they were not a "benchmark" to anything; as discussed above, the AWP for Teva's generic drugs had no predictable relationship whatsoever to what pharmacies paid to acquire them.

3. Teva's "Term of Art" defense is unavailing.

Teva's argument that its AWP were not "false" because AWP is a "term of art" is unavailing for numerous reasons.

First, the Legislature has already determined that "it *is* deceptive" to publish a price as a "wholesale" price unless it is not "more than the price regularly paid by retailers." Wis. Stat. § 100.18(10)(b) (emphasis added). The alleged understanding of an industry or anyone else that the price is "more than the price regularly paid by retailers," *i.e.*, that the price does not comply with the law, does not change the fact that the price does not comply with the law.

Second, to be a "term of art," a term must have a "specific, precise meaning in a given specialty." Black's Law Dictionary (9th ed. 2009). Here, Teva cannot show a "specific, precise

meaning” of “Average Wholesale Price” that is contrary to its plain meaning. Teva’s own expert, Dr. Helms, testified in 2011 that AWP has had *no* established and settled meaning in the industry with respect to generic drugs going back to the 1970s. Helms Dep. (8/23/11) in *Kentucky v. Watson*, at 55:12-56:12; 193:18-21; 208:22-209:11.

Third, to establish that an asserted term is a “term of art,” a defendant must show more than that industry participants had knowledge of the falsity of the assertion. Nothing in Wisconsin law provides that a “false statement or representation for use in determining rights to” Medicaid payments is not “false” if Medicaid or those in the pharmaceutical industry understand that the statement is “false.” Wisconsin law still prohibits the making of such statements, and as the Supreme Court ruled in the Pharmacia matter, even though Medicaid “knew the AWP’s were inflated,” the AWP’s “harmed Medicaid” and caused damages. *State v. Abbott Labs.*, 2012 WI 62, ¶ 78, 341 Wis. 2d 510, 557, 816 N.W.2d 145, 168.

Fourth, there can be no established, settled meaning of AWP contrary to its plain meaning since market participants – including FDB, manufacturers, trade associations, and Congress – have continued to describe AWP as a real average price charged by wholesalers to retail customers. As Judge Peter Flynn noted, “as late as 2003, Congress itself, that is in a sense defendants’ biggest customer for these purposes, asserted and understood that ‘AWP is intended to represent the average price used by wholesalers to sell drugs to their customers.’” *People of the State of Illinois v Abbott Labs., et al.*, No. 05-CH-2474 (Cir. Ct. of Cook Cnty., Ill.) Transcript of March 20, 2012 Hearing, p. 34, (citing U.S. House of Representatives report). He continued, “[I]f your own biggest customer doesn’t agree with your asserted meaning, it’s pretty hard to argue that there is a custom and usage.” *Id.* at 35. Other courts addressing the issue have agreed. *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F.Supp.2d 277, 278, 284-88

(D. Mass. 2006); *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 168-72 (1st Cir. 2009); Order, 8/18/10, *State of Hawaii v. Abbott Labs, et al.*, No. 06-1-0720-4), Minute Order, 8/23/10.

C. The Remaining Requirements of § 49.49.

The testimony of Teva's officials cited above establishes that Teva acted "knowingly," as required by Wis. Stat. § 49.49(4m). Teva knew and expected that FDB would publish the AWP's for Teva's drugs based on the pricing information that Teva sent it. This, by itself, satisfies the "knowingly" element. *Abbott Labs.*, 2012 WI 62, ¶ 107 ("Pharmacia reported its AWP's to FDB so that FDB would in turn convey them to Medicaid. It therefore knowingly caused those statements to be made.").

However, Teva knew even more: Teva knew that its AWP's were not averages of wholesale prices, nor reasonable estimates of such prices. Teva officials knew and intended that payers, including state Medicaid agencies, would rely on their AWP's in order to reimburse pharmacies that dispensed the Teva's drugs. Furthermore, Teva knew that the government disapproved of its AWP-related practices.²⁴

Further, Teva's false statements were material. *See Neder v. United States*, 527 U.S. 1, 16 (1999) ("In general, a false statement is material if it has 'a natural tendency to influence, or

²⁴ In any event, knowledge of Medicaid's rules and requirements should be imputed to Teva. As Judge Saris ruled:

[H]aving entered into the rebate agreements, the defendants were required, as a matter of law, to familiarize themselves with the legal requirements, standards and procedures of the Medicaid program. *Heckler v. Community Health Servs.*, 467 U.S. 51, 63-65 (1984). These include the procedures and legal requirements applicable to reimbursements. *United States v. Mackby*, 261 F.3d 821, 828 (9th Cir. 2001). The defendants were required to know that the Commonwealth's EAC was "the agency's best estimate of the price generally and currently paid by providers."

Massachusetts v. Mylan Labs., et al., 608 F. Supp.2d 127, 154 (D. Mass. 2008).

[is] capable of influencing, the decision of the decision making body to which it was addressed”). Any representation concerning the price of a product or service is presumptively material,²⁵ and Wisconsin Medicaid used Teva’s AWP’s in its reimbursement process.

Teva’s contention that its AWP’s were not material where reimbursement was based on the MAC or usual and customary amount has already been rejected. As shown in the following section on causation, this Court has ruled—and the Supreme Court has affirmed—that inflated AWP’s that resulted in reimbursement at the MAC caused a pecuniary loss to the State. *State v. Abbott Labs.*, 2012 WI 62, ¶ 78 (“in both [brand and generic] contexts, the reporting of inflated AWP’s harmed Medicaid, and in both the reporting of accurate AWP’s would have saved Medicaid money”). Since these AWP’s caused a pecuniary loss, they are *a fortiori* material. This same evidence also establishes that the false AWP’s were “for use in determining rights to a ... payment,” as required under § 49.49(4m)(a)2.

D. The Causation Element.

The State’s evidence establishes that Teva’s inflated AWP’s caused the State a pecuniary loss. The Court is familiar with the State’s reimbursement methodology from the evidence presented at the Pharmacia trial. When determining reimbursement for a drug, the State compares (1) the published AWP minus a percentage (“discounted AWP”) plus the dispensing fee, (2) the MAC plus the dispensing fee, and (3) the usual and customary (“U&C”) amount submitted by the pharmacy. The State then pays the lowest of these. Pharmacia Trial Tr.,

²⁵ Cases decided under the Federal Trade Commission Act support this conclusion. *FTC v. Windward Marketing Ltd.*, 1997 WL 33642380 at 9 (N.D. Ga. 1997) (“any representations concerning the price of a product or service are presumptively material.”); *Sullivan’s Wholesale Drug Co. v. Faryl’s Pharmacy, Inc.*, 214 Ill. App.3d 1073, 1086 (1991) (“There can be no dispute that the representation made by the defendants went to a material fact, *i.e.*, the price which the nursing home residents were being charged for their prescriptions.”); *FTC v. The Crescent Publishing Group, Inc.*, 129 F.Supp. 2d 311, 321 (S.D.N.Y. 2001) (“Information concerning prices or charges for goods or services is material”).

Feb. 9, 2009, Ted Collins, at 61:6-15. Separately, if the AWP that was published had been accurate, Wisconsin would have used them to set the MAC. *Id.* at 60:22-61:1.

This Court ruled in rejecting Pharmacia's motion for summary judgment that even where the State's reimbursement payment was at the MAC, a jury nevertheless could find that "the misrepresented AWP nonetheless caused a pecuniary loss because the state was required to jettison the unreliable AWP as the standard, and had to employ a different benchmark which set a higher reimbursement rate than would have been the case had the true AWP been represented."

January 21, 2009 Decision at 1. The Supreme Court affirmed:

The State did not argue at trial that Medicaid paid too much for generic drugs because it was incorporating inflated AWP into its reimbursement process; rather, it argued that it paid too much for generic drugs because it *did not have actual wholesale prices* to use. Indeed, the State's theory regarding damages in the generic context was not substantively different in this respect than its theory in the brand name context. With brand drugs as well as generics, the State never contended that Medicaid paid ...the amounts Pharmacia supplied in its AWP; it contended that Medicaid *estimated* what pharmacies paid to wholesalers because it knew the AWP were inflated, but did not know by how much. Thus, in both contexts, the reporting of inflated AWP harmed Medicaid and in both the reporting of accurate AWP would have saved Medicaid money. *See In re Pharm. Indus. AWP Litig.*, 582 F.3d 156, 190 (1st Cir. 2009) (affirming damages in AWP litigation as non-speculative where expert testimony established "that had the AWP not been inflated, the plaintiffs would not have paid as much as they did"), *petition for cert. dismissed*, 561 U.S. ___, 131 S.Ct. 60, 177 L.Ed.2d 1150 (2010).

State v. Abbott Labs., 2012 WI 62, ¶ 78 (emphasis in original).

III. Relief to Which the State Is Entitled.

A. Enforcement Relief.

The State seeks two forms of relief in its enforcement capacity—forfeitures and an injunction. As this Court has already held, "causation arguments are not a defense to enforcement actions under §100.18 (11)(d)." Decision and Order on Certain Defense Cross-Motions for Summary Judgment, July 29, 2008, at 4. The same is true for violations of

§ 49.49(4m). Thus, both an injunction and forfeitures require only a “violation” of a statute, and do not require any proof of resulting harm. *See Varljen v. Cleveland Gear*, 250 F.3d 426, 429-30 (6th Cir. 2001) (“Recovery under the FCA is not dependent upon the government’s sustaining monetary damages”); *United States ex. rel. Schwedt v. Planning Research Corp.*, 59 F.3d 196, 199 (D.C. Cir. 1995) (holding that “regardless whether the submission of the claim actually causes the government any damages . . . its very submission is a basis for liability”); *United States ex. rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991) (holding that the government need not show damages in order to recover civil penalties under the FCA). Finally, the State is entitled to mandatory surcharges.

1. Forfeitures.

The State seeks forfeitures under both § 100.18 and § 49.49(4m). In the event that the jury finds Teva committed any violations of either statute, the jury must determine *how many* violations have occurred based upon a standard that is now well-settled by prior rulings. The Court must then determine the amount of forfeitures to be imposed for each violation.

a. Forfeitures under the Medicaid Fraud statute

Section 49.49(4m)b provides that a person who violates the statute “may be required to forfeit not less than \$100 nor more than \$15,000 for each statement, representation, concealment or failure.”

The Supreme Court affirmed that a § 49.49(4m) violation occurred each time “FDB transmitted an inflated AWP for [an NDC] to Medicaid, and Medicaid then relied upon it at least once in the reimbursement process.” *Abbott Labs.*, 2012 WI 62, ¶ 109. Although in pre-trial briefing Teva asserted otherwise, this Court counted as a violation in the Pharmacia trial each time the State relied on an AWP in the reimbursement process —*i.e.*, each time it compared the

AWP to the other pricing metrics and paid the lowest amount, regardless of whether the ultimate reimbursement was at the discounted AWP, the MAC, or the U&C. These violations also include an “implicit affirmative representation” that an “AWP remained as previously represented” where “a drug was not updated” in a subsequent FDB update sent to Wisconsin Medicaid.²⁶

The State’s economic damages expert, Dr. Thomas DiPrete, performed calculations in accordance with this standard. Specifically, Dr. DiPrete determined the number of NDCs for Teva and Ivax drugs that were reimbursed by the Wisconsin Medicaid at least once during each FDB reporting period during the damages period. FDB transmitted AWP’s to Wisconsin Medicaid once a month through 1995, then twice a month through 2005, and then once a week thereafter. Based on Dr. DiPrete’s calculations, during the relevant time period for the § 49.49(4m) claim (*i.e.*, November 1, 1994 to December 31, 2008), Teva and Ivax caused 59,079 AWP’s to be sent to Medicaid, which Medicaid then relied upon at least once. PX-0219; PX-0201.

b. Forfeitures under the Deceptive Trade Practices Act

Section 100.26(4) provides that any “person who violates s. 100.18 ... is subject to a civil forfeiture of not less than \$50 nor more than \$200 for each violation.” The controlling case on counting forfeitures under § 100.26 is *State v. Menard, Inc.*, 121 Wis.2d 199, 121 Wis.2d 199, 358 N.W.2d 813 (Wis. App. 1984), which explained that a violation “occurred each time an improper advertisement was published, and that each newspaper edition ... constituted a separate publication.” *Abbott Labs.*, 2012 WI 62, ¶ 98 (citing *Menard*, 121 Wis.2d at 201, 358 N.W.2d

²⁶ This Court held that even if monthly/weekly AWP updates from FDB to Medicaid included only the AWP’s that changed from the previous update, such updates “constitute an implicit affirmative representation, condoned by [the manufacturer], that where a drug was not updated, its AWP remained as previously represented.” September 30, 2009 Decision and Order on Remaining Forfeiture Issues, at 4.

813). The Supreme Court likened “each newspaper edition” to “each time ... updates were purchased by Wisconsin for each drug.” *Id.*, ¶ 86.

The forfeitures at issue in *Menard* were those under § 100.26—the same statute at issue here for § 100.18 violations. Thus, the same legal standard applies, with one exception. The Court required that in order for a false AWP to be “false statement ... of material fact” under § 49.49(4m), the AWP had to have been relied upon at least once in the reimbursement process. By contrast, given the broad scope of the Deceptive Trade Practices Act, *Menard* holds that a “violation occurs each time [a deceptive price] is published,” as discussed above, with no reliance requirement. *Menard*, 121 Wis.2d at 201.

Section 100.18 Forfeitures Based on FDB AWPs

The State will ask the jury to count as a § 100.18 violation each time Teva caused a false AWP for each of its NDCs to be transmitted from FDB to Wisconsin Medicaid. Although there is no reliance requirement for § 100.18 forfeitures, the State will voluntarily limit the FDB counts to AWP that were used by the State at least once during a FDB reporting period. The State used an AWP for an NDC during a reporting if it paid a reimbursement for the NDC, regardless of whether the discounted AWP, the MAC, or the U&C was the lowest figure and thus the amount paid.

Section 100.18 Forfeitures Based on Red Book AWPs

The State will also ask the jury to count as a violation each time Teva caused the AWP for each of its NDCs to be published in the annual and monthly editions of Red Book from November 2001 to December 2008. The State intends to present evidence that Teva’s AWP were published in Red Book editions that were received by the UW School of Pharmacy.

2. Injunctive Relief.

Upon a verdict for the plaintiff, Wisconsin requests that the same injunctive order be entered against Teva that was previously entered against Pharmacia in this litigation.

3. Surcharges

In addition to other surcharges, Wis. Stat. § 100.261 requires that a mandatory 25% consumer protection surcharge be added for forfeitures imposed for a violation of Wis. Stat. § 100.18, and Wis. Stat. § 757.05(1)(a) requires a mandatory surcharge of 26% of any forfeiture imposed.

B. Civil Damages.

The State also seeks damages under §§ 100.18(11)(b)2 and 100.263, and under § 49.49(6). In addition to the elements required under the State's enforcement action, the element of causation of damages, as discussed above, is necessary. The State's damages expert, Dr. DiPrete, will present evidence and opinion regarding the State's economic damages using the same sources of information and basic methodology that were relied upon by the State in the Pharmacia trial, which was ultimately endorsed by the Supreme Court. *State v. Abbott Labs.*, 2012 WI ¶ 57, 66. Specifically, Dr. DiPrete has estimated the amount of money Wisconsin Medicaid would have saved had it received, and used, true average wholesale prices. His calculations are based upon the difference between what Medicaid reimbursed pharmacies and the average of the prices actually paid by the pharmacies to wholesalers. Dr. DiPrete estimates that the present value of the State's share of damages²⁷ for both Wisconsin Medicaid and Wisconsin Senior Care claims for Teva's drugs for the entire damages period was \$15,724,539

²⁷ Teva previously settled the federal share with the United States.

using national wholesale sales data, and \$15,452,303 using Wisconsin-only wholesale sales data.²⁸

Dated this 3rd day of October, 2014.

Respectfully submitted,


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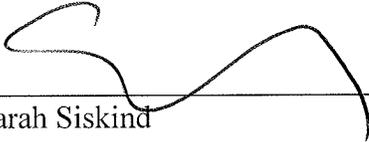
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²⁸ Expert Report of Thomas DiPrete, April 1, 2014 at pp. 15-17.

CERTIFICATE OF SERVICE

I hereby certify that I caused a true and correct copy of the foregoing to be served upon all counsel of via LexisNexis File and Serve this 3rd day of October, 2014.



Sarah Siskind