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In this brief, the State will set forth the elements of its claims and generally summarize the evidence that fulfills 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, 151-52, 749 N.W.2d, 544, 553. It is not necessary to prove that Pfizer Inc. (“Pfizer”) caused any harm to establish a violation of § 100.18. As this Court has 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 Pfizer caused any harm to establish a violation of § 49.49(4m).

II. The State's Evidence Satisfies All Elements of its Claims.

A. "Made or caused to be made" element:

Both statutes require that Pfizer either made or caused to be made a statement. Section 100.18 provides that Pfizer 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 "which is untrue, deceptive or misleading." Wis. Stat. § 100.18(1) (emphasis added). Similarly, § 49.49(4m) provides that Pfizer shall not "make or *cause to be made* any false statement." The State's evidence establishes that Pfizer caused to be made statements—*i.e.*, their false AWP—in pricing compendia, such as Red Book and First DataBank ("FDB").

Testimony and documents from Pfizer (including its predecessor companies whose drugs are at issue in this case¹) overwhelmingly establish this. Pfizer knew that the pricing compendia, FDB and Red Book, published wholesale acquisition costs ("WACs") and AWP for all of its drugs. Parke-Davis, which Pfizer acquired in 2000 and whose drugs (including Lipitor, the world's largest selling drug) are at issue in this case, consistently reported prices called "AWPs" and "Suggested AWP" to FDB and Red Book up until 2000. Parke-Davis knew, expected, and intended that FDB and Red Book would publish AWP identical to the AWP and Suggested AWP that it reported. FDB and Red Book did in fact publish AWP in this manner. For the remaining drugs at issue in this case (and for the Parke-Davis drugs after they were acquired by Pfizer in 2000), Pfizer reported prices it called "list prices" (and other similar names) to FDB and Red Book, with the knowledge, expectation, and intent that these prices would be published as WACs and with the knowledge, expectation, and intent that such prices would be marked up by either 20% or 25% and published as AWP. When it suited Pfizer's business interests, Pfizer

¹ Pfizer acquired Parke-Davis in 2000.

requested that FDB change the markup it applied to Pfizer's WACs to derive AWP's from 20% to 25%, or vice-versa, and FDB complied. Pfizer purchased FDB's electronic database as well as Red Book's hard copy publications, and therefore knew the WACs and AWP's that both publishers were publishing for Pfizer's drugs. Pfizer corrected and verified the published AWP's. Pfizer knew that the AWP's published by FDB and Red Book were greater than the actual average wholesale prices retailers paid to acquire Pfizer drugs.

In 2002, Pfizer learned that FDB would begin publishing AWP's for some of Pfizer's drugs that were 25% above the list prices (WACs) Pfizer submitted to FDB, even though the published AWP's for those drugs had previously been 20% above the list prices (WACs) Pfizer submitted. This "bump-up" in the FDB AWP's occurred only when Pfizer reported a new list price (WAC) to FDB. Pfizer knew that this "bump-up" in FDB's AWP's would cause payers, such as Wisconsin Medicaid, to pay more to pharmacies when reimbursing them for dispensing the affected Pfizer drugs, even though the real average wholesale prices had not increased. Pfizer went along with this bump-up and neither complained, objected, nor otherwise opposed it. Nor did Pfizer disclose to Wisconsin Medicaid any of the facts it knew about this bump-up.

In sum, by reporting AWP's for many NDCs during the damages period, and by reporting list prices (WACs) that it knew, expected, and intended, would be marked up by 20% or 25% by the publishers to derive AWP's, Pfizer caused the publication of AWP's by both FDB and Red Book.

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 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.” Pfizer’s causing 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. Pfizer caused AWP’s to be published through the pricing compendia because it was necessary to ensure that its customers received reimbursement from third-party payers, including state Medicaid programs. Pfizer knew that state Medicaid programs such as Wisconsin used the AWP’s that Pfizer caused to be published to determine the amount of reimbursement to Medicaid providers such as retail pharmacies, and knew the specific formulas used by these programs, including Wisconsin Medicaid.

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. Thus, in addition to being untrue and misleading, Pfizer’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 and causing to be published “average wholesale prices,” Pfizer represented that they were *prices*; that they were an *average* of prices; and that they were an average of prices at the *wholesale level*. Pfizer’s AWP’s are false three different ways. Pfizer’s AWP’s were not prices at

which anything was sold; they were not averages of anything; and they represented no reality at the wholesale level.

According to the testimony of Pfizer's own witnesses, its published AWP's were not averages of prices at which wholesalers sold the Pfizer drugs to retailers. Nor were they prices that any retail pharmacy ever paid to acquire the drugs. The State's expert, Dr. Thomas DiPrete, confirmed this fact by analyzing wholesaler data reflecting the prices at which they sold Pfizer's drugs to retailers. In short, the State's evidence makes clear that Pfizer's AWP's were false and deceptive.

C. The Requirement of § 49.49 that the False Statements Were Caused to be Made *Knowingly* and that the Statements Were of *Material Fact*.

The Pfizer evidence summarized in Section II.A above establishes that Pfizer acted "knowingly," as required by Wis. Stat. § 49.49(4m). Pfizer knew and expected that FDB would publish AWP's for Pfizer's drugs based on the pricing information that Pfizer 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."). When Pfizer only reported WAC's for its drugs, it knew, expected, and intended that FDB and Red Book would mark up those WAC's by 20% or 25% and publish that figure as an AWP.

However, Pfizer knew even more: Pfizer knew that its AWP's were not averages of wholesale prices, nor reasonable estimates of such prices. Pfizer officials knew and intended that payers, including state Medicaid agencies, would rely on their AWP's in order to reimburse pharmacies that dispensed Pfizer's drugs. Pfizer had knowledge of the prices retail pharmacies were paying to acquire drugs, including the markups on its drugs charged by wholesalers to retail

pharmacies. Furthermore, Pfizer knew that the government disapproved of its AWP-related practices.²

Further, Pfizer'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 [is] capable of influencing, the decision of the decision making body to which it was addressed"). Wisconsin Medicaid used Pfizer's AWP's in its reimbursement process. And Pfizer's AWP's caused the State damage. Cases decided under the Federal Trade Commission Act support this conclusion.³ *See also FTC v. Windward Mktg. Ltd.*, 1997 WL 33642380 at 9 (N.D. Ga. 1997) ("any representations concerning the price of a product or service are presumptively material."); *FTC v. Crescent Publ'g Group, Inc.*, 129 F. Supp. 2d 311, 321 (S.D.N.Y. 2001) ("Information concerning prices or charges for goods or services is material").

D. The Causation Element.

The State's evidence establishes that Pfizer'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 brand-name drug, the State compares and pays the lower of (1) the published AWP minus a percentage ("discounted AWP") plus the dispensing fee, or (2) the usual and customary ("U&C") amount submitted by the pharmacy. The State's evidence will demonstrate, as it did at the Pharmacia trial, that had

² In any event, knowledge of Medicaid's rules and requirements should be imputed to Pfizer. 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).

³ Using FTC precedent is endorsed in Wisconsin case law. *See Tim Torres Enter., Inc. v. Linscott*, 142 Wis. 2d 56, 66, 416 N.W.2d 670, 674 (Wis. App. 1987).

Pfizer reported and published a true AWP for its drugs, the State would have used that AWP as the ingredient cost portion of reimbursement. Hence, Pfizer's practice of causing the publication of false AWP's caused damage to the State by causing the State to reimburse pharmacies a higher level than it otherwise would have with true AWP's.

This Court ruled during the Pharmacia trial that even where the State's reimbursement payment was based on a metric other than AWP, such as the U&C (or, where one is in place for a drug with generic equivalents, a Maximum Allowable Cost), a jury 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 jury did not impermissibly speculate as to the damage award with respect to brand name drugs because the jury received credible evidence supporting a reasonable inference that, had actual wholesale prices been provided, the legislature would have used them to reimburse pharmacies for brand name drugs

...

With brand drugs as well as generics, the State never contended that Medicaid paid ...the amounts Pharmacia supplied in its AWP's; [the State] contended that Medicaid *estimated* what pharmacies paid to wholesalers because it knew the AWP's were inflated, but did not know by how much. Thus, in both contexts, the reporting of inflated AWP's harmed Medicaid and in both the reporting of accurate AWP's 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's 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, ¶¶ 60, 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). Nor are causation arguments a defense to the State’s claims for forfeitures, as both an injunction and forfeitures require only a “violation” of a statute, and do not require any proof of resulting harm. *See id.* (“[T]he whole purpose for an enforcement action is to *forestall* any harm caused by the targeted conduct.”) (emphasis in original); *see also 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).

1. Forfeitures.

The State seeks forfeitures under both § 100.18 and § 49.49(4m). In the event that the jury finds Pfizer committed any violation 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. 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 update.⁴

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 Pfizer drugs that were reimbursed by the Wisconsin Medicaid or Senior Care programs at least once during each FDB reporting period during the damages period. FDB reported AWP 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.*, June 3, 1994 to December 31, 2008), Pfizer caused 32,989 AWP to be sent to Medicaid, which Medicaid then relied upon at least once.

⁴ This Court held that even if monthly/weekly AWP updates from FDB to Medicaid included only the AWP 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.

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 under § 100.26, 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 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.

100.18 Forfeitures Based on FDB AWPs

The State will ask the jury to count as a § 100.18 violation each time Pfizer caused a false AWP for each of its NDCs to be transmitted from FDB to Wisconsin Medicaid. As with violations under § 49.49(4m), these violations also include an “implicit affirmative representation” that an “AWP remained as previously represented” where “a drug was not

updated” in a subsequent update.⁵ From June 3, 2001, to December 31, 2008, at least 24,166 of Pfizer’s AWP’s were reported by FDB to the State.

100.18 Forfeitures Based on Red Book AWP’s

The State will also ask the jury to count as a violation each time Pfizer caused the AWP for each of its NDC’s to be published in the annual and monthly editions of Red Book from June 2001 to December 2008. The State intends to present evidence that the Pfizer AWP’s were published in Red Book editions that were received by the UW School of Pharmacy. From June 3, 2001, to December 31, 2008, at least 5,434 of Pfizer’s AWP’s were reported in monthly Red Book editions that were received by the Ebling Library at the UW School of Pharmacy.

2. Surcharges

In addition to other mandatory surcharges, Wis. Stat. § 100.261 provides 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.

3. Injunction.

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

B. 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

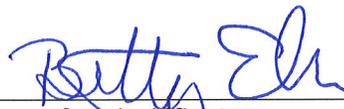
⁵ See footnote 4.

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. *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 based on data subpoenaed from two national wholesalers, Cardinal Health and McKesson Corporation.

Dr. DiPrete has calculated that the damages for both Wisconsin Medicaid and Wisconsin Senior Care claims for Pfizer's drugs for the entire damages period (1994-2008) are \$31,802,977 using national wholesale sales data, and \$32,815,508 using Wisconsin-only wholesale sales data. The State will seek the present value of these damages, which Dr. DiPrete calculated to be \$58,543,894 using national wholesale sales data and \$59,248,167 using Wisconsin-only wholesale sales data.

Dated this 22nd day of January, 2016.

Respectfully submitted,



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