



to acquire the drugs. Defendants have done this without telling any state or the public that the prices were false, much less disclosing the often breathtaking degree to which they were marking them up from the true average wholesale price. They then sat back and watched while First DataBank published these false and inflated AWP's. Defendants thereby corrupted the principal source of data which Wisconsin and other states use to determine "estimated acquisition cost."

Not one word of the preceding description is disputed by the Responses defendants have filed. Even more significantly, defendants offer no explanation, much less evidence, of *why* they have done what they have done. Why have they not simply told First DataBank the truth about their drugs' AWP's, so that states like Wisconsin can make their own decisions about provider reimbursements, and make them on the basis of truthful information? What has motivated them to provide prices, under the name "Average Wholesale Price," that are not averages of anything, much less averages of real wholesale prices?

Defendants' Responses never address these questions, because the only truthful answer is that defendants acted as they did *to inflate reimbursements to providers*. It serves defendants' interests in selling their drugs to interfere in the process by which payers decide how much to pay providers. By reporting inflated AWP's, the defendants became players in this game. Whatever level of reimbursement a state or other third party payer decides on, the defendants can change that level by manipulating the AWP's they report to First DataBank. They have become "the proverbial pharmaceutical fox in charge of the reimbursement chicken coop." *In re Pharm. Indus. AWP Litigation*, 491 F. Supp.2d 20, 95 (D. Mass. 2007).

The State's motions demonstrated that the defendants' practice is unlawful under Wis. Stat. §§100.18(1) and 100.18(10)(b). As those motions showed, providing untruthful data to the public about prices as material as AWP's violates the statute, period, without more.

The State's motions have produced individual Responses and cross-motions from AstraZeneca, Johnson & Johnson, Novartis, and Sandoz, a huge "Joint Response" and cross-motion from all other defendants (joined in large part by the four defendants against whom the State moved), and a separate cross-motion for summary judgment from Schering-Plough and Warrick. In the present brief, the State addresses all of these Responses and cross-motions. As Section I shows, defendants do not dispute the essential facts entitling the State to summary judgment on liability. As Section II shows, Wisconsin law rejects defendants' key assertion -- that in an action by the State under §100.18, proof of *liability* requires proof that the State was actually deceived by the defendants' practices and actually suffered monetary damage. As a result, defendants' many arguments claiming issues of fact as to whether the State was deceived or suffered damage are irrelevant to this motion. Section III will answer legal arguments which defendants failed to make on the motion to dismiss three years ago, asserting that §100.18 does not apply to their conduct. Section IV will answer miscellaneous arguments on the merits. Section V will answer the argument that this case involves a nonjusticiable question. Section VI will show that the defendants' cross-motions must be denied.

**I. DEFENDANTS DO NOT DISPUTE THE FACTS ON WHICH THE STATE BASES ITS MOTIONS.**

Defendants raise no genuine issue as to any material fact underlying the State's motions.

1. Defendants do not dispute knowing at all relevant times that federal law requires the State, in determining reimbursements to providers, to establish drugs' "estimated acquisition cost." As the State's motions showed, a state's Medicaid agency must pay for drugs at the lowest of (1) the "Federal Upper Limit" ("FUL") for a particular drug, if such a limit has been set by the federal Centers for Medicare and Medicaid Services; (2) the provider's "estimated acquisition cost" ("EAC"), as set by the State, plus a reasonable dispensing fee; or (3) the

provider's "usual and customary" charges. 42 C.F.R. § 447.512. The regulations define "estimated acquisition cost" as the relevant State agency's "best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers." 42 C.F.R. § 447.502. As voluntary participants in the Medicaid program, defendants are charged by law with knowing these regulations. None of the defendants denies being familiar with them. *See, e.g.,* AstraZenca Response, p. 8, ¶14; Novartis Response, p. 6, ¶7.

2. Defendants do not dispute that to comply with these regulations, the State must determine the "Estimated Acquisition Cost" of each relevant drug. Otherwise the State cannot make the comparison called for by the regulations to determine which method of reimbursement should be used. Nor do defendants dispute knowing that for a large numbers of drugs, the State pays providers under the method of paying "estimated acquisition cost" plus a dispensing fee. *See* Joint Response at 61.

3. Defendants do not dispute knowing that to establish "estimated acquisition cost," the State uses AWP's published by First DataBank. Defendants themselves describe how they send data to First DataBank and how data is then sent to the State. *See* Joint Response at 51-53.

4. Defendants admit, and in fact allege in detail, that the AWP's they send to First DataBank are not averages of real wholesale prices to providers, but at all relevant times have been much higher than what providers are paying. *See* Joint Response at 22-49.

These are the material facts on which the State bases its motions for summary judgment on liability. They remain undisputed. There is no need to prolong this brief by analyzing defendants' efforts to dispute the truth of other facts which the State listed as undisputed, based

on sworn deposition testimony of defendants' own corporate designees. Appendix A to this reply brief dissects some of the worst examples.

## **II. IN A SUIT BY THE STATE UNDER § 100.18, PECUNIARY LOSS AND ACTUAL DECEPTION ARE NOT ELEMENTS OF LIABILITY.**

Perhaps defendants' most important argument against summary judgment is that the State cannot establish *liability* under §100.18 unless it proves that defendants' false statements about average wholesale prices caused it pecuniary loss. Defendants then assert that to prove such causation, the State must prove that it was actually deceived by defendants' representations, or that those representations 'materially induced' it to act differently." *See, e.g.*, Joint Response at 4, 85-86, 119; AstraZeneca Response at 39; Johnson & Johnson (hereafter "J&J") Response at 21-24; Sandoz Response at 60-62. This assertion about the elements of liability under §100.18 is the legal underpinning for defendants' many arguments that there are purported issues of material fact as to whether the State was deceived, induced to act differently, or monetarily harmed by defendants' practice of providing untrue AWP's.

In denying defendants' motions to dismiss two years ago, Judge Krueger held that in a suit by the State under §100.18, it is *not* an element of liability that anyone was misled, induced to act differently, or monetarily harmed by the defendants' practices. Remainder of The Decision and Order On Defendants' Motions To Dismiss (May 18, 2006), p. 4. That holding was required both by the statute's text and the case law.

**The statutory text.** Section 100.18 defines the conduct made unlawful, in §100.18(1) through (10); gives the State a broad right to bring suit, in 100.18(11)(d); and separately affords a *private* right of action, in 100.18(b)(2). As the State will now show, the definition of unlawful conduct does *not* include, as an element, that the conduct caused pecuniary loss. Likewise, the remedial provision giving the State the right to sue does *not* require, as a condition of suing,

proof that the conduct caused pecuniary loss. Only the remedial provision affording a *private* right of action requires such proof as a condition of suing.

Section 100.18(1) contains the basic definition of unlawful conduct. It reads:

No person, firm, corporation or association, or agent or employee thereof, with intent to sell, distribute, increase the consumption of or in any wise dispose of any real estate, merchandise, securities, employment, service, or anything offered by such person, firm, corporation or association, or agent or employee thereof, directly or indirectly, to the public for sale, hire, use or other distribution, 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 real estate, merchandise, securities, employment or service, shall 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, in this state, in a newspaper, magazine or other publication, or in the form of a book, notice, handbill, poster, bill, circular, pamphlet, letter, sign, placard, card, label, or over any radio or television station, or in any other way similar or dissimilar to the foregoing, an advertisement, announcement, statement or representation of any kind to the public relating to such purchase, sale, hire, use or lease of such real estate, merchandise, securities, service or employment or to the terms or conditions thereof, which advertisement, announcement, statement or representation contains any assertion, representation or statement of fact which is untrue, deceptive or misleading.

As can be seen, nothing in the text of §100.18(1) conditions the illegality of the specified conduct on its succeeding in deceiving anyone, inducing anyone to act differently, or causing pecuniary loss to anyone. To the contrary, the wording of the provision is inconsistent with any such requirement. For example, §100.18(1) says that statements made with the requisite intent are unlawful if they are “untrue.” An untrue statement is untrue regardless of whether the listener knows it is untrue, whether it induces the listener to act differently, and whether it causes pecuniary damage.

Subsections 100.18(2) through (10) supplement §100.18(1) by declaring certain specific statements “deceptive.” The State relies on §100.18(10)(b), which declares: “It is deceptive to represent the price of any merchandise as a manufacturer’s or wholesaler’s price, or a price equal

thereto, unless the price is not more than the price which retailers regularly pay for the merchandise.” Again, nothing in this language conditions the illegality of the specified conduct on its having succeeded in deceiving anyone, having induced anyone to act differently, or having caused pecuniary loss to anyone.

The remedial provisions for §100.18 are found in §100.18(11). Section 100.18(11)(d) gives a broad remedy to the State. It reads:

The department [of agriculture, trade and consumer protection] or the department of justice, after consulting with the department, or any district attorney, upon informing the department, may commence an action in circuit court in the name of the state to restrain by temporary or permanent injunction any violation of this section. The court may in its discretion, prior to entry of final judgment, may 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. The department and the department of justice may subpoena persons and require the production of books and other documents, and the department of justice may request the department to exercise its authority under par. (c) to aid in the investigation of alleged violations of this section.

Nothing in this subsection requires the State to prove that anyone was actually deceived by the “violation of this section” in question, or was induced to act differently, or suffered pecuniary loss. To the contrary, the subsection’s structure makes clear that it is intended, among other things, to allow the State to sue for an injunction *before* the violation in question ends up hurting anyone. If defendants were correct that proof of pecuniary loss were an element of liability in an action by the State under this section, the intolerable result would be that the State would have to wait until the practice in question had done harm before suing to enjoin it. Likewise, the second sentence, referring to the court’s power to issue orders making whole those who “may have suffered pecuniary loss,” makes clear by the words “may have” that it is not preconditioning the State’s right to sue on such loss having necessarily occurred.

In contrast, the provision affording a private right of action, §100.18(11)(b)(2), while not changing the simple elements of a violation of §100.18(1), expressly conditions the right to sue on the plaintiff having suffered pecuniary loss. It reads (emphasis added):

*Any person suffering pecuniary loss* because of a violation of this section by any other person may sue in any court of competent jurisdiction and shall recover such pecuniary loss, together with costs, including reasonable attorney fees, except that no attorney fees may be recovered from a person licensed under ch. 452 while that person is engaged in real estate practice, as defined in s. 452.01(06). *Any person suffering pecuniary loss* because of a violation by any other person of any injunction issued under this section may sue for damages therefore in any court of competent jurisdiction and shall recover twice the amount of such pecuniary loss, together with costs, including reasonable attorney fees, except that no attorney fees may be recovered from a person licensed under ch. 452 while that person is engaged in real estate practice, as defined in s. 452.01(06).

It should be noted that by affording a private right of monetary recovery for damages incurred on account of a violation of “any injunction issued under this section,” this provision makes even clearer that there is *no* requirement of pecuniary loss for actions by the State for an injunction under §100.18(11)(d).

**The case law.** Wisconsin case law reflects the distinction discussed above between suits by the State under §100.18(11)(d) and suits by private plaintiffs under §100.18(11)(b)(2). In *State v. American TV & Appliance of Madison, Inc.*, 146 Wis.2d 292 (Wis. 1988), a suit by the State under §100.18(11)(d), the Supreme Court defined the elements of the claim as follows: “There are two elements to this offense: There must be an advertisement or announcement, and that advertisement must contain a statement which is untrue, deceptive or misleading.” *Id.* at 300. The Court neither said nor implied that the State in addition had to prove actual deception, inducement to act differently, or causation of pecuniary damage.

Only in cases brought by private plaintiffs under §100.18(11)(b)(2) do Wisconsin courts require plaintiff to prove the additional element of pecuniary loss, and those cases specifically

cite §100.18(11)(b)(2) as the source of this requirement. See *K & S Tool & Die Corp. v. Perfection Machinery Sales, Inc.*, 2007 WI 70, ¶19, 301 Wis.2d 109, ¶19; *Tietsworth v. Harley-Davidson, Inc.*, 2004 WI 32, ¶¶38, 39, 270 Wis.2d 146, ¶¶38, 39. Defendants cite *K & S Tool & Die* for their argument that the State must prove pecuniary loss in order to be entitled to summary judgment on liability. But neither *K & S Tool & Die*, nor any other Wisconsin case, imposes such a requirement in a suit by the State under §100.18(11)(d), which, unlike §100.18(11)(b)(2), does not mention pecuniary loss as a condition of suing.

Case law from other jurisdictions with similarly structured consumer protection laws reflects the same distinction. For example, the Illinois Consumer Fraud Act, like Wisconsin's §100.18, has a section declaring what conduct is unlawful (815 ILCS 505/2), a section affording a broad remedy to the Attorney General (815 ILCS 505/7), and a section affording a private right of action to plaintiffs who can prove they suffered pecuniary loss (815 ILCS 505/10a). The Illinois Supreme Court has held that in suits by the Attorney General, a defendant who commits unlawful conduct as defined in the statute is liable regardless of whether anyone suffered damage, but that in private suits, the plaintiff must prove actual damage. *Oliveira v. Amoco Oil Co.*, 201 Ill.2d 134, 149 (2002).

In short, Judge Krueger was right when she held that “the Amended Complaint was [not] filed pursuant to Wis. Stat. §100.18(11)(b)(2), and no argument or authority is offered to support the proposition that causation or reliance by a consumer is required for an action filed pursuant to §100.18(11)(d).” Remainder of The Decision and Order On Defendants’ Motions To Dismiss (May 18, 2006), at 4. The elements of a violation of §100.18(1) or §100.18(10)(b) do not include proof that anyone was actually deceived, was actually induced to act differently, or suffered any pecuniary loss. When the State sues to enforce these provisions under

§100.18(11)(d), it need neither plead nor prove any these things. If the State establishes the elements of a violation of §100.18(1) or §100.18(10)(b) as a matter of law, as it has done on the present motions, it is entitled to summary judgment on liability. Only in a suit by a private plaintiff under §100.18(11)(b)(2) need the plaintiff establish the additional requirement of pecuniary loss.

This result has sweeping consequences for the present motions, because it renders irrelevant the many arguments defendants make to the effect that the State “has not set forth undisputed material facts showing that it was materially induced by Defendants’ representations to act” and hence that it suffered pecuniary loss. Joint Response at 87. For example, the Joint Response claims that the State has not set forth undisputed facts showing that it relied on AWP as representing an actual average of wholesale prices, or that defendants’ AWP induced it to act differently. *Id.* at 87-93. AstraZeneca, Novartis, and Sandoz argue that to show causation of damage, the State should be required to show “reasonable reliance” and that it cannot do so. AstraZeneca Response, at 43-46; Novartis Response at 58; Sandoz Response at 60-63. Sandoz argues that AWP is “rarely used to reimburse for Sandoz drugs,” on account of a mechanism called “generic substitution,” and hence the State with respect to “virtually all of its claims” has not established that Sandoz’s reporting of AWP or WAC to First DataBank caused injury. Sandoz Response at 57-63. Schering and Warrick argue that many of their drugs are reimbursed on the basis of a State-set “Maximum Allowable Cost” (MAC) rather than AWP, so that the State cannot demonstrate that the false AWP that Schering and Warrick reported influenced provider reimbursements as to these drugs. Schering/Warrick Memorandum at 26-29.<sup>1</sup> These

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<sup>1</sup> At the appropriate time, the State will show that even as to drugs reimbursed on the basis of “Maximum Allowable Cost,” the inflated AWP and WACs defendants announce for those drugs frequently raised the amounts the State paid. Not only did AWP and WACs influence the MACs the State set, but under federal regulations, even where a MAC has been set, if the State’s “Estimated

and all other such arguments in defendants' Responses can and must be determined at the damages stage, because to prove liability, the State is not required to prove causation of pecuniary loss, inducement to act differently, or actual deception.

Not that the State agrees for a second that defendants' practices caused it no damage. The contention is absurd on its face. The prices the State paid providers were an arithmetic consequence of a formula in which AWP was the only variable. Lower AWP's would have meant lower payments. This situation illustrates why, contrary to defendants' arguments, the "causation" requirement is not phrased in terms of "reasonable reliance," but merely causation.

*K & S Tool and Dye Corp., supra*, 2007 WI 70, ¶36.

Moreover, the State disputes many of the assertions on which the defendants base their "causation" arguments. The footnote below gives illustrative examples,<sup>2</sup> and more detail

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Acquisition Cost" is lower than the MAC price, the State must reimburse on the basis of the EAC, not the MAC. The State intends to prove that in many instances, if defendants had reported honest AWP's, the EAC (which was determined by reference to AWP) would have been lower than the MAC, and the State would have therefore paid less than it paid.

<sup>2</sup> a. No State official whose deposition testimony defendants quote has even hinted at what defendants charge – that the State intended to give pharmacists a profit by illegally inflating the ingredient-cost component of reimbursements to levels far beyond providers' actual costs to acquire the drugs. Defendants cite to James Vavra's testimony (Joint Response at 30), but that testimony makes clear that the State intended to adhere to "the Federal principle of estimated acquisition cost close to what the pharmacists obtained the [drugs] at" and that any profit the pharmacists would earn had to come through the dispensing fee. Vavra Tr. (Ex. 1 to Joint Response) at 77:5-14.

b. Defendants suggest that they disclosed that "[First DataBank's] AWP's did not represent actual prices." Joint Response at 9 and n. 31, *citing* Joint Response Ex. 14. Exhibit 14 is a letter from defendant Novartis to a Wisconsin Medicaid official, announcing a change in the AWP of COMTAN®. The letter includes a disclaimer saying that AWP, "in keeping with current industry practices, is set as a percentage above the price at which each product is offered generally to wholesalers. Notwithstanding the inclusion of the term price, in Average Wholesaler Price, AWP is not intended to be a price charged by Novartis for any product to any customer." This disclaimer is meaningless, because the name "average wholesale price" does not *imply* that it is the price charged *to wholesalers* or to customers of Novartis. Rather, the plain meaning of the words is the price charged *by wholesalers* when they resell Novartis's drugs *to providers*. Thus, Novartis's disclaimer told Wisconsin Medicaid nothing of value, and nothing that it would not have already assumed from the plain meaning of the term "AWP." The other disclaimers defendants cite are of the same ilk. Amgen, like Novartis, said that AWP is not the

appears in the State's response (Appendix B to this reply brief) to the "proposed undisputed facts" in defendants' Responses. In short, at the appropriate stage, the State will show enormous damage from defendants' conduct. But the validity or invalidity of defendants' "causation" arguments is irrelevant to the present motions, which concern liability only.

## **II. DEFENDANTS' ARGUMENT THAT THEY MADE NO "UNTRUE, DECEPTIVE OR MISLEADING STATEMENTS" HAS NO MERIT.**

In its motions, the State showed that under §108.18(1), "a statement is untrue which does not express things exactly as they are." *Tim Torres Enterprises, Inc. v. Linscott*, 142 Wis.2d 56, 65 n.3 (Wis. Ct. App. 1987); Wisconsin Pattern Jury Instructions (Civil) §2418 (1998). As Judge Saris held, the plain meaning of the words "average wholesale price" is "the average price at which wholesalers sell their drugs to their customers." *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp.2d 277, 287-288 (D.Mass. 2006). As the State's motions further showed, the untruth of defendants' statements of average wholesale price is particularly objectionable. Counts interpreting §100.18 follow court interpretations under the Federal Trade Commission Act. *Tim Torres Enterprises*, 142 Wis.2d at 66-67. For more than forty years it has

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price at which Amgen sell its drugs. Joint Response, Ex. 16. Schering professed not even to know the average wholesale price of its drugs (but now contends the State should have). *Id.* Ex. 17.

c. Defendants cite various reports from an advisory commission called the Governor's Pharmacy Commission, which was not even constituted until 2005. Those reports are filled with material that contradicts defendants' position that the State intended to pay more than providers' acquisition costs. For example, the Commission's "Medicaid Briefing Papers" for 2005 assume that defendants' AWP's mean what the name implies: "AWP represents the package price reported by the manufacturer or based on surveys of drug wholesalers and drug manufacturer-supplied information for a drug product." Joint Response, Ex. 8, p. 5. Similarly, the Commission's 2006 report asserts that one of the Commission's guiding principles is that "Payment to pharmacists should cover the reasonable operational cost of the services they provide, *with ingredient costs reimbursed as close to actual costs as can reasonably be determined.*" Joint Response, Ex. 5, p. 7 (emphasis added).

d. Defendants' material frequently documents that it was impossible for the State, in the face of defendants' false announced AWP's, to figure out what real provider acquisition costs were. For example, in its 2006 report, the Pharmacy Commission admitted that its own members had not been able to "reach agreement on what it costs pharmacies to acquire the brand drugs they are dispensing." Joint Response, Ex. 5, p. 4.

been unlawful under that Act to publish a price, regardless of the name attributed to it, where the price does not truly represent a price at which significant sales are made. *See, e.g., State's AstraZeneca Motion at 23-24.*

In responding to this argument, defendants do not and cannot dispute certain things. First, they do not dispute that their AWP's were not really average wholesale prices.

Second, defendants do not and cannot dispute that a factual *name* assigned to data makes a *statement* about what that data is. For example, if General Motors states that the "average MPG" of one of its cars is 30 miles per gallon, assigning the name "average MPG" to that figure results in a statement of fact that is either true or false.

Third, defendants cannot dispute that the *plain English meaning* of the words "average wholesale price" is what Judge Saris held it was. Defendants try to evade that holding by arguing that she was construing the meaning of the term "Average Wholesale Price" in the federal Medicare statute, whereas no statute or regulation defines the term for purposes of the State's Medicaid program. Joint Response at 84-85. This is sophistry. Judge Saris was interpreting the Medicare statute through the usual means: she began with the plain meaning of the words. She held that the plain meaning of "average wholesale price" was just what the words implied. The fact that no statute or regulation is involved in the present case *strengthens* the case for holding that the name "average wholesale price" means what the words plainly mean, for there is no legislative history to turn to try to establish that a term with a plain English meaning really means something different.<sup>3</sup>

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<sup>3</sup> In a footnote, defendants argue that in a later opinion that remanded Florida's AWP claims to state court, Judge Saris found that "the federal definition of AWP did not inform 'the meaning of the term under the Florida Medicaid statute.'" Joint Response at 85, n. 113, *citing In re Pharm. Indus. Average Wholesale Price Litig.*, 457 F. Supp.2d 65, 73-74 (D.Mass. 2006). All that Judge Saris held was that "How Florida defines AWP [in its Medicaid statute] is by definition not a federal question." *Id.* at 74. Hence she had no federal jurisdiction over Florida's state-law AWP claims and lacked the power to

Defendants nonetheless argue that they were not making an untrue statement by announcing price data under the name “average wholesale prices” that were far higher than average wholesale prices. Their argument asserts, in effect, that in the drug industry, the term “average wholesale price” has *no quantitative meaning whatsoever*, despite its plain-English meaning. Defendants argue that information has leaked into the marketplace over the years that AWP as published by the drug compendia are significantly inflated over true averages of true wholesale prices. On that basis, they claim that AWP has become a “term of art.” AWP, they say, “is and was widely understood by both the reimbursement community (providers, Medicaid, Medicare officials, etc.) and the State itself to be a benchmark figure, that did *not* represent actual averages of wholesale prices.” Joint Response at 81 (italics in original). Accordingly, defendants say, reporting their prices under the name “average wholesale prices” said *nothing* about what real wholesale prices were, and therefore could not have been “false.” *Id.* at 81-84; J&J Response at 19-20; Novartis Response at 32-42; Sandoz Response at 63-73.

This argument has no merit. First, no authority supports it. Second, the argument conflicts with the statutory scheme. Third, the argument fails on its own terms. Even if §100.18 allowed, in some circumstances, a statement’s plain meaning to be ignored on the ground that the statement was a “term of art” whose universally accepted meaning was something else, the term “average wholesale price” could never qualify as a “term of art” under such a rule.

**A. No Case Authority Supports Defendants’ “Term Of Art” Argument.**

None of the defendant’ Responses cites any Wisconsin authority in which a statement whose plain English meaning was untrue was held *not* to be “untrue,” “misleading,” or “deceptive” on the ground that the statement contained a “term of art” universally understood to

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consider what the Florida legislature had meant by the term “Average Wholesale Price.” Judge Saris’s remand decision in no way qualifies her earlier holding – that the plain English meaning of the words “average wholesale price” is “the average price at which wholesalers sell their drugs to their customers.”

mean something utterly different than what its plain English meaning said. Rather, the simple law in Wisconsin, as discussed above, is that a statement is untrue when it does not “represent things exactly as they are.” *Tim Torres*, 142 Wis.2d at 65 n.3.

Defendants cite cases holding that the truth of a statement must be determined in context. *See, e.g.*, Novartis Response at 34-35. These cases do not help defendants. All they did was use “context” to decide among competing interpretations, each of which was at least plausible under the plain English meaning of the words in question. For example, in *Avis Rent A Car Sys., Inc. v. Hertz Corp.*, 782 F.2d 381 (2d Cir. 1986), the court, construing a Hertz ad, held that in context, the claim “Hertz has more new cars than Avis has cars” clearly meant “than Avis has cars available for rental.” *Id.* at 385. In *Plough, Inc. v. Johnson & Johnson Baby Prods. Co.*, 532 F. Supp. 714 (D.Del. 1982), the court, in a motion for preliminary injunction, used context to decide what the term “sunscreen” would mean to a reasonable distributor of suntan and sun protection products. (Ironically for Novartis, which cites the case in support of its argument that “average wholesale price” is a “term of art,” the Court concluded: “I cannot conclude on this record that “sunscreen” is a term of art . . .” *Id.* at 718.) In *Princeton Graphics Operating, L.P. v. NEC Home Electronics (U.S.A.) Inc.*, 732 F. Supp. 1258 (S.D.N.Y. 1990), the defendant was held *liable* for its misleading use of the term “compatibility.” In words that could describe the present case, the court wrote:

[T]he term “compatible” does not have the broad and flexible meaning as suggested by defendant when, as here, there is a possibility that a more precise definition may be applied. [Footnote omitted.] Indeed, if there was one overarching impression left on this court after the testimony given in this case it was that the computer industry is concerned with and depends upon accuracy. Thus, the testimony confirms our view that in an industry which depends upon accuracy, a lack of precision in the use of common terms, particularly in circumstances where those terms have the potential to be specific, would be an anomaly.

*Id.* at 1261. Similarly, in the drug business, states depend on accuracy in estimating providers' acquisition costs, and "average wholesale prices" have the "potential to be specific," to put it mildly. In short, none of defendants' cases are authority for holding that the term "Average Wholesale Price" means what defendants claim: "whatever prices we choose to provide to First DataBank for our products under the name 'Average Wholesale Price.'"

**B. A "Term Of Art" Exception To What Statements Are "Untrue, Misleading Or Deceptive" Would Disrupt The Statutory Framework.**

As discussed above in Section II, the framework of §100.18 is to ban statements made under the requisite circumstances with the requisite intent that are "untrue, deceptive, or misleading." As also discussed above, under §100.18(11)(d), the State may sue to enjoin practices that violate the statute without making any showing that the statement actually deceived or damaged anyone or induced them to act differently. There is an obvious conflict between this statutory framework and defendants' asserted "term of art" exception to the "untrue statement" element of liability. If defendants' "term of art" exception existed, one could anticipate precisely what is happening in this case: defendants would argue that statements which are patently false according to their plain meaning are instead not false at all. That would conflate the issue of falsity with the issue of whether the statements actually misled anyone and what relief, as a result, should be granted.

The Seventh Circuit made this point in *B. Sanfield, Inc. v. Finlay Fine Jewelry Corp.*, 168 F.3d 967, 974 (7th Cir. 1999). *B. Sanfield* was a false advertising case under the federal Lanham Act and the Illinois Consumer Fraud Act. The trial court held that if "consumers generally understand that a retailer makes little or no effort to sell at a stated regular price, then stating the price as regular would be neither deceptive nor misleading." The Seventh Circuit reversed:

That logic departs from the state and federal provisions in two important ways. Like the court's observation as to the inherent meaning of the term "regular price," it disregards the judgment of state and federal regulators as to the deceptive potential of that term. The Illinois regulation, for example, does not simply suggest that a comparison to the regular price *might* be misleading if substantial sales have not been made or attempted at that price, it unequivocally provides that the comparison *is* misleading unless one of those criteria is met. 14 Ill. Admin. Code § 470.220. Moreover, in elevating subjective consumer perceptions to preeminence, the court's approach appears to demand proof of actual consumer deception before an act is deemed deceptive. To that extent, it is at least in part inconsistent with the federal and state statutes alike, neither of which (as we have already noted) focuses strictly on actual perception to the exclusion of practices which are *likely* to mislead. *See* 815 ILCS § 505/2 (declaring unfair or deceptive acts unlawful regardless of "whether any person has in fact been misled, deceived or damaged thereby"); *United Indus. Corp. v. Clorox Co.*, 140 F.3d at 1181, 1183 (nothing that proof of actual confusion is not required under Lanham Act when the challenged advertising is literally false, nor where advertise has acted willfully or with intent to deceive).

168 F.3d at 974.

**C. The "Term Of Art Exception" Argument Fails On Its Own Terms.**

Even if this Court were to recognize a "term of art" exception that excuses a statement that is flatly untrue according to its plain English meaning, this case would be a terrible candidate for such an exception. By any test of "term of art" that serves the purposes of §100.18, publishing price data as "average wholesale prices" cannot qualify.

*First*, if a statement is to be treated as a "term of art," and held to mean something utterly different than and unconnected with its plain English meaning, then that different meaning needs to be clearly defined. "By definition, a term must have an established and settled meaning to constitute a term of art." *In re Pharm. Indus. Average Wholesale Price Litig.*, *supra*, 460 F. Supp.2d at 285; *see also Stewart v. Dutra Constr. Co.*, 543 U.S. 481, 487 (2005) ("'[S]eamanship' is a term of art that had an established meaning under general maritime law."); *Pfizer, Inc. v. Gov't of India*, 434 U.S. 308, 315 (1978) ("The word 'person,' however, is not a term of art with a fixed meaning wherever it is used, nor was it in 1890 when the Sherman Act

was passed.”). The need for a precise meaning is particularly true of statements whose plain English meaning is *quantitative*, which is the case for price data labeled as “average wholesale prices.”

The term “Average Wholesale Price” flunks this test. In the multi-district AWP proceedings, Judge Saris’s court-appointed expert pointed out that “inconsistent and ambiguous information exists even currently concerning what type of price AWP measures. The continuing confusion is real and understandable.” *In re Pharm. Indus. Average Wholesale Price Litig.*, *supra*, 460 F. Supp.2d at 285.

Indeed, defendants themselves never tell us with any precision what they think “Average Wholesale Price” *does* mean. They only say that it means a “benchmark” or “reference” point. Benchmark or reference for what? Defendants never say. For example, they do not claim, much less provide evidence, that the AWPs they fed to First DataBank were an average of *undiscounted* wholesaler prices to which discounts were then provided in sales to providers. Likewise, they do not claim, much less provide evidence, that those AWPs represented “suggested” prices that they *wanted* wholesalers to charge to providers. To the contrary, as Judge Saris found, over the years, some defendants have in fact “marketed the spread” of their drugs by urging providers to take advantage of the fact that they can acquire their drugs for far less than AWP. *In re Pharm. Indus. AWP Litigation*, *supra*, 491 F. Supp.2d at 32-40.

In other words, the description of AWPs as “benchmark” or “reference” points is *meaningless* unless defendants provide evidence that there is some universally accepted understanding in the marketplace as to what AWPs were benchmarks *for*. There is no such evidence, because there is no such understanding. When defendants call AWP a “benchmark” or “reference,” point, they really are asserting that the words “Average Wholesale Price” mean

“whatever figure we choose to provide to First DataBank and other compendia under the name ‘Average Wholesale Price.’” In other words, defendants’ position is circular. Whatever else the phrase “term of art” may mean, it cannot possibly mean “whatever we choose it to mean.” Judge Saris rightly rejected this circular view, under which the words “average wholesale price” mean nothing more than “a metric that is wholly dictated by the pharmaceutical industry.” *In re Pharm. Indus. Average Wholesale Price Litig.*, *supra*, 460 F. Supp.2d at 286.

A concrete example will bring this point home. Defendants include various excerpts from the corporate deposition of Shopko, one of Wisconsin’s largest retail pharmacies. Here is some testimony they left out. Shopko acquires its drugs by paying the published wholesale acquisition cost of these drugs minus 3.8% -- not only far below the defendants’ published average wholesale prices, but well below even the price that defendants publicly represent to be the wholesaler’s acquisition cost (WAC). Neuman Tr. at 262, attached hereto as Appendix F. The State of Wisconsin has never been informed of Shopko’s acquisition prices, because: “That’s confidential.” *Id.* at 264. At its deposition, Shopko produced what it termed “movement reports.” One such report shows that Shopko was able to buy a certain volume of a drug called Fluconazole at an actual cost of for \$2,267.28. When it sold it to consumers, it was reimbursed \$57,606.00 based on the published average wholesale price. Shopko can make this astounding profit because it bills payers like the State at defendants’ inflated average wholesale prices, not the price it pays for these drugs:

Q. When a drug goes from a brand to generic and the price drops precipitously, you continue to bill at the AWP and you don’t tell, for example, the State of Wisconsin that the price now, the acquisition price has dropped precipitously. You wait for Wisconsin to figure that out itself, is that correct? \* \* \*

A. What we send, regardless of brand or generic or at any given point, we send AWP of that drug. Has nothing to do with the cost that we pay for it. So that we’re paid on a formula based on AWP. We submit AWP to our third parties and

that's what we're paid off of . . . We send 100 percent of AWP to our third-party payers, to anybody. That's how we bill for a drug, yes.

*Id.* at 272, 274. A price labeled “average wholesale price” that can be up to *twenty-seven* times the price at which the provider acquired it is not a “benchmark” price. It is a scam.

*Second*, a statement cannot qualify as a “term of art” when, as here, those who are actually making the statement specifically contradict the supposed meaning of that term of art. For many years, and continuing to as late as 2003, First DataBank told the marketplace that the AWP's it published – which were almost entirely the prices that defendants had supplied to them – were what their name represents them to be. In 1991, First DataBank wrote:

AWP represents an average price which a wholesaler would charge a pharmacy for a particular product. The operative word is *average*. AWP never means that every purchase of that product will be exactly at that price. There are many factors involved in pricing at the wholesale level which can modify the prices charged even among a group of customers from the sale wholesaler. AWP was developed because there had to be some price which all parties could agree upon if machine processing was to be possible.

Appendix H to this reply brief (*italics in original*), Tab 1. In 1999, First DataBank was still saying the same thing:

As you know, AWP represents the average wholesale price: the average price a wholesaler would charge a customer for a particular product. The operative word is *average*. AWP was developed to provide a price which all parties could agree upon for electronic processing to be possible.

Appendix H, Tab 2 (*italics in original*). Similarly, in 2000, First DataBank said:

AWP is the average **wholesale** price. That is, AWP is the average of the prices charged by the national drug wholesalers for a given product (NDC) often referred to by FDB as the “Blue Book Price.”

Appendix H, Tab 3. In 2000, First DataBank's glossary defined AWP as follows:

Average Wholesale Price (AWP): The unit or package price of an NDC when sold from wholesaler to the pharmacy.

Appendix H, Tab 4. In 2002, First DataBank's glossary stated:

AWP: Average Wholesale Price is that price paid by the pharmacy to the wholesaler

Appendix H, Tab 5. In 2003, First DataBank's glossary stated:

*Average Wholesale Price.* Represents the most common wholesaler price charged to the retailer or hospital. To ensure both the accuracy and timeliness of reporting this information, DB determines the AWP by a variety of methods. See also *Blue Book AWP Package Price (BBPKG)*.

Appendix H, Tab 6. Defendant Novartis similarly defined average wholesale price in its publicly available 2001 Pharmaceutical Benefit Report:

*Average wholesale price (AWP)*—A published suggested wholesale price for a drug, based on the average cost of the drug to a pharmacy from a representative sample of drug wholesalers. There are many AWP's available within the industry. AWP is often used by pharmacies to price prescriptions. Health plans also use AWP—usually discounted—as the basis for reimbursement of covered medications.

Appendix I at 47 (Bates NOV/WIS 000100541).

Defendants are thus arguing: “AWP is a term of art that means something different than its plain English meaning, even though the mouthpiece through which we broadcast our AWP's was saying that it meant what its plain English meaning says.” No such statement can qualify as a “term of art.”

*Third*, even if there were a “term of art” exception to what is an “untrue statement” under §100.18, it would flout the purpose of the statute to allow that exception to include terms which originated, within recent memory, in deliberate deception. The practice of inflating AWP's indisputably started out as a deliberate practice of inflating price data over their real level, and defendants never acknowledged that the term in question had a different meaning than its plain-English meaning until they found it necessary to invent the “term of art” argument to stave off liability in AWP lawsuits. This history was traced in detail by Judge Saris in her decision imposing liability on three defendants who are also defendants in this case (AstraZeneca, Bristol

Myers-Squibb and Schering/Warrick). *In re Pharm. Indus. AWP Litigation, supra*, 491 F. Supp.2d at 32-40. In such a situation, defendants' argument amounts to this: "When enough people have seen through our deception, it becomes a "term of art" with a meaning other than its plain English meaning, even though we ourselves don't tell the public what that other meaning is." That argument is contrary to everything §100.18 stands for.

*Fourth*, it is difficult to imagine a term qualifying as a "term of art" when the speaker has a strong economic interest in the listener interpreting that term according to its plain English meaning rather than according to the purportedly different meaning. It serves defendants' interests for payers such as the State to believe that AWP's are actual averages of prices providers pay to wholesalers to acquire their drugs.

*Fifth*, statements about *prices* are poor candidates to be considered "terms of art." As the State discussed in its motions (*see, e.g.*, State's AstraZeneca Motion at 23-24), pricing information is considered material as a matter of law, and for decades, decisions under the Federal Trade Commission Act, to which Wisconsin courts look in interpreting §100.18, have been implacably hostile to playing word games with prices.

In short, even if a "term of art" exception existed to §100.18(1)'s concept of an "untrue" statement, the term "Average Wholesale Price" could not qualify for that exception under any test that is faithful to the purposes of the statute.

This is in contrast to the examples of "terms of art" given by defendants: "World Series" and "2 x 4" (Joint Response at 82); "barley," "honey," "candy," and "meatball" in the scrap trade (J&J Response at 20); and "sunscreen" (Novartis Response at 35). First, unlike "Average Wholesale Price," each of these terms has a precise meaning in the relevant marketplace. ("World Series" is a perfect example.) Second, unlike "Average Wholesale Price," no key

player in the relevant market disagrees with the meaning defendants cite for them. (No one in the lumber trade is stating in trade publications, “2 x 4’s measure exactly two by four inches.”) Third, none of defendants’ illustrative terms originated in a deliberately deceptive practice. (No one in the scrap trade gave copper with scrap in it the name “candy” hoping that someone would believe it really was candy.) Fourth, no one in defendants’ illustrations gains from buyers taking the term of art literally. Fifth, none of these examples concerns the subject of price.

Defendants’ “term of art” argument has no merit. The price data they gave to First DataBank under the name “Average Wholesale Prices” were “untrue, deceptive, or misleading” statements within the meaning of §100.18(1). What impact those untrue statements had on the State, and what damage they caused, are for later determination. But for now, defendants cannot avoid summary judgment as to liability by asserting that the statements were not “untrue.”

#### **IV. DEFENDANTS’ ARGUMENTS THAT §100.18 DOES NOT COVER THE CONDUCT ALLEGED BY THE STATE HAVE NO MERIT.**

##### **A. The Argument That §100.18 Does Not Apply To Drugs.**

Defendants argue that §100.18 does not apply to drugs. They base this argument on *Gallego v. Wal-Mart Stores, Inc.*, 2005 WI App. 244, 288 Wis.2d 229, *review granted*, 289 Wis.2d 9 (Wis. 2006). (After the Supreme Court of Wisconsin accepted review of the Court of Appeals decision, the parties settled *Gallego* and the Supreme Court appeal was dismissed.) *Gallego* held that because a separate provision, Wis. Stat. §100.183, makes it unlawful to make false advertising or statements “regarding articles of food,” the term “merchandise” in §100.18(1) must be construed to exclude food.

Defendants argue that another statute, §100.182, governs certain false statements with respect to drugs, and hence, by analogy to *Gallego*, the word “merchandise” in §100.18 should be construed to exclude drugs. Joint Response at 74-78. Remarkably, defendants never quote

the statute they rely on, §100.182. Thus, before discussing *Gallego* and defendants' attempt to extend *Gallego* to drugs, it is necessary to quote and describe the different statutes in question.

Section 100.18 was originally passed in 1911. The general prohibition of that law, §100.18(1), is quoted above at page 6. It is this subsection that bans deceptive, misleading and untrue statements relating to "merchandise."

Section 100.183, relating to "articles of food," was passed originally in 1927, and was on the books in 1969, when the legislature renumbered §100.183 and also revised the general statute, §100.18, to provide a private right of action. *See Gallego*, ¶14. Section 100.183(1) reads (emphasis added):

No person, firm, corporation or association shall, with intent to sell, or increase the consumption thereof, or create an interest therein, make, publish, disseminate, circulate, or place before the public in this state, or cause, directly or indirectly to be made, published, disseminated, or placed before the public in this state, in a newspaper or other publication, or in the form of a book notice, handbill, poster, bill, circular or pamphlet, or in any other manner, an advertisement *of any sort regarding articles of food*, which advertisement contains any assertion, representation or statement which is untrue, deceptive or misleading.

As can be seen, the coverage of this ban relating to "articles of food" is parallel to the coverage of §100.18(1)'s general ban relating to "merchandise." Section 100.183(1) bans *any* untrue assertion, representation, or statement regarding "articles of food," just as §100.18(1) bans *any* untrue assertion, representation, or statement regarding "merchandise."

Section 100.182, relating to drugs, was originally passed in 1981. Laws 1981, ch. 90, §1. Section 100.182's operative prohibitions read:

- (2) No person may advertise the availability of any drug or publish or circulate such an advertisement with the intent of selling, increasing the consumption of or generating interest in the drug if the advertisement contains any untrue, deceptive or misleading representations *material to the effects of the drug*.
- (3) No person may expressly or impliedly represent that a substance may be used to obtain physical or psychological effects associated with the use of a drug in

order to promote the sale of the substance unless it is lawfully marketed for human consumption under the United States food, drug and cosmetic act under 21 U.S.C. 301 to 392. A representation that the substance is not intended for human consumption is not a defense to prosecution for violating this subsection.

(4) No person may advertise a drug that the person knows is intentionally manufactured substantially to resemble a controlled substance or that the person represents to be of a nature, appearance or effect that will allow the recipient to display, sell, deliver, distribute or use the drug as a controlled substance, unless the drug is controlled under ch. 961.

It should be clear why defendants' Joint Response never quotes these provisions: they do not ban all misrepresentations or false statements relating to drugs, but only those dealing with their effects and quality. In particular, they do not govern misrepresentations relating to *price*. In contrast, prices are a major concern of §100.18, many of whose subsections (including subsection (10)(b), which the State invokes in this suit) deal with false pricing practices.

With this background, it is clear that *Gallego* does not control the present case. In *Gallego*, the Court of Appeals began by determining that the term “merchandise” in §100.18 did not unambiguously include food. The primary definition of “merchandise” in the 1987 edition of Black’s Law Dictionary was “the manufactured goods bought and sold in any business.” *Gallego*, ¶13. That definition could include food, but did “not necessarily do so in all contexts.” Because of the uncertainty as to whether “food” fit the term “merchandise”, the Court therefore turned to the “statutory background” for guidance.

In considering the “statutory background,” the Court declared:

If the former statute [§100.18] covered the sale of food, the legislature would have had no reason to enact a separate statute to prohibit misrepresentations in the sale of food. Moreover, in 1969, the legislature renumbered the food-only provision as §100.183, and, in separate legislation, created a private cause of action under §100.18. *See* 1969 Wis. Laws, chs. 286 and 425. The fact that the legislature, in a single session, acted on both statutes and added a private cause of action to only one of them, is another strong indication that it intended two different anti-fraud provisions – one governing “real estate, merchandise,

securities, service or employment” that creates a private cause of action, and the other governing “articles of food” that does not.

*Gallego*, ¶14. Thus, the Court said, to apply §100.18 to the sale of food would render §100.183 “superfluous.” *Id.*, ¶16.

The Court went on to consider what purpose the legislature might have had in “creating and retaining a separate anti-fraud provision regarding articles of food.” The plaintiff argued that the legislature simply wanted to add a criminal penalty to an existing scheme which allowed civil remedies only. The Court found this analysis “not unreasonable,” but said that it did not account for the “statutory background” of §100.183. *Id.*, ¶19. Defendant Wal-Mart, in contrast, argued that the “narrower enforcement mechanism” of §100.183 was consistent with both federal food and drug law enforcement mechanisms and with the enforcement provisions of Wis. Sta. ch. 97, entitled “Food Regulation,” since neither the federal mechanism nor Wisconsin’s chapter 97 provided a private right of action, and neither does §100.183. The Court found it “plausible” that the legislature created a separate provision dealing with fraud in the sale of food as part of a “larger, comprehensive scheme for regulating the handling, sale and labeling of food items.” *Id.*, ¶20. The Court found further support for this conclusion from the initial placement of §100.183 among “other food and health-related provisions.” *Id.*, ¶14, n. 9.

Not one step of the *Gallego* rationale can be applied to the drug provision, §100.182.

For starters, as opposed to food, drugs are unambiguously “merchandise,” meaning that there is no need to resort to the “statutory background” for guidance. This is true whether one considers dictionary definitions in effect today or in 1911 (when §100.18 was first passed). As for the current definition, as *Gallego* noted, the lead definition of “merchandise” in one standard dictionary is the “manufactured goods bought and sold in any business.” *Gallego*, ¶13, quoting Random House Dictionary of the English Language at 1202 (2d ed. 1987). Prescription drugs

are a quintessential manufactured product. As for past definitions, in 1911, Black's Law Dictionary defined "merchandise" as

All commodities which merchants usually buy and sell, whether at wholesale or retail; wares and commodities such as are ordinarily the objects of trade and commerce. But the term is never understood as including real estate, and is rarely applied to provisions such as are purchased day by day, or to such other articles as are required for immediate consumption.

Black's Law Dictionary (2d Ed. 1910), p. 773 (Appendix J to this reply brief). Defendants fail to quote the full definition, and after quoting the phrase "required for immediate consumption," they add "such as drugs" – their own words, not the Dictionary's. Joint Response at 78. To the contrary, drugs clearly are not articles purchased "day by day" or "required for immediate consumption." Unlike food, which in 1910, with limited technology for refrigeration, had to be eaten almost immediately after purchase, drugs were not then and are not now purchased "day by day" or typically consumed immediately. Rather, drugs are goods which typically are consumed over considerable periods of time, as any purchaser of a month of cholesterol or blood pressure medicine can attest.

More generally, if defendants argue that drugs are "required for immediate consumption," and hence are not "merchandise," they would have to concede that motor fuel is required for immediate consumption and is not "merchandise" either. After all, motor fuel is clearly closer to the category of "required for immediate consumption" than drugs are, because people who buy motor fuel start consuming it the moment they leave the gas station. But under §100.18, motor fuel *is* "merchandise." Sections 100.18(6) and (8) declare certain statements with respect to motor fuel to be *per se* deceptive under 100.18(1). As defendants themselves point out, the particular "deceptive" practices listed in §§100.18(2) through (10) do not create separate causes of action, so that a claim based on one of these listed practices must still satisfy

all elements of a claim under §100.18(1). Joint Response at 93. Hence, statements about motor fuel must be covered by §100.18(1). That means motor fuel must be, and is, “merchandise.” And if motor fuel is “merchandise,” defendants cannot expel drugs from the category of “merchandise” on a “required for immediate consumption” argument.

In short, unlike food, drugs fit, and have always fit, the dictionary definition and plain-English understanding of “merchandise.”<sup>4</sup> There is consequently no warrant for the “statutory background” analysis that *Gallego* found necessary to decide whether food fit that definition.

But in any case, the “statutory background” analysis of *Gallego* provides no support for holding that drugs are not “merchandise.” First, even though drugs are “merchandise,” §100.18 does not substantively duplicate §100.182, and hence there was nothing “superfluous” about §100.182, the later-enacted statute. §100.18 applies to any deceptive, misleading or untrue statement about merchandise, but §100.182 only applies to a limited subset of misleading, deceptive or untrue statements about drugs. Section 100.182 is therefore an example of a commonplace legislative practice: enacting a general prohibition applicable to many different subjects, yet also enacting narrower prohibitions limited to particular subjects. Thus, there was nothing “superfluous” about passing §100.182 to make clear that statements dealing with a particular subject matter of drugs – namely, the physical and psychological effects the drugs would have – are unlawful. The fact that §100.18(1) already included a general prohibition that applied to drugs as “merchandise” did not make it superfluous for the legislature, in 1981, to zero in on particular categories of statements about the medical effects of drugs or to think that

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<sup>4</sup> It is particularly unlikely that the legislature in 1911 intended to exclude manufactured drugs from its new false advertising statute, because in that era, false claims about drugs were perhaps the most blatant and harmful example of false advertising, and the press was crusading for reform. A few years before the Wisconsin legislature acted, *Colliers*, reviewing its efforts to expose the “patent medicine fraud,” wrote that “Gullible America will spend this year some seventy-five millions of dollars in the purchase of patent medicines.” *Colliers*, October 7, 1906, reprinted in Perlongo, *Early American Advertising* (New York, 1985), p. 89.

such categories deserved their own separate statutory ban. On defendants' theory, it would have been "superfluous" for the legislature, having enacted the general prohibition of deceptive, misleading and untrue statements in §100.18(1), to later add, as it did, further subsections to §100.18 specifying specific kinds of statements regarding specific items of merchandise (like motor fuel) that are deceptive.

Second, the other prong of *Gallego's* "statutory background analysis" -- that in 1969, the legislature added a private right of action to §100.18 but not to §100.183 -- is inapplicable to §100.182. Section 100.182 did not *exist* in 1969.

Third, calling §100.182 part of a "comprehensive regulation of drugs" is unpersuasive. Wisconsin does little general regulation of drugs. The provisions cited by defendants (Joint Response at 75-76, nn. 81, 82) almost entirely concern pharmacies. Wisconsin has no regulation at all, much less "comprehensive" regulation, of drug manufacturing or pricing, and §100.182 does not apply to these areas. The contrast with the subject of food is striking. As might be expected from an important agricultural state, Wisconsin regulates food production, sales, and sometimes pricing, in many areas and in detail. *See, e.g.,* Wis. Stat. ch. 97. In holding that §100.183 could "plausibly" be considered part of a comprehensive scheme regulating food, *Gallego* cited the fact that the original version of §100.183 had been located in chapter 97's provisions on food regulation. But §100.182 was never located in the Wisconsin Statutes' chapter 450, regulating pharmacies. When the legislature first passed it, it placed it immediately following the general consumer fraud law, §100.18.

In short, there is no convincing argument that the term "merchandise" in §100.18(1) was intended by the legislature in 1911 to exclude drugs. Thus, defendants' argument amounts to asserting that in enacting §100.182 in 1981, the legislature impliedly repealed §100.18(1)'s

coverage of drugs. Any such assertion would be preposterous. “Repeals by implication are not favored in the law. The earlier act will be considered to remain in force unless it is so manifestly inconsistent and repugnant to the later act that they cannot reasonably stand together.”

*Pattermann v. City of Whitewater*, 32 Wis.2d 350, 356 (Wis. 1966). Defendants could never meet this standard. These statutes are not inconsistent in any way. Instead, §100.182 reinforces the general prohibition of §100.18(1) by specifying three particular categories of statements about the effects of one category of merchandise – drugs – which are unlawful. Not surprisingly, therefore, both statutes are typically invoked by plaintiffs asserting unfair competition claims involving the effects of drugs. See *Schwarz Pharma, Inc. v. Breckenridge Pharmaceutical, Inc.*, 388 F. Supp.2d 967, 980 (E.D.Wis. 2005). That the two statutes may overlap to some extent does not aid the defendants. As the Court stated in *Wisconsin v. Automatic Merchandising of America, Inc.*, 64 Wis.2d 659, 665 (Wis. 1974):

Defendants’ argument that there may be other statutes which effectively deal with the situation involved has no bearing on this case. The fact that there may be an overlapping of coverage in this case between Sec. 100.18(1), Stats. and other statutes does not alter the fact that Sec. 100.18(1), Stats. is applicable under the facts of this case.

Finally, even if there were doubt about the applicability of the term “merchandise” to drugs, §100.18 is remedial legislation. “The court has often stated that remedial legislation should be broadly construed to effectuate its purpose.” *Racine Harley-Davidson, Inc. v. State, Div. of Hearings & Appeals*, 2006 WI 86, ¶93, 292 Wis.2d 549, 600, ¶93. Hence §100.18 is construed “broadly, not narrowly.” *Winkelman v. Kraft Foods, Inc.*, 2005 WI App. 25, ¶16, 279 Wis.2d 335, ¶16 (Ct. App. 2005), citing *Dorr v. Sacred Heart Hosp.*, 228 Wis.2d 425, 445 (Wis. Ct. App. 1999) (“Section 100.18 prohibits deceptive, misleading, or untrue statements of any kind to the public made in a commercial setting, no matter how made.”). An interpretation of

§100.18(1)'s term "merchandise" which leaves the State unable to sue to stop a massive scheme relating to the price of drugs, a crucial consumer product, will flout this principle of construction, unless defendants can show in unanswerable terms that "merchandise" plainly does not include drugs. To the contrary, it plainly does.

**B. The Argument That The State Has No Standing Under §100.18(1) Because Defendants' AWP's Did Not "Induce" It Into An "Obligation."**

Defendants argue for a requirement of "standing" to sue under §100.18(1) that does not exist. They assert that §100.18(1) "only provides a remedy for a person who was induced or was in a position to be induced into an obligation by a false or misleading representation." Joint Response at 78, citing *Land's End, Inc. v. Remy*, 447 F. Supp.2d 941 (W.D.Wis. 941), *K & S Tool & Die Corp. v. Perfection Machinery Sales, Inc.*, 2006 WI App. 148, *affirmed*, 2007 WI 70, 301 Wis.2d 109, *Kailin v. Armstrong*, 2002 WI App. 70, 252 Wis.2d 676, and *Zeller v. Northrup King Co.*, 125 Wis.2d 31 (Wis. Ct. App. 1985). On the basis of this assertion and these citations, defendants argue that the State was not induced by defendants' false AWP's into "*purchasing drugs,*" or "*reimbursing providers for drugs,*" or "*reimbursing providers based on AWP.*" Joint Response at 79-80 (emphasis in original). Hence, they conclude, §100.18(1) cannot apply.

The argument has no merit. First, defendants' assertion of who has standing under §100.18 is not the law. Second, the argument fails even on its own terms.

**1. Neither The Statute Nor The Case Law Support Defendants' "Standing" Argument.**

Nothing in §100.18 says or implies that the only person who has standing to sue under the statute is one who "was induced or was in a position to be induced into an obligation by a false or misleading representation." No such requirement appears in either of the statute's two

remedial provisions (quoted above at pages 7-8) affording the right to sue -- §100.18(11)(d) for the State, and §100.18(11)(b)(2) for private persons who have suffered pecuniary loss.

Nor is there any such requirement in §100.18(1)'s formulation of the conduct made unlawful. The only phrase in §100.18(1) that refers at all to the concept of "inducing" appears as part of the statute's formulation of the requisite intent:

. . . with intent to sell, distribute, increase the consumption of or in any wise dispose of any real estate, merchandise, securities, employment, service, or anything offered by such person, firm, corporation or association, or agent or employee thereof, directly or indirectly, to the public for sale, hire, use or other distribution, *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 real estate, merchandise, securities, employment or service . . .* [Italics added.]

Nothing in the italicized words creates a requirement that to have standing to sue, the plaintiff must have been "induced" or have been in a "position to be induced into an obligation." First, the italicized words are one of *two independent forms* of intent that suffice. The other form – "intent to sell, distribute, [or] increase the consumption of . . . any . . . merchandise" – does not refer to inducing anyone into entering an obligation. Thus, if the present defendants' untrue, misleading, or deceptive statements were made with intent to sell or increase the consumption of their drugs – and as shown in the State's motions, both common sense and the evidence show that that was defendants' intent in reporting AWP's to First DataBank – then those statements are unlawful under §100.18, regardless of whether the statements were made with intent to induce the State to enter into any obligation relating to the purchase of drugs. Second, the quoted phrase is a statement of the intent required for a violation, not a statement of who has standing to sue.

Nor does the case law support defendants' "standing" argument. No Wisconsin case, much less the four cases defendants cite, holds that §100.18(1) "only provides a remedy for a

person who was induced or was in a position to be induced into an obligation by a false or misleading representation.”

The main case defendants rely on is *Land's End*. Land's End sells much merchandise through its Internet website, “landsend.com.” To increase the number of Internet users who use Land End's website, it makes affiliate agreements with owners of approved websites. When an internet user clicks on a link on the affiliate's website, the user is automatically transferred over to Land's End's website. The affiliate agreement provides that if the user then makes a purchase on Land's End's website, the affiliate earns a 5% commission on the purchase. The defendants made an affiliate agreement with Lands End under which their websites, “savingsfinder.com” and “shopperseguid.com”, became approved websites. Unbeknownst to Land's End, however, the defendants also owned a number of domain names whose spellings were very similar to landsend.com. Through clever technology, when a user mistyped one of these names instead of “landsend.com,” he would be referred to landsend.com, and Land's End would believe that the referral came from one of the two approved websites (savingsfinder.com and shopperseguid.com), whereas in reality the user had never visited those two approved websites. The result was that Land's End would pay defendants commissions for referrals from the approved websites. When Land's End discovered this “typosquatting” scheme, it sued under federal and Wisconsin law to stop it.

The federal court dismissed the §100.18 claim. It neither said nor held that §100.18 “only provides a remedy for a person who was induced or was in a position to be induced into an obligation by a false or misleading representation.” Instead, it dismissed the claim because the Internet users who had purchased and paid for goods from Lands End had not been subjected to any misrepresentations. They had obtained exactly what they had sought: Land's End

merchandise from the Land's End website. The court noted that §100.18 "was not designed to protect product manufacturers from paying commissions on the sale of their own products, however unearned those commissions may be." 447 F. Supp.2d at 950.

The differences between *Land's End* and the present case are obvious. First, in *Land's End*, the plaintiff was the *seller*. A *seller* of merchandise cannot plausibly claim under §100.18 (1), which prohibits conduct by those who aim to increase *sales* of their products. Second, in *Land's End*, those who paid for the merchandise were not harmed by the deceptive scheme, and got what they paid for, whereas here, the plaintiff is the State, which paid providers for the drugs dispensed to Medicaid patients. Indeed, the sales in question – transfers of the drugs from the provider to the Medicaid recipient, with most or all of the consideration paid by the State -- would not have taken place but for the State being willing to incur the obligation of paying the provider for the drugs. Thus, in this case, the concerns of §100.18 *are* implicated.

Nor do the remaining three cases cited by defendants support them. *K & S Tool & Die* considered whether an individual prospective purchaser, dealing with a seller he already knew and had had contact with before, was a member of the "public" for purposes of evaluating whether the false statements in question had been disseminated to the "public." 2006 WI App. 14, ¶19. As will be discussed in Section IV(C) below, defendants' reporting of false AWP's to First DataBank for purposes of affecting prices that the State will pay under Medicaid constitutes causing statements to be made to the "public." *Kailin* involved the same issue as *K & S Tool & Die* – the point at which a person stops being a member of the "public."

*Zeller* simply held that §100.18 was not violated by statements whose intent (and result) was to *discourage* plaintiffs from buying a product. The plaintiffs bought soybean seeds to plant on their farms. After the purchase, they consulted the dealer to see whether they should also

purchase an “inoculant” to add to the seeds for the purpose of avoiding bacterial infection. The dealer told them that the inoculant was unnecessary, and they did not buy it. Later their soybeans developed problems. Plaintiffs sued the dealer for common-law misrepresentation. After the jury returned a verdict for plaintiff, the trial court awarded attorney’s fees on the apparent theory that the actions of the defendant had also violated §100.18, which has a fee-shifting statute. The Court of Appeals affirmed the misrepresentation verdict but reversed the fee award. As it noted, §100.18 requires the defendant to act with intent to sell or increase the consumption of its products while the Zeller the defendants’ alleged misrepresentation was made to do just the reverse. 125 Wis.2d at 39. In contrast, discouraging the sales of their drugs was the last thing in the world the defendants here had in mind when they sent inflated AWP’s to First DataBank.

**2. Even On Its Own Terms, Defendants’ “Standing” Argument Fails.**

Defendants’ AWP’s determined the *price* that would be paid in the consumer market for their drugs. For Medicaid consumers, most or all, of that price was paid by the State. In plain English usage, a misrepresentation that determines the *size* of the State’s obligation to pay under the Medicaid program “induces the State into an obligation.”

Anticipating this argument, defendants argue that the State is not the “purchaser” of the drugs within the meaning of §100.18. Joint Response at 79; AstraZeneca Response at 47, *citing In re Rezulin Prods. Liab. Litg.*, 390 F. Supp. 319, 333 (S.D.N.Y. 2005). It would not matter even if this argument were right, because §100.18 bans misrepresentations “relating to” a purchase. A deceptive scheme which inflates the payments by the supplier of consideration for the purchase “relates to” the purchase, regardless of whether that supplier is labeled the “purchaser” or not.

But in fact, the State *does* “purchase” goods within the meaning of §100.18. In two other AWP cases, courts considered precisely this issue under Idaho’s Consumer Protection Act, which, like §100.18, does not define “purchaser.” Two separate Idaho trial judges have now held that the State of Idaho was a “purchaser” under that Act when it supplied the payment to providers for drugs dispensed to Medicaid patients. *State of Idaho v. Alpharma USPD, Inc. et al.*, No. CV-OC-0701847 (4th Jud. Dist. Idaho, Aug. 31, 2007) (Appendix C to this brief), p. 7; *State of Idaho v. Ben Venue Labs. Inc. et al.*, No. CV-OC-0710321 (4th Jud. Dist. Idaho, Feb. 20, 2008) (Appendix D to this brief), pp. 2-3. In *Alpharma*, Judge Sticklin considered and rejected defendants’ reliance on *Rezulin Prooducts*. In *Rezulin Products*, a suit for breach of warranty under the Uniform Commercial Code, a federal court had held that the term “purchaser” could only mean the party to whom title passed in a sales transaction, even if insurers ultimately reimbursed that party. But Judge Sticklin found *Rezulin’s* rationale unpersuasive in a case involving a remedial statute like the Idaho Consumer Protection Act. “Here it is apparent that the State is the ultimate purchaser in the chain of distribution and the one directly affected by the alleged manipulation of the AWP.” App. C, p. 7. In *Ben Venue Laboratories*, Judge Wilper similarly relied on the remedial nature of the Idaho act in finding that the State was a “purchaser” where it “purchases goods on behalf of its citizens.” App. D, p. 3.

**C. The Argument That Defendants Do Not Cause False AWPs To Be Made To “The Public.”**

Section 100.18(1) requires that defendants make, or cause, directly or indirectly, to be made, an untrue, deceptive, or misleading statement “to the public.” Several defendants argue that that the State fails to meet this requirement. Novartis Response at 51-55; AstraZeneca Response at 40; Schering/Warrick Memorandum at 19-22. The argument has no merit. Defendants supply AWPs and WACs to First DataBank, which uses them to provide AWPs to a

very broad group of public and private payers, including the State of Wisconsin. This constitutes causing statements to be made to the “public” within the meaning of §100.18.

First, a representation to the State of Wisconsin, in its capacity as purchaser of drugs on behalf of Medicaid recipients, is *per se* a representation to “the public.” By definition, the State is the *embodiment* of the public, and in the Medicaid program, it buys drugs for nearly a million people. Defendants have not cited any case holding or implying that the State is not “the public” within the meaning of §100.18. How could it not be?

Indirectly addressing this point, Novartis argues that §100.18 was only intended to protect “vulnerable” persons, not persons with “positions of power relative to all other market participants.” Novartis Response at 53. No case has imposed this kind of limitation on the plain language of the statute. In *K & S Tool & Die Corp.*, the Supreme Court affirmed a verdict for plaintiff in a case between two corporations of no noticeable difference in “market power” or sophistication. No implied limitation on §100.18 depending on relative “market power” or “vulnerability” would be workable. Moreover, the State can be *highly* vulnerable to the kind of untruths and deceptions regulated by §100.18. Compared to the State’s Medicaid operation, virtually every defendant is a behemoth. It is precisely because of the states’ lack of resources that they have been so hard-pressed to keep up with defendants’ ongoing manipulation of AWP.

Second, even if the State were not *per se* the “public,” it is a member of the “public” under the circumstances of this case. A statement made even to *a single listener* can be made to the “public” within the meaning of §100.18. *State v. Automatic Merchs. Of Am., Inc.*, 64 Wis.2d 659, 664 (1974); *K & S Tool & Die Corp.*, *supra*, 2007 WI 70, ¶33 (sustaining jury verdict under §100.18(1) where the statement was made to a single corporate buyer). “A plaintiff remains a

member of ‘the public’ unless a particular relationship exists between him or her *and the defendant.*” *Id.*, ¶27 (italics added).

In *K & S Tool & Die Corp.*, the Supreme Court noted that “a statement made to the particular party with whom one has contracted is not a statement to ‘the public.’” *K & S Tool & Die*, ¶49. Novartis then tries to jimmy itself into this principle’s coverage. It argues that that “First DataBank does not publish to ‘the public.’ Rather, it provides information to sophisticated market participants who purchase it.” Novartis Response at 52. Specifically, it says, Wisconsin contracts with EDS, a fiscal agent, and EDS contracts with First DataBank. Hence, “Wisconsin Medicaid and EDS have a particular contractual relationship with First DataBank that precludes application of section 100.18(1) to relations made by First DataBank . . . “ *Id.*

The obvious error in this argument is that First DataBank is not the defendant. *K & S Tool & Die Corp.* requires the “particular relationship” to exist “between [plaintiff] *and the defendant.*” 2007 WI 70, ¶27 (emphasis added). Defendants have no contractual relationship with the State of Wisconsin that requires them to provide AWP or regulates the AWP they do provide. Thus, the contractual relationship between Wisconsin and EDS, and between EDS and First DataBank, has no relevance, because all those contractual relationships do is to provide the pipeline through which defendants’ false AWP to First DataBank end up being relayed to the State and others. If defendants’ theory were right, a manufacturer could publish false advertising on cable television, and then argue that the subscription contracts between listeners and the cable company created a “particular relationship” between the listener and the advertising manufacturer.

Novartis and Schering/Warrick also claim that the “contractual relationship” rule applies to them because they have entered into contracts with the federal government that provide

rebates to Wisconsin and other states, and (since 2004) have entered into supplemental rebate contracts with Wisconsin Medicaid as to certain drugs. Novartis Response at 52-53; Schering/Warrick Memorandum at 19-21. But these contracts have nothing to do with defendants' AWP practices. They do not mention AWP and in no way regulate AWP. The federal contracts do not require defendants to report *any* prices to the states. The only prices that must be reported (to the federal government, not the states) are so-called "average manufacturer prices" ("AMPs") charged by defendants for selling their drugs, and the only reason why such reporting is required is that the rebates are calculated on the basis of such prices.<sup>5</sup>

Such contracts, which are irrelevant to the legality of the practice being attacked in the lawsuit, cannot create a "particular relationship" that immunizes defendant from attack under §100.18. Huge corporations like defendants are likely to have various contracts with states like Wisconsin. Yet it would be bizarre to hold that such contracts protect defendants under §100.18 for practices that are outside the coverage of those contracts. Suppose, for example, that someone leases a Chevrolet from a car dealer. Under defendants' theory, that person would cease to be a member of "the public" under §100.18, so that the dealer would be free under §100.18 to lure him through false advertising into buying a Hummer.

*Uniek v. Dollar Gen. Corp.*, 474 F. Supp.2d 1034 (W.D.Wis. 2007), is hardly "instructive," as Novartis claims. Novartis Response at 55. In *Uniek*, plaintiff was a supplier of picture frames to defendant, a distributor. They had a longstanding relationship in which defendant had bought up to \$12 million worth of frames annually. After the defendant replaced

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<sup>5</sup> In a footnote, Schering and Warrick insinuate that from the "average manufacturer prices" that they report to the federal government under these rebate agreements, states can calculate what real "average wholesale prices are." Scherick/Warrick Memorandum at 20, n. 14. They cite no evidence for this false assertion. As they well know, federal law *prohibits* the federal Center for Medicaid Services from reporting to the states the "average manufacturer prices" that defendants report to them. 42 U.S.C. §1396r-8(k)(1).

plaintiff with another primary supplier, plaintiff sued, invoking §100.18, alleging that the defendant had induced it unnecessarily to manufacture picture frames by failing to tell it of its plans to switch primary suppliers. The court held that the ongoing commercial relationship of supplier and distributor prevented the plaintiff from being considered a member of the “public.” In contrast to *Uniek*, there are no direct dealings relevant to this case between the State and defendants at all, much less millions of dollar of annual sales. And in *Uniek*, the alleged misrepresentations occurred within the heart of the relationship in question – the continuation or noncontinuation of the supplier-distributor relationship.

**D. The Argument That §100.18(10)(b) Does Not Apply.**

Count II of the State’s Amended Complaint alleges violation of §100.18(10)(b), which, as discussed above, declares: “It is deceptive to represent the price of any merchandise as a manufacturer’s or wholesaler’s price, or a price equal thereto, unless the price is not more than the price which retailers regularly pay for the merchandise.” Defendants argue that by its terms, this provision cannot apply to the conduct charged by the State. Joint Response at 93-96; Novartis Response at 60-63.

First, defendants argue that §100.18(10)(b) is not a cause of action separate from §100.18(1), but merely defines one type of conduct that is deemed “deceptive” conduct under §108.18(1). Hence, argue defendants, their defenses to liability under §100.18(1) also apply to the State’s alleged violation of §108(10)(b). Joint Response at 92-94. The State agrees, and in fact so stated in its Motions. *See, e.g.*, State’s AstraZeneca Motion at 29 (“Wis. Stat. §100.18(10)(b) provides a specific example of conduct that is *per se* deceptive”). But this truism does not help defendants, since their arguments against liability under §100.18(1) have no merit, as discussed in this reply brief.

Second, despite the unequivocal language of the section, defendants argue that it only forbids “the improper use of comparative price advertising, in which retailers advertise that merchandise is being sold at a ‘manufacturer’s price’ or a ‘wholesaler’s price,’ when the advertised price is actually much higher than the ‘real’ wholesaler’s price or manufacturer’s price.” Joint Response at 94. In support of this argument, defendants cite a sentence from the “drafting record” of the bill. *Id.*, quoting from Joint Response Ex. 189.

Defendants’ argument has no merit. First, “if the statute is unambiguous, we do not consult extrinsic sources such as legislative history to ascertain its meaning; we simply apply its plain meaning.” *Wisconsin Citizens Concerned for Cranes & Doves v. Wis. Dep’t of Natural Res.*, 2004 WI 40, ¶6, 270 Wis.2d 318, 329, ¶6. There is no ambiguity in the text of §100.18(10)(b). It says nothing about being limited to statements by retailers. Under its plain language, it is unlawful for *anyone* to represent the price of any merchandise as a wholesaler’s price unless the price is not more than the price which retailers regularly pay for the merchandise. Defendants’ representations about the AWP’s of their drugs fit this language like a glove. They make representations that the prices they provide for their drugs are “wholesale” prices, but those prices are far more than what the “retailers” in question – here, the providers who acquire the drugs and then resell them – are paying for the drugs.

Second, even if the “drafting record” could be considered, it supports, rather than refutes, the State’s position. The original drafting record gave the three proposed sections of the bill, followed by an “explanation”:

- (a) It is deceptive to represent the nature of any business by use of the words manufacturer, factory, mill, importer, wholesaler or words of similar meaning, in a corporate or trade name or otherwise.
- (b) It is deceptive for any person to represent that he is selling at wholesale unless such person is selling to others for the purpose of resale.

- (c) It is deceptive to represent the price of any merchandise as a manufacturer's or wholesaler's price, or a price equal thereto, unless the price is not more than the price which retailers regularly pay for the merchandise.

Explanation

This bill is designed to specifically prohibit current advertising abuses by some retailers, particularly those who operate a 'mail order' or 'catalogue' business and who either represent themselves or their prices as 'wholesaler's' or 'manufacturer's', or by similar terminology.

Joint Response, Ex. 189. Two changes were then made to this "drafting record." First, subsection (b) – the only provision that specifically banned conduct by the *seller* of the merchandise – was stricken from the bill, and accordingly was crossed out on the "drafting record." Subsection (c) was renumbered subsection (b) on the "record," and as thus reduced and renumbered, the bill was enacted into law. Second, *the "explanation" was crossed out on the "drafting record."* *Id.* Clearly someone in the legislative process concluded that the original "explanation" did not appropriately describe the amended bill. Accordingly, no inference can be drawn from this deleted "explanation." What remains is an unambiguous provision and no legislative history to suggest that it should be given a restriction its language does not contain.

Defendants also argue that they never represented that AWP was a "wholesaler's price" within the meaning of §100.18(10)(b), because the State "knew and understood, during the relevant time period, that AWP was not a wholesaler's price." Joint Response at 95. This argument merely repeats the "term of art" argument answered in Section III above.

**V. DEFENDANTS' MISCELLANEOUS ARGUMENTS ON THE MERITS ARE ERRONEOUS.**

**A. The Argument Based On 42 U.S.C. 1396(a)(30)(A).**

An obsessive theme in defendants' Responses is that it is necessary to provide a profit to pharmacies and other providers on their Medicaid business. Defendants repeatedly quote 42

U.S.C. 1396(a)(30)(A)'s phrase that a state's Medicaid plan must assure that provider payments "are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." *See, e.g.,* Joint Response at 22, 60, 74.

The truth, however, is that there is no federal requirement of providing Medicaid providers a profit, and 42 U.S.C. 1396(a)(30)(A) emphasizes the need of state Medicaid plans to *save money*. That section provides that State plans for Medicaid Assistance must

provide such methods and procedures relating to the utilization of, and the payment for, care and services . . . *as may be necessary to safeguard against unnecessary utilization of such care and services* and to assure that payments are consistent with *efficiency, economy, and quality of care* and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

One would never know from defendants' Responses that the statute contains the italicized words. Nor would one know from those Responses that providers have no right to a "profit" from state Medicaid payments. "Congress enacted Title XIX of the Social Security Act to provide health care for the poor and aged, not to subsidize or otherwise to benefit health care providers." *Pennsylvania Pharm. Ass'n*, 542 F. Supp. 1349, 1355-1356 (E.D. Pa. 1982).<sup>6</sup>

#### **B. The "Cross-Subsidization" Argument.**

In arguing that their practices have caused the State no harm, defendants assert that the State has deliberately chosen to rely on AWP's that it knew to be inflated as a means of "cross subsidizing" inadequate dispensing fees that it pays to providers. As noted in Section I, the State's Medicaid program reimburses providers for the majority of prescription drugs by using

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<sup>6</sup> In support of their argument, defendants submit the affidavit of Robert Helms who sets forth various unsubstantiated interpretations of what he thinks federal law allows, requires, or permits. Dr. Helm's personal interpretation of federal law is entitled to no weight. *See United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004) (holding that the "non-public or informal understandings of agency officials concerning the meaning of a regulation" are "not relevant")

the method, required by the federal regulations, of making a two-part payment. One part reimburses for what is popularly called the provider's "ingredient cost," while the other part is the "dispensing fee." 42 C.F.R. §447.512. Under the regulations, the ingredient cost is limited to the "Estimated Acquisition Cost" and is defined as the State's best estimate of what providers are actually paying to acquire the drug. 42 C.F.R. §447.502. Likewise, under the regulations, the "reasonable dispensing fee" is defined as the fee which "[i]s incurred at the point of sale or service and pays for costs in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed." *Id.*

Defendants claim that that the State has deliberately held down the payment for the dispensing fee to an unreasonably low level, but then, to make up for those inadequate dispensing fees, has deliberately inflated payments for ingredient cost to a level far higher than actual ingredient cost. Defendants seem to imply that they have done the State a service by providing inflated AWP's that enable the State to inflate these ingredient costs. Joint Response at 2, 29-32, 63-64. Even more remarkably, defendants claim that the federal government knows and approves of this practice of "cross-subsidization" (*id.* at 32), and they argue that it is perfectly legal under the federal regulations. *Id.* at 64-65.

From start to finish, this argument makes no sense. First, defendants provide no clue as to *why* the State would engage in this practice. According to defendants, the State is deliberately robbing Peter to pay Peter. Why would the State deliberately pay an unreasonably low dispensing fee, then deliberately pay a swollen ingredient cost?

Second, the evidence defendants cite for such "cross-subsidization" shows no such thing. Appendix B contains the State's point-by-point response to defendants' "Additional Proposed Undisputed Facts." The State particularly refers the Court to its response to the Joint Response's

“Additional Proposed Undisputed Facts,” ¶¶ 95-104. Reduced to essentials, what the evidence really shows is this:

- While the pharmacists’ lobby continually and vociferously complains about the level of the dispensing fee, and while surveys depending on responses from pharmacists have sometimes concluded that the dispensing fee should be raised, Wisconsin Medicaid has been unimpressed by these complaints, particularly because Wisconsin’s dispensing fees have been consistently higher than those paid by private payers. If anything, Wisconsin Medicaid has sometimes believed that its dispensing fees are too high, not too low.
- No Wisconsin Medicaid official has testified that Wisconsin uses the ingredient cost to cross-subsidize an inadequate dispensing fee. Defendants rely principally on a brutal misstatement of the testimony of James P. Vavra. Vavra testified that in fact the State intended to adhere to “the Federal principle of estimated acquisition cost close to what the pharmacists obtained the [drugs] at” and that any profit the pharmacists would earn had to come through the dispensing fee. Vavra Deposition (Exhibit 1 to Joint Response), p. 77:5-14.
- Defendants’ assertion that the federal government knows of and approves of this practice is supported exclusively by the statement of one Reagan-era official about what a task force did in 1987. Far from approving of defendants’ inflation of AWP’s, the Department of Justice under the Bush Administration has filed its own AWP suits under the federal False Claims Act against several defendants.

Indeed, currently operative federal guidelines from the Office of Inspector General condemn defendants’ pricing practices. Those Guidelines, 68 Fed. Reg. 23731 (2003) and attached as Appendix E to this reply brief, state:

a. Integrity of Data Used To Establish or Determine Government Reimbursement. Many federal and state health care programs establish or ultimately determine reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. The government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent, or misleading information is actionable. A pharmaceutical manufacturer may be liable under the False Claims Act if government reimbursement (including, but not limited to, reimbursement by Medicare and Medicaid) for the manufacturer’s product depends, in whole or in part, on information generated or reported by the manufacturer, directly or indirectly, and the manufacturer has knowingly (as defined in the False Claims

Act) failed to generate or report such information completely and accurately. Manufacturers may also be liable for civil money penalties under various laws, rules and regulations. Moreover, in some circumstances, inaccurate or incomplete reporting may be probative of liability under the federal anti-kickback statute.

Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers.

*Id.* at 23733.

Third, there is no legal merit to defendants' argument that the federal Medicaid regulations allow States deliberately to pay unreasonably low dispensing fees and then to cross-subsidize those inadequate fees with artificially inflated ingredient-cost payments. Defendants cite nothing in the regulations that says or implies any such thing. Instead, their legal argument consists of the following two sentences:

Reimbursement for brand name drugs is limited to the *aggregate* of the lower of: (1) the EAC [Estimated Acquisition Cost] *plus* reasonable dispensing fees; or (2) providers' usual and customary charges to the general public. [Citation omitted.] Thus, as long as the combined reimbursement amount for the drug cost and dispensing fee is lower than providers' usual and customary charges, the State has not violated federal regulations.

Joint Response at 64. This is a *non-sequitur*. EAC under the regulations is a defined term. It does not mean whatever the State decrees. It means Wisconsin Medicaid's "best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers." 42 C.F.R. §447.502. Under 42 C.F.R. §447.512, the State cannot make aggregate payments for drugs that exceed the aggregate of EACs and dispensing fees. Conversely, if the aggregate of EACs and dispensing fees is *lower* than the aggregate of all "reasonable and customary charges" for each reimbursed prescription, then the State is limited to the lower aggregate, however much

lower it may be than the aggregate of all “reasonable and customary charges.” This means that the lower defendants’ AWP, the lower will be the limit the State can pay.

Defendants’ “cross-subsidization” theory flouts common sense as well as the regulations. According to defendants, the federal government has no problem with states violating both halves of the Medicaid regulations by setting dispensing fees lower than is reasonable, setting ingredient payments far higher than ingredient cost, and then declaring that two wrongs make a right. What bureaucracy in the world behaves this way?

The cross-subsidization argument also suffers from another incurable problem. As the State showed in its motions, even if State employees had deliberately done what defendants claim they did, the State cannot be estopped by such conduct from pursuing defendants for the damage their false reporting cost it. As the State showed, those who deal with the government “may not rely on the conduct of Government agents contrary to law.” *Heckler v. Community Health Services*, 467 U.S. 51, 63 (1984). Under this principle, the failure by a governmental body to enforce laws intended for the public health and welfare cannot estop it from later enforcement proceedings. *State v. City of Green Bay*, 96 Wis.2d 195, 201-202 (Wis. 1980); *Westgate Hotel, Inc. v. E. R. Krumbiegel*, 39 Wis.2d 108, 113 (Wis. 1968). See State’s AstraZeneca Motion at 31-33.

Defendants’ more than 300 pages of briefs devote just one footnote to this crucial point. Joint Response at 83, n. 111. That footnote make two unelaborated contentions. First, defendants claim they “do not contend that the State’s *employees* committed any error or misconduct. The State’s knowledge of the true meaning of AWP is *not* limited to a few employees, but was shared by the two branches of Wisconsin government involved in setting reimbursement, and was an integral part of each decision to maintain or change the

reimbursement rate or methodology.” *Id.* (emphasis in original). If defendants mean to say that State employees would not be committing “error or misconduct” because “cross-subsidization” is legal under federal Medicaid regulations, they are wrong, because it is not allowed by those regulations. Moreover, there is no evidence that Wisconsin legislators knew of defendants’ practice of inflating their AWP’s or that the legislature approved of using such inflation to cross-subsidize.

Second, defendants claim that “Wisconsin courts have applied the doctrine of estoppel to prevent the State from prevailing on similar claims.” They cite *Green Bay, supra*, as well as *Wisconsin Dept. of Revenue v. Moebius Printing Co.*, 89 Wis.2d 610 (Wis. 1979). Joint Response, p. 83, n. 111. The argument has no merit. *Green Bay* in fact holds that to obtain estoppel against the government, defendants must prove that “the government’s conduct would work a serious injustice and . . . the public’s interest would not be unduly harmed.” *Green Bay, supra*, 96 Wis.2d at 201. Defendants cannot prove either element.

Indeed, defendants cannot prove even the basic elements to estop *any* plaintiff, even a non-governmental one. *Heckler* cited the traditional formulation for estoppel:

If one person makes a definite misrepresentation of fact to another person having reason to believe that the other will rely upon it and the other in reasonable reliance upon it does an act . . . the first person is not entitled \* \* \*

(b) to regain property or its value that the other acquired by the act, if the other in reliance upon the misrepresentation and before discovery of the truth has so changed his position that it would be unjust to deprive him of that which he thus acquired.

*Heckler*, 467 U.S. at 59, quoting Restatement (Second) of Torts, §894 (1979). Defendants can point to no “definite misrepresentation of fact” by the State, much less any reasonable reliance by defendants on such a misrepresentation, much less any injustice in allowing the State to pursue this action. Wisconsin has required the same showing in other contexts. *See State v. City*

of *Green Bay*, 96 Wis.2d 195, 202-203 (1980), which also held that “the proof of estoppel must be clear and convincing and may not rest on conjecture.”

In short, the “cross-subsidization” argument is contradicted by the evidence, by the federal Medicaid regulations, and by the settled law of estoppel.

**C. The “No Affirmative Misrepresentation” Argument.**

Defendants argue that the State fails to set forth “undisputed material facts demonstrating that Defendants *affirmatively represented* that the AWP’s obtained from the pricing compendia were actual averages of wholesale prices.” Joint Response at 91. This argument repeats the “term of art” argument answered above, which asserts that providing price data under the name “Average Wholesale Prices” makes no statement about what those data represent.

**D. The “WAC Claims” Argument.**

During part of the relevant time period, certain defendants reported data under the name “Wholesale Acquisition Cost” (WAC) rather than “Average Wholesale Prices” to First DataBank. There is no dispute about the relevant facts. The WACs reported by defendants were not the prices wholesalers actually paid to acquire defendants’ drugs, but were much higher, because they did not include discounts, rebates, or chargebacks. As defendants knew, First DataBank would mark those WACs up by 20 to 25 per cent in order to arrive at the AWP’s that it published for the drugs in question. From a functional point of view, the result, therefore, was indistinguishable from defendants reporting inflated AWP’s and having First DataBank report those inflated AWP’s unchanged.

The defendants who announced false WACs nonetheless make three arguments to escape summary judgment on liability. First, they argue that it is not an “untrue statement” to announce price data to First DataBank under the name “Wholesale Acquisition Cost” when in fact almost

all wholesalers are acquiring defendants' drugs at far lower prices. Joint Response at 96. This argument repeats, as to the name "Wholesale Acquisition Cost," the same invalid argument defendants make as to the name "Average Wholesale Price": the argument that the name is meaningless and makes no statement whatsoever. The argument has no more merit as to WAC than as to AWP. The name "Wholesale Acquisition Cost" has just as clear a plain-English meaning as the name "Average Wholesale Price." In Webster's Ninth New Collegiate Dictionary, "acquisition" is defined as "the act of acquiring" and "cost" as "the amount or equivalent paid or charged for something." Thus, in plain English, Wholesale Acquisition Cost means the amount it costs wholesalers to acquire the drugs. The WACs that some defendants reported to First DataBank were *not* the amounts it cost wholesalers to acquire those drugs; they were much higher.

Second, the "WAC" defendants argue that the State's motions for summary judgment have not "set forth undisputed facts showing that the published WACs caused its losses." Joint Motion at 96. As defendants acknowledge, this argument is based on the premise that "causation is an essential element of a §100.18 claim." *Id.* To the contrary, as shown in Section II above, the State need not prove causation to obtain summary judgment on liability. The question of the damage the State suffered because of the publication of inflated AWP's that were derived from the inflated WACs some defendants provided to First DataBank will be for later.

Finally, the "WAC" defendants offer a "WAC variation" on the "Term of Art" theme. They assert that "it was widely understood that published WACs were list prices that represented wholesale prices of drugs not including account rebates and discounts." Joint Response at 97. The argument has no merit. The evidence to which defendants cite shows only that certain people understood that WACs were list prices that could be discounted for things such as

“volume purchasing.” *See* Joint Response at 20, ¶¶47-48. But that is a different matter than understanding that almost nobody pays list price and that most people pay far less.

In imposing liability on several defendants under the Massachusetts consumer fraud law, Judge Saris considered precisely this issue. There defendant Bristol-Myers-Squibb (BMS) argued that it did not report AWP to First DataBank, but reported WACs (which BMS calls “Wholesale List Prices,” or WLPs). Judge Saris held that this made no difference:

For list prices, like WLP, it is expected that there may be some discounting, but that most customers are paying at or about the list price. Since BMS’s AWP were simply a formulaic 20 to 25 percent markup over WLP, the standard industry practice, I do not find [liability under the Massachusetts statute] when a substantial number of sales were made at the WLP. However, when discounting became so prevalent that the list price no longer reflected the price that most people paid, it became unfair and deceptive to continue publishing such a list price upon which the AWP is based.

*In re Pharm. Indus. AWP Litigation*, 491 F. Supp.2d at 105. Judge Saris’s reasoning likewise disposes of the assertion that two defendants (GSK and Aventis) explicitly defined the WACs or WAC equivalents they provided to First DataBank as “list prices.” Joint Response at 96, n. 141 & 56, n. 42. Even if they did, it is deceptive, as Judge Saris held, to represent a price as a “list price” when virtually everyone pays much less than that price.

**E. The Argument That Defendants Made No “Statements” To The State.**

Various defendants argue that any “statements” they made about their AWP were made to First DataBank, not to the State, and they further seem to argue that those statements had absolutely no role in determining the AWP that First DataBank sent to the State for purposes of determining the State’s reimbursements. *See* Joint Response at 93, n. 132; AstraZeneca Response at 40-42; J&J Response at 22; Novartis Response at 45-46; Sandoz Response at 74-75. These arguments miss the mark.

First, it makes no difference under §100.18(1) that a defendant reported its false price data to First DataBank rather than directly to the State. Section 100.18(1) does not require a statement directly from the defendant to the public. Section 100.18(1) makes it unlawful for any defendant to “cause, directly or indirectly, [a false, misleading or deceptive statement] to be made to the public.” See the text of the statute, quoted above at page 6. Because the defendants’ reporting of AWP’s and WAC’s influenced the AWP’s and WAC’s that First DataBank published, then the defendants were causing, directly or indirectly, a statement to be made to the public.

Second, recognizing this obvious deficiency in their legal argument, various defendants imply – although they stop short of flat-out asserting -- that in fact, the AWP’s published by First DataBank were absolutely unaffected by the defendants’ provision of AWP’s or WAC’s to First DataBank. Specifically, defendants assert that the AWP’s they report to First DataBank are published by First DataBank in a database field called “suggested AWP;” that the data used by the State for its reimbursements are published by First DataBank in a different database field called “Blue Book AWP;” and that First DataBank’s calculation of the Blue Book AWP is absolutely unconnected to the data provided by defendants. Defendants rely on the testimony of First DataBank witness Kay Morgan to argue that the Blue Book AWP comes not from the drug companies but rather from a survey of wholesalers. Even if that were true (which it is not), this hardly helps the defendants, because the wholesalers simply adopt the WAC’s and AWP’s provided to them by the defendants themselves so that any survey of wholesalers simply reflects defendants’ false prices. See Appendix B hereto, Plaintiff’s Response to the Defendants’ Joint Proposed Undisputed Facts, ¶ 4, citing the testimony of witnesses from national wholesalers Amerisource Bergen (Dennis Lindell) and Cardinal (Thomas Sartori). Both testified that the information, if any, that they provide to First DataBank through “surveys” are the WAC’s and

AWPs that they received from the drug manufacturers themselves, and Ms. Morgan from First DataBank testified that she was unaware of this fact.

Third, even if it were the case that the AWP reported by defendants went into a First DataBank database field called “SWP” and the data field “Blue Book AWP” was based on wholesaler surveys, this would not help defendants on this record. It is undisputed that the defendants not only know the AWP that are published by First DataBank in the “Blue Book AWP” data field (because they purchase this data from First DataBank), they know that the published AWP are identical to the AWP they provide to First DataBank, and they in fact intend for this to happen. *See, e.g.,* State’s AstraZeneca Motion, PUF 50-53; State’s Novartis Motion, PUF 32-33; State’s Sandoz Motion, PUF 17-18. Moreover, defendants have verified the accuracy of the published AWP after being asked to do so by First DataBank, thereby adopting them as their own. *See, e.g.,* State’s AstraZeneca Motion, PUF 54-56; State’s Sandoz Motion, PUF 21-22. Furthermore, except in a handful of instances, when defendants have asked First DataBank to change the published AWP for one of their drugs, First DataBank has done so. *See, e.g.,* State’s AstraZeneca Motion, PUF 56; State’s Sandoz Motion, PUF 23.

Fourth, the precise argument advanced by defendants here was rejected by Judge Saris after a lengthy bench trial in which she found as facts that AstraZeneca, Bristol Myers-Squibb (“BMS”), and Schering-Plough/Warrick “caused the publication of false and inflated average wholesale prices” and thereby violated the Massachusetts consumer protection statute. *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F. Supp. 2d at 31; *see also id.* at 95 (“I find that the defendants unfairly and deceptively caused to be published false AWP (or their formulaic counterparts: false WACs or WLPs) . . .”). In so doing, she explicitly found that these defendants controlled the AWP for their drugs published by First DataBank. *See id.* at 33

(“BMS effectively controlled the AWP published in the compendia.”); *id.* at 51 (“AstraZeneca effectively controlled the AWP for its drugs.”); *id.* at 90 (“the AWP for branded drugs was a fictitious price effectively controlled by the drug manufacturers.”). Other courts have rejected the argument that manufacturers do not control the AWP published by First DataBank. *See, e.g., In re Lorazepam & Chlorazepate Antitrust Litigation*, 467 F. Supp.2d 74, 85 (D.D.C. 2006) (“It was established at trial that the generic manufacturers, including Mylan, do influence the average wholesale price (“AWP”), even though they do not publish it . . .”).

**F. AstraZeneca’s “No Statements Were Made In Wisconsin” Argument.**

AstraZeneca argues that for liability to attach, it is required to make a statement in Wisconsin, and that it made no such statement. The fact that neither the Joint Response nor any other individual Response makes or cross-adopts this argument is sufficient tribute to its worth. AstraZeneca makes this argument only through a shameless excising of the relevant language of §100.18(1). Section 100.18(1) does not state, as AstraZeneca writes, that “No person . . . *shall make . . . in the state . . . a statement . . . relating . . . to merchandise . . . which is untrue, deceptive, or misleading.*” AstraZeneca Response at 42 (italics in original). AstraZeneca leaves out the “cause to be made” language discussed in the previous section. In relevant part, §100.18(1) says that “No person . . . *shall make . . . or cause, directly or indirectly, to be made . . . in the state . . . a statement . . . relating . . . to merchandise . . . which is untrue, deceptive, or misleading.*” Thus, if AstraZeneca causes a statement to be made in Wisconsin, by anyone, directly or indirectly, it satisfies the “in the state” requirement.

It is undisputed that First DataBank provides AWP directly to the State of Wisconsin by electronic transmission to the computers of the State’s payment agent, EDS. AstraZeneca does

not and cannot dispute that this transmission makes a statement “in the state” for purposes of §100.18(1).

**G. AstraZeneca’s Limitations Argument.**

AstraZeneca appears to assert that the State has failed to prove that it published false AWP’s on or after the June 16, 2001 cutoff date that Judge Krueger held was the beginning date for the State’s §100.18 claims. AstraZeneca Response at 38-39. This argument is a throwaway. AstraZeneca’s corporate witnesses were asked questions about AstraZeneca’s price reporting that were not limited as to time. If the answer to the question varied as of different times, it was the witness’s responsibility to say so. AstraZeneca itself offers no evidence that the AWP’s or WAC’s reported *were* accurate during some particular time period.

**H. AstraZeneca’s “EDS” Arguments.**

AstraZeneca notes that the State gets its AWP data and processes claims through a third-party administrator, EDS, and that the contract with EDS calls for EDS to maintain drug pricing using First DataBank’s tape pricing mechanism. AstraZeneca appears to argue that because the State did not specifically ask EDS to furnish *truthful* AWP’s – that is, AWP’s that were what their name represents them to be – the State has no right to complain that AstraZeneca was causing First DataBank’s AWP’s (and hence the AWP’s furnished to the State by EDS) to be falsified. AstraZeneca Response at 48-49. This murky argument seems to be a variation on the “you knew that AWP’s weren’t accurate and therefore you can’t show pecuniary harm” argument, to which the State has responded in Section II above.

AstraZeneca also claims that since 2003, it has been reporting “Average Sales Price” (“ASP”) information for several of its drugs to Wisconsin, and claims that “such ASP’s represent a figure close to the actual costs of those drugs to providers.” AstraZeneca Response at 49. As

AstraZeneca well knows, “Average Sales Price” is *not* the average wholesale price that providers pay. It is an average of sales prices from the *manufacturer*, AstraZeneca, to *wholesalers* – one step earlier in the distribution chain than the sale by wholesalers to providers. Arguments like these illustrate the attitude from AstraZeneca that led a jury to impose significant punitive damages as part of a \$215 million verdict against the company in the trial in February 2008 of Alabama’s AWP case.

**I. The “No Proof Of Intent” Argument.**

Several defendants argue that the State has failed to offer evidence that it misrepresented its AWP’s “with the intent to induce an obligation by the State.” *See, e.g.*, J&J Response at 18-19; Novartis Response at 55-57. This argument rehashes, in “intent” guise, the argument that §100.18(1) only provides a remedy for a person who was induced or was in a position to be induced into an obligation by a false or misleading representation, that the State must be a “purchaser” to be able to sue, and that the State was not a “purchaser” even though it paid most of the consideration for the drugs. The State has answered these arguments in Section IV(B).

Johnson & Johnson’s “no intent” argument also fails because it depends on an incomplete description of §100.18(1)’s intent requirement. Section 100.18(1) contains two *alternate* intent elements, either of which is sufficient: (a) “intent to sell, distribute, increase the consumption of or in any wise dispose of any . . . merchandise . . . or anything offered by such . . . corporation”, *or* (b) “intent to induce the public in any manner to enter into any contract or obligation relating to the purchase . . . of any . . . merchandise.” Johnson & Johnson omits the first of these two different and alternative intent elements. It does not and cannot dispute that it reported AWP’s to First DataBank with the intent of selling its products. As it and all other defendants admit, they are not required by law to report AWP’s. The only inference is that

defendants report purported “average wholesale prices” because it helps the company sell its drugs. Why else would it do so? Even AstraZeneca -- surely the most evasive of the four defendants against whom the State directs its motions -- when asked through its corporate representative why it has chosen to report AWP and WACs for its drugs to the pricing compendia, replied that it wants its customers to have ready access to the prices of its products. See State’s AstraZeneca Motion, PUF 49, *citing* Hyde Transcript at 184. When a reporting service started reporting less inflated AWP for defendant Dey’s products, Dey found that “Our customers told us they would stop buying from us with the lower AWP.” Testimony of Dey Chief Financial Officer Pamela Marris before the House Subcommittee on Oversight and Investigations, 108<sup>th</sup> Cong., 2d Session (Appendix G hereto).

Unlike Johnson & Johnson, Novartis does acknowledge the “intent to sell” prong of §100.18’s intent requirement. It argues that at most, the State can show only that “Novartis intended to facilitate reimbursement by third party payers who had already decided to reimburse pharmacies for dispensing drugs to covered patients for whom the drugs were prescribed,” and that this falls “far short” of proving that Novartis reported AWP with the “intent to sell” its drugs. Novartis Response at 56. This makes no sense, because almost all of the sales of Novartis’s or any other defendants’ drugs would never occur at all but for the willingness of third party payers to pay for them. No one disputes that the market for defendants’ drugs depends predominantly on third party payments. Under these circumstances, any provision of false pricing information to third party payers is undeniably done with intent to sell their drugs. Various defendants’ witnesses have explicitly admitted to this obvious point.<sup>7</sup>

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<sup>7</sup> For example, Hector Armando Kellum, Sandoz’s corporate designee, agreed that “one of the reasons that Sandoz has chosen to report AWP and WACs, to the pricing publications like First DataBank is because Sandoz’s customers expect and want Sandoz to do that.” See State’s Sandoz Motion, Proposed Uncontested Facts, ¶16. Another Sandoz witness (the former Pricing Director who had responsibility for

## **J. The Argument Based On Judge Saris's 2007 Decision.**

Novartis, Johnson & Johnson, and Schering/Warrick argue that Judge Saris's decision on the merits in a 2007 trial against AstraZeneca, Johnson & Johnson, Schering-Plough/Warrick, and Bristol Myers-Squibb shows that their false AWP's could not have been deceptive. Novartis Response at 37-38; J&J Response at 20; Schering/Warrick Memorandum at 32-33. The argument has no merit.

The case in which Judge Saris held this trial was brought on behalf of private insurance companies and health insurance plans. One subclass consisted of all Massachusetts third-party payors whose payments for prescription drugs which were calculated on the basis of AWP. *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F. Supp.2d at 30. This subclass asserted claims under the Massachusetts consumer protection statute and several other Massachusetts legal theories.

In 2007, after a bench trial, Judge Saris found AstraZeneca, Bristol-Myers Squibb, and Warrick (Schering-Plough) liable, declined (reluctantly) to impose liability on Johnson & Johnson and imposed damages on the liable defendants as to certain drugs. Her opinion is a devastating indictment of these defendants' behavior, and by extension, of the system used by the pharmaceutical industry to inflate reimbursements by third party payers to providers.

Defendants nonetheless cite this decision because Judge Saris found the "expectations" of private payers as to how much AWP might be inflated a relevant consideration in determining whether to impose liability under the Massachusetts statute. This does not help defendants here. First, as construed by Judge Saris, the Massachusetts consumer fraud law contains a requirement

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reporting prices to First DataBank) agreed that the company reported AWP's and WAC's to the pricing compendia "because it was necessary in order to sell Sandoz products." Galownia Tr. at 108 (Ex. 5 to Sandoz Response). *See also* State's AstraZeneca Motion, Proposed Uncontested Facts, ¶49, *citing* Hyde Tr. at 107, 136; State's Novartis Motion, Proposed Uncontested Facts, ¶29, *citing* Conley Tr. at 22-23.

of proving “egregious misconduct.” This was in fact the legal basis for her holding that the private payers’ “expectations” were relevant to whether the statute had been violated. For example, she wrote: “While *Johnson & Johnson’s* conduct was at times troubling, it did not rise to the level of egregious misconduct actionable under the Massachusetts Chapter 93A, because its spreads never substantially exceeded the range of what was generally expected by the industry and government.” 491 F. Supp.2d at 31. No Wisconsin court has ever hinted at an “egregious misconduct” standard under §100.18.

Second, plaintiffs in the case tried before Judge Saris asserted a conservative theory of what constituted deceptive conduct under the Massachusetts statute. That approach was dictated by the “egregious misconduct” standard they had to meet, and by the fact that the plaintiff payers included enormous and highly sophisticated insurers (like Blue Cross) who had an intimate knowledge of the marketplace for prescription drugs. Plaintiffs asserted this theory through their expert witness, Raymond S. Hartman. Hartman took the position that during the relevant period, the “marketplace” had an “expectation that AWP did not exceed the average sales price [the price paid by providers to obtain the drugs] by more than 30%.” 491 F. Supp.2d at 40. Plaintiffs’ expert used this test “to find liability wherever a drug exceeds that threshold.” *Id.* at n. 20. In short, Judge Saris merely used the test of deceptive and unfair conduct that plaintiffs offered her. The State of Wisconsin does not advance the same theory advanced by the private payor plaintiffs before Judge Saris. Moreover, plaintiffs in the MDL advanced a theory of liability that required a showing that defendants intended to defraud the plaintiff class, eschewing state consumer protection statutes like Wisconsin’s which require a lower standard of proof. They did so because in the briefing on class certification, defendants had argued that a nationwide class under the consumer protection statutes of the 50 states was inappropriate

because of variations in the statutes with respect to numerous issues, including whether intent to deceive was required, thereby defeating the showing required under Fed. R. Civ. P. 23 that common issues “predominate.” To overcome this hurdle, plaintiffs’ counsel voluntarily assumed the highest burden of proof required of any state consumer protection statute, *i.e.*, that defendants intended to defraud the plaintiffs, the theory being that if plaintiffs prevailed under this heightened standard, they would be entitled to judgment in states with less onerous burdens of proof. In granting plaintiffs’ motion for class certification, Judge Saris adopted plaintiffs’ position:

For the remaining states, defendants flag differences in requirements for establishing reliance, proximate cause, scienter, damages, and statutes of limitations, but in the context of the claims of consumer-patients under Medicare Part B, these variations in legal standards are unlikely to be material. Significantly, plaintiffs have wisely noted that they are pressing only the theory that defendants intentionally made fraudulent misrepresentations of AWP. Therefore, different standards governing scienter do not present individual issues.

*See In re Pharmaceutical Industry Average Wholesale Price Litigation*, 230 F.R.D. 61, 85 (D.Mass. 2005) (emphasis added). As demonstrated earlier, intended to defraud is not an element of Wis. Stat. § 100.18; rather all that the State needs to show is that defendants made an untrue statement.

Third, neither the State of Wisconsin nor any other government was a plaintiff in the trial before Judge Saris, and neither the federal Medicaid program nor any state’s Medicaid program was at issue, much less government regulations setting the terms of reimbursement to providers in Medicaid programs. This is a decisive difference. As a general matter, no statute or government regulation limits how much private payers can pay a provider who has provided a drug to one of the persons they insure. But that is not true of governments like the State, who purchase drugs for their citizens under programs like Medicaid. The law does place strict limits

on how much the State can pay providers. As discussed in Section IV(B) above, it is limited to paying no more than the estimated acquisition cost of the drugs plus a reasonable dispensing fee.

Moreover, as also discussed in Section IV(B), defendants are not free to deal with a government like the State of Wisconsin in the same fashion as they may deal with private parties. In *Heckler, supra*, the Secretary of Health and Human Services sued a provider to recover a Medicare overpayment. Like defendants here, the provider claimed that the Department knew of and acquiesced to the level of payment. The United States Supreme Court replied:

Justice Holmes wrote: “Men must turn square corners when they deal with the government.” *Rock Island, A. & L.R. Co. v. United States*, 254 U.S. 141, 143 (1920). This observation has its greatest force when a private party seeks to spend the Government’s money. Protection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of the law.

467 U.S. at 63. This is the rule everywhere. For example, under the federal False Claims Act (“FCA”), which allows suits to recover money paid out under false claims to the federal government, the fact that a governmental official knew of the fraud is not a defense to a FCA claim. *U. S. ex rel. Kreindler & Kreindler v. United Technologies Corp.*, 985 F.2d 1148, 1156 (2d Cir. 1993); *U.S. ex rel. Hagood v. Sonoma Cty. Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991). It would eradicate this rule if the defendants could avoid liability under §100.18 for deceptive practices by showing that officials within a state’s government “expected” to be paying out more than the law allowed the state to pay providers.

**K. The Argument That The Federal Trade Commission No Longer Cares About Publishing Untrue Prices.**

The State’s motions supported its interpretation of §100.18 by citing federal court decisions under the Federal Trade Commission Act and by citing the FTC’s “price guidelines.” *See, e.g., State’s AstraZeneca Motion* at 23-27. Those decisions and guidelines say that it is deceptive to publish a price of any kind—list, suggested, regular or wholesale—where that price

does not represent a price at which significant sales are made. In response, Novartis and Johnson & Johnson try to argue that these decisions and guidelines are no longer the law. Novartis Response at 41, n. 10; J&J Response at 19, n. 4. Both Responses cite a law review article written by a former FTC chairman and two others who claim that the FTC has “concluded that enforcement actions in this area do more harm than good because they discourage discounting.” They note that the FTC has filed no deceptive-pricing enforcement actions in recent years, and they urge the FTC to repeal its “price guidelines.” Pitofsky *et al.*, “Pricing Laws Are No Bargain For Consumers,” *Antitrust*, Summer 2004 (Novartis Response, Grimmer Affidavit Ex. 43).

Whatever these individual former government officials may think of the FTC price guidelines, the FTC has not repealed them, and no federal court has overruled or backed away from the many decisions cited by the State under the Federal Trade Commission Act.<sup>8</sup> Moreover, the reason Pitofsky dislikes these guidelines and this law is inapplicable here. He believes that in the typical retail discount situation, consumers “are in a good position to mitigate any harm from unscrupulous pricing practices by comparing the values offered by one retailer to those offered by another.” Pitofsky, *op. cit.*, at p. 4. But the present case does not involve a typical retail discount situation, and the State is in no position to protect itself by comparison shopping. As discussed above, for practical purposes, the pricing compendia are the only source for the continuing, instantaneous data the State needs to make the requisite estimates of providers’ acquisition costs for thousands of drug transactions each week. Unscrupulous pricing practices by defendants about their AWP’s enable them to corrupt that source.

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<sup>8</sup> Moreover, the personal opinions of these former government officials is irrelevant. *See United States v. Lachman, supra*, 387 F.3d at 54.

## V. THERE IS NO BASIS FOR “ABSTENTION.”

Defendants’ most startling argument is that this Court should “abstain from deciding this case on the merits,” on “separation of powers” or “political question” principles. Joint Response at 66-74. According to defendants, this lawsuit impermissibly seeks to second-guess legislative judgments about Medicaid reimbursements for prescription drugs.

Legally, this argument is hopeless. No Wisconsin decision has ever refused, on “political question” or “separation of powers” grounds, to decide the merits of a lawsuit brought by the State under a valid remedial statute that expressly affords the State a remedy. It is extraordinary in *any* kind of case for Wisconsin courts to abstain from deciding the merits on “political question” or “separation of powers” grounds. Defendants cite not one case from Wisconsin or anywhere else which so abstained. To the contrary, in the cases they cite, the “political question” argument lost, and the court decided the case on the merits:

- In *In re John Doe Proceeding*, 2004 WI 65, 272 Wis.2d 2008, the Supreme Court rejected a variety of “political question” arguments in refusing to quash a subpoena issued in a John Doe investigation to the director of the Legislative Technology Services Bureau. *Id.*, ¶¶25-33.
- In *State v. Chvala*, 2004 WI App. 53, 196 Wis.2d 947, the Court of Appeals refused to quash, on “political question” grounds, a prosecution of a state senator who had hired and directed staff to work on political party campaigns using state resources, even though the prosecution depended in part on interpretation of a legislative rule. *Id.*, ¶52.
- In *Vincent v. Voight*, 2000 WI ¶93, 236 Wis.2d 588, the Supreme Court rejected the argument that a constitutional challenge to Wisconsin’s system of financing the public schools was a nonjusticiable political question. *Id.*, ¶2, n. 2.
- In *Mills v. Vilas Cty. Bd. Of Adjustments*, 2003 WI App 36, 261 Wis.2d 598, the Court of Appeals held that a suit seeking to enforce a mediation agreement between a private seller and an Indian tribe as prospective purchaser was not a nonjusticiable political question, even though the suit challenged the validity of a requirement for the tribe to hold a referendum to authorize the purchase under the tribe’s constitution. *Id.*, ¶18.

- In *Casanova Retail Liquor Store, Inc. v. State*, 196 Wis.2d 947 (Wis. Ct. App. 1995), the Court of Appeals decided the merits of a suit over whether a corporation could be reinstated after the Secretary of State had instituted proceedings to dissolve it. The Court’s remarks on “separation of powers” were made in the course of its adopting one of two competing interpretations of the statute in question. *Id.* at 954-955.
- In *Baker v. Carr*, 369 U.S. 186 (1962), the United States Supreme Court rejected the “political question” argument and decided the merits of a constitutional challenge to the apportionment of state legislative districts.

*John Doe, Chvala, Vincen, and Baker* rejected the “political question” argument even though the cases raised highly politicized matters that raised serious threats of confrontation between different branches of government. The same is true for other cases where the “political question” argument lost. In *State ex rel. Reynolds v. Zimmerman*, 22 Wis.2d 544 (Wis. 1964), the Supreme Court, following *Baker*, held that the political question doctrine did not prevent the Court from deciding the constitutionality of legislative redistricting. In *State v. Jensen*, 2004 WI App 89, the Court of Appeals, reaffirming *Chvala*, refused to quash the indictment of a legislator for abusing his office. *Id.*, ¶¶41 ff.

Despite this avalanche of hostile authority, defendants soldier on with three meritless arguments.

**The “you’ll reverse the legislature’s and executive’s policy determination” argument.** Defendants argue that the State has “chosen, as a policy matter, to allow providers to realize an appropriate return on Medicaid transactions” and that “[i]n retaining an AWP-based reimbursement system, the State has acted with the specific understanding that AWPs reflected something greater than a providers’ actual cost for a drug.” Joint Response at 68. Allowing this suit to go forward, defendants argue, would somehow “reverse” these “legislative and executive branch” determinations of “policy.” *Id.* at 69.

This argument has no merit. What the State asserts in this lawsuit is that when defendants choose to provide price data to First DataBank that they know will influence the ingredient-cost component of reimbursements, §100.18 requires that data to be truthful. While there is evidence that at various times various people in State government were told, or believed, that published AWP's could be too high, there is no evidence that anyone in State government *approved* of defendants inflating their AWP's. To the contrary, what the record shows is how hard it is for both the executive and legislative branches to set appropriate reimbursement rates for providers in an information vacuum that, unbeknownst to them, defendants were responsible for creating. There is no evidence that anyone in either branch liked, much less approved of, having to guess at what sort of discount should be applied to First DataBank's data. Nor is there evidence that either branch understood, until recently, the key role defendants were playing in the excess level of First DataBank's AWP's. When the executive branch found out about that role, far from approving it, it joined the executive branches of two dozen other states (and the executive branch of the federal government) by suing to stop defendants' practice.

Defendants argue that the legislative and executive branches must be happy with the present system, because after filing this lawsuit, the State has not jettisoned its system of using AWP-based reimbursement for a majority of its drugs. *See, e.g.,* Joint Response at 69-70. Defendants also claim that the State has access through various sources to providers' "real" acquisition costs, yet has not increased the discount off of AWP during the last two years. *Id.*

The argument ignores the State's real-world needs. Wisconsin Medicaid must pay for many thousands of Medicaid prescriptions every week, covering a multitude of different drugs whose prices are constantly subject to change. To do that task successfully, the State needs a system that is *computerized*, and the database for that system must be updated by computer as

well. This is why Wisconsin, like virtually every other state, still relies heavily on AWP-based reimbursement, which runs on a computerized database that is constantly and instantaneously updated by First DataBank, the largest and most comprehensive source of electronic pricing information for drugs. Despite that system's drawbacks and susceptibility to abuse at the hands of the defendants, it meets, as no other system can, the necessary condition of being able instantly to compute a reimbursement amount each time a claim is filed.

The State has reduced its reliance on this system where it can. For example, the State has aggressively set "Maximum Allowable Cost" (MAC) figures for certain drugs, and for those drugs, it reimburses on the basis of MACs rather than AWP. But setting MACs is a difficult process with its own difficulties, as the State's consultant pharmacist who sets MACs for the State has attested. Affidavit of Ted Collins (Appendix K to this reply brief), ¶¶ 2-3; *see also* State's Response to Defendants' Joint Additional Proposed Undisputed Facts (Appendix B hereto), ¶ 30. Neither Wisconsin nor most other states have had the resources to abandon AWP-based reimbursement for the majority of the drugs they reimburse.

Nor can the defendants legitimately cite whatever adjustments or non-adjustments the State makes to its AWP discount rate at a given time to argue that the State approves of their current AWP practices. Being told that published AWPs may be inaccurate does not tell the State what providers' average acquisition costs *really are*. And as discussed above, the State cannot fill this information vacuum with supposed alternative sources of information on the comprehensive and computerized basis that is required. The State also knows that no matter what discount rate it sets, the pharmacists and other interested groups will raise cane, claiming that any discount is too great. In this situation, any discount the State sets from AWP amounts to shooting blindfolded. The State does the best it can. *See* Appendix B hereto, ¶¶ 24, 25. If

defendants provided accurate pricing data to First DataBank, the State would have accurate information on which to base its reimbursement policies, and whatever decisions it made would not be subject to secret countermanding by defendants.

**The “no judicially discoverable and manageable tools” argument.** Defendants argue that this lawsuit seeks to “change the State’s Medicaid reimbursement formula” and that the Court lacks the resources and tools to do so. Joint Response at 70-72. The State is *not* asking this Court to “change the State’s Medicaid reimbursement formula.” All the State wants is truthful rather than false data that it can apply to whatever reimbursement policy meets its interest and complies with federal law. If defendants are required to provide truthful rather than false AWP data, the State may well adjust the discount rate it applies to AWP. But regardless of what adjustment it makes, that will be the State’s decision. The Court will not be changing the rate, and will not be involved in whatever adjustment the State sees fit to make.

***In terrorem* arguments.** Defendants argue that if they had to provide honest data to First DataBank, the effect “might be to cripple Wisconsin’s Medicaid program.” Joint Response at 72-73. First, a handful of defendants claim that they do not know the prices at which wholesalers resell their drugs, and therefore “may have difficulty in determining” truthful AWPs. Joint Response at 16-17, 72. The argument does not pass the straight-face test. If these defendants do not know the true AWPs of their products, it is because they have willfully kept from themselves a fact that all the other defendants admit knowing. It is particularly ridiculous for these defendants simultaneously to claim that the *State* has full access to what wholesalers are charging providers, but that they themselves do not. Moreover, this argument from a minority of defendants is contradicted by the admissions of the remaining defendants that they

know wholesalers charge their customers only slightly more (in the range of 2-3%) above what the wholesalers pay the manufacturers to acquire their drugs.

Second, defendants protest that “There is no definition of or explanation for how to determine an average of wholesale prices.” Joint Response at 72. Even if that were true, defendants can explain to First DataBank how they calculate their AWP. Whatever the nuances of calculation, the numbers will be a lot closer to average provider acquisition costs than the meaningless numbers defendants currently provide.

**The “parade of horrors” arguments.** Defendants envision a potential “catastrophe” in which the Court orders defendants to report honest AWP, defendants start doing so, the State continues to reimburse at the present level of AWP minus 13%, providers start incurring losses and stop participating in Medicaid, the federal government cuts Wisconsin out of the Medicaid program, the Court has to “recalculate the dispensing fee,” and the Court has to “sit for years as a monitor of price reporting.” Joint Response at 73-74. If over-the-top parades of horrors like these could justify a court refusing to decide a case on the merits, few cases would get decided. Nothing about the State’s current reimbursement system is cast in stone. Adjustments can be and will be made to take account of the fact that First DataBank’s published AWP, for the first time, are what they purport to be. This Court can and will include appropriate provisions in any decree to assure that consequences such as those envisioned by defendants do not occur.

## **VI. DEFENDANTS’ CROSS-MOTIONS SHOULD BE DENIED.**

### **A. Most Arguments In The Cross-Motions Need No Further Response.**

The Joint Defendants and various individual defendants cross-move on the basis of various arguments discussed above that were offered in opposition to the State’s arguments. *See,*

e.g., Joint Response at 98-99. These arguments have been answered above and need no further response.

**B. The Limitations Argument Addressed To Counts III, IV, and V Has No Merit.**

While the State's motions concern exclusively the §100.18 claims, the limitations argument in the Joint Response's cross-motion is directed only at the State's other claims – Count III's claim under Wis. Stat. §133.05, Count IV's claim under Wis. Stat. §49.49, and Count V's claim for common-law enrichment. As defendants note, Judge Krueger's earlier decision held that each of these Counts is governed by a six-year limitations provision requiring the claim to be brought six years after the cause of action "accrues." Defendants also concede that each of the limitations provisions applicable to these three Counts is subject to the "discovery rule," under which a cause of action "accrues" when the plaintiff "discovers, or with reasonable diligence should have discovered that he or she has suffered actual damage due to wrongs committed by a particular, identified person." Joint Response at 100, quoting *Pritzlaff v. Archdiocese of Milwaukee*, 194 Wis.2d 302, 315-316 (Wis. 1995). Defendants then argue that *all* of the State's claims under these three statutes "accrued" more than six years before the filing of the complaint—*i.e.*, before June 3, 1998.

The argument has no merit. First, at a minimum, any claim by the State that is based on conduct that occurred on or after June 3, 1998 clearly "accrued" within the limitations period and cannot be barred. Second, even as to claims based on conduct that occurred before June 3, 1998, defendants provide no evidence that would entitle them to a determination that the State as a matter of law should have discovered the cause of action prior to that date. Third, in any event, the limitations period for Count III's claim under §49.49 is ten years, not six.

**1. There Is No Basis For Barring Claims Based On Conduct Occurring On Or After June 3, 1998.**

Without explaining why, defendants appear to assert that even those claims that are based on AWP's that defendants provided *after* June 3, 1998, and on payments made by the State after that date, "accrued" *before* that date. Defendants do not even try to explain on what basis they make this argument. Even if it were true that the State knew or should have known prior to June 3, 1998, that defendants were providing false AWP's to First DataBank, no claim based on behavior by the defendants *after* that date could possibly "accrue" *before* that date. Every time the defendants published false AWP's, and every time that false price led the State to pay providers, a new claim "accrued" for limitations purposes.

The relevant statutory provisions are violated each time a single "false statement" or "secret payment" is made. *See* Wis. Stat. § 49.49; Wis. Stat. § 133.05; *State v. Williams*, 179 Wis.2d 80, 85 (Wis. Ct. App. 1993) (each allegedly fraudulent application for reimbursement for health services gave rise to a count of medical assistance fraud pursuant to § 49.49). *See also United States v. Halper*, 490 U.S. 435, 437 (1989) (submission of 65 false claims amounted to 65 distinct violations of the federal false claims act), *abrogated on other grounds by Hudson v. United States*, 22 U.S. 93 (1997); *State v. Kurzawa*, 180 Wis.2d 502, 506 (Wis. 1994) (each forgery of a check gives rise to a unique violation of Wis. Stat. § 943.38(2)).

Moreover, each violation plainly starts a new limitations period running for that violation. For example, in *Noonan v. Northwestern Mut. Life Ins. Co.*, 2004 WI App 154, 276 Wis.2d 33 (Wis. Ct. App. 2004), an insurance policyholder alleged that the insurer had breached its contract and breached its fiduciary duty by making a change in 1985 in the way it distributed its surplus profit to annuity policyholders. After the initial change in 1985, the company continued to make annual distributions on the basis of its new method. The policy holder sued many years later.

The insurer argued that the action was barred by the six-year statute of limitations, since the policy holder had known in 1985 all the facts on which she based her claim. The Court of Appeals, however, held that the violation was a continuing one, and that every year that the insurer paid out on the basis of the wrongful formula, a new violation accrued for limitations purposes. Hence, all claims based on payouts within the six years before filing the complaint were timely. *Id.*, ¶32. Similarly, every time the defendants announced new false prices, and every time the State paid providers on the basis of those false prices, a new cause of action accrued under the statutes in question here.

If defendants' argument were accepted, it would lead to outrageous results. A party who was committing daily unlawful behavior against a particular person could continue to engage, *for all eternity*, in that same daily unlawful behavior against that same person, so long as the person did not file a suit within the first six years after that behavior first began. If the person sued after that six-year period, he or she would be met by defendants' argument: "Your entire cause of action accrued more than six years ago when you first should have known I was acting unlawfully. No new cause of action has accrued since then. So I can keep behaving the same way toward you every day for the rest of my life, and damaging you every day for the rest of my life, and you can never sue me." The Wisconsin Court of Appeals pointed out this absurdity when it held that a discrimination claim accrues each time a child is assigned to a school under a racially discriminatory policy. Otherwise, it noted, a child whose parents neglected to sue during the two year limitations period could be doomed to "another 10 years of discriminatory education." *Barry v. Maple Bluff Country Club*, 221 Wis.2d 707, 728-29 (Wis. Ct. App. 1998) (quoting *Palmer v. Bd. of Educ. Cmty. Unit Sch. Dist.*, 46 F.3d 682, 685 (7th Cir.1995)).

For this reason, no claims under these Counts based on false AWP's or other conduct by defendants that occurred on or after June 3, 1998 can be barred under any circumstances.

**2. Defendants Are Not Entitled To Summary Judgment For Claims Based On Conduct Occurring Before June 3, 1998.**

As defendants admit, under Wisconsin's "discovery rule," it is not enough to suspect that someone is doing something wrongful. It is necessary that the plaintiff discover that it "has suffered actual damage due to wrongs committed by a particular, identified person." In this case, that "particular, identified person" means the defendants themselves.

The evidence on which the Joint Cross-Motion seeks summary judgment does not show, much less show as a matter of law, that the State discovered or should have discovered before June 3, 1998 that the defendants were committing the violations charged in Counts III, IV and V. Defendants claim that various reports at various times received by the State put it on notice that "AWP did not represent an actual average of wholesale prices [citation omitted], thereby establishing that the State had knowledge prior to June 3, 1998 for purposes of accrual of the State's claims." Joint Response at 103. But other information disputed these sporadic reports. First DataBank, as discussed above in Section III, published statements all the way through 2003 insisting that its AWP's *did* represent what providers were paying to acquire the drugs.

More importantly, even if the State was told that AWP's as published by First DataBank tended to be higher than real AWP, that information did not put the State on notice, much less as a matter of law, that it was being defrauded by *defendants*. See *Spitler v. Dean*, 148 Wis.2d 630, 636 (Wis. 1989) ("We therefore conclude that Spitler's cause of action did not accrue until Spitler knew the identity of the defendant, or in the exercise of reasonable diligence, should have discovered the identity of the defendant."). Such explanations as appear in these reports from persons who believed AWP's to be higher than real average wholesale prices were entirely

benign. Some of these reports, for example, stated that AWP's were "list" or "sticker" prices – which, as discussed above, has turned out to be poppycock. None of these reported the fact that *defendants* were intentionally gaming the system. *See, e.g.*, Joint Response, Ex. 19 at Bates number 1122993, which summarizes the relevant history.<sup>9</sup>

### **3. The Limitations Period For The State's Claims For Medicaid Fraud Under §49.49 Is Ten Years, Not Six.**

Defendants assert that the statute of limitations for a Medicaid fraud claim is six years. Joint Response at 99, *citing* Wis. Stat. §893.93 (which defendants misnumber as §839.93 or 893.43). However, the §49.49 claim is governed by the ten-year statute of §893.87.<sup>10</sup> That

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<sup>9</sup> In addition, the State reiterates, for the record, its position (which Judge Krueger rejected) that the "continuing violation" doctrine makes any defendant's conduct actionable from the time that conduct first began. This doctrine, which first developed in negligence cases, provides that "if a defendant engages in a continuum of separate negligent acts which cause the plaintiff damage, the cause of action is not complete until the last act of negligence occurs." *Kolpin v. Pioneer Power & Light Co., Inc.*, 162 Wis.2d 1, 24 (Wis. 1991). Under this theory, the Supreme Court has affirmed damage awards for continuous courses of conduct that began long before the limitations period began. *See Kolpin, supra* (limitations period of six years, but judgment awarding damages for a ten-year period of continuous conduct affirmed); *Vogel v. Grant-Lafayette Electric Cooperative*, 195 Wis.2d 198, 214 (Wis. Ct. App. 1995) (six year limitations period, but judgment awarding damages for continuous conduct over seventeen-year period affirmed). The doctrine has also been applied to deliberate statutory torts such as sex discrimination "hostile environment" claims. *Barry v. Maple Bluff Country Club*, 221 Wis.2d 707, 728 (Wis. Ct. App. 1998); *Bowen v. Labor & Industry Review Com'n*, 2007 WI App 45, ¶14, 299 Wis.2d 800, ¶14. In the second part of her decision denying defendants' motion to dismiss, Judge Krueger rejected the applicability of the "continuing violation" doctrine, finding it incompatible with the State's position (which she necessarily accepted) that each time the defendants caused a false AWP to be published, a new violation of §100.18 "accrued." Decision of May 18, 2006, pp. 8-9. With deference, the State sees nothing "inconsistent" between this fact and the application of the continuing violation doctrine. It is precisely the continuing nature of defendants' violations that opens the door to allowing conduct to be actionable that occurred earlier than the otherwise applicable limitations period.

<sup>10</sup> The issue of what statute of limitation is applicable to a claim under Wis. Stat. 49.49 has not been briefed by any party. In her decision and order dated May 18, 2006, Judge Krueger stated that "the balance of the claims are governed by the six year statute of limitations for contractual matters under Wis. Stat. 893.43 or the default statute of limitations in Wis. Stat. 893.93." However, the defendants in their brief dated January 20, 2005 never cited or mentioned sec. 49.49. Instead, defendants made a single sweeping, and incorrect, conclusory statement that "[e]ach of the remaining claims are governed by the six year statute of limitation." In truth, each of the remaining claims are governed by the ten year statute of limitation. Defendants, however, cannot complain of the State raising this argument now. The defendants' Responses and cross-motions offer four new legal arguments (answered in Section III above) about the coverage of §100.18 that defendants failed to raise before Judge Krueger. Moreover, as

provision specifies a ten-year period for actions by the State unless Chapter 893 prescribes a different period. The defendants presumably argue that §893.93 prescribes a six-year period for claims “sounding in fraud”; that the State’s §49.49 claim is a claim “sounding in fraud,” and hence that Chapter 893 prescribes a “different period” than the ten-year statute of §893.87.

For two reasons, such reasoning is erroneous. First, when the State is acting in protection of the public, it is not bound by general statutes of limitations unless the legislature has clearly expressed its intention that the State be so bound. *State v. Jofisberg*, 275 Wis. 142, 150-151 (Wis. 1957); *see also In re Allen’s Estate*, 43 Wis.2d 260, 264 (Wis. 1969), which held that a claim under §46.10 is covered by the ten-year statute of §893.87, rather than the six-year limitations period of §893.19(4) for “liability created by statute.”

Second, welfare fraud under chapter 49 is a “continuing offense” for purposes of the criminal statute of limitations. *Johns v. State*, 96 Wis.2d 183, 188 (Wis. 1980). The “statute of limitations for a continuing offense does not begin to run until the last act is done, which, viewed by itself is a crime.” *Id.* There is no reason to apply a more favorable rule for a defendant when the State brings a civil action than when it brings a criminal action.

Accordingly, for its §49.49 claim, the State, at a minimum, may recover for conduct occurring on or after June 3, 1993.

### **C. The Johnson & Johnson “Claim Preclusion” Argument.**

In its separate cross-motion for summary judgment, Johnson & Johnson argues that Judge Saris’s ruling in the MDL proceedings – which found that Johnson & Johnson did not violate the Massachusetts consumer protection statute in connection with two of its drugs, Procrit and Remicade – entitles Johnson & Johnson to summary judgment here against the State with respect

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discussed in Section II, defendants reiterate an argument that they did make, and lost, before Judge Krueger – the argument that the State is required to allege facts showing pecuniary loss to state a claim under §100.18.

to its claims relating to Medicare Part B beneficiaries under the doctrine of claim preclusion. This argument has no merit, and in fact is ironic, because Judge Saris's opinion has preclusive effect *against* Johnson & Johnson, as well as Schering-Plough and AstraZeneca, under the doctrine of *issue* preclusion.

Claim preclusion (formerly called *res judicata*) requires three elements: (1) identity between the parties or their privies in the first and second actions, (2) identity between causes of action in the first and second causes of action, and (3) a final judgment in the first action. *See, e.g., Northern States Power Company v. Bugher*, 189 Wis.2d 541, 551 (Wis. 1995). It is unnecessary to discuss any element other than the first, which Johnson & Johnson fails.

It is undisputed that the State was not a party in the MDL case in question, that it was not present at the MDL trial, and that the class plaintiff's counsel in the MDL did not purport to represent the State.

To circumvent this obvious problem, Johnson & Johnson seeks to characterize the class members with Wisconsin state-law claims in the MDL case as "parties" to the present case by the State of Wisconsin. To make this characterization, Johnson & Johnson characterizes the State's action here as a "*parens patriae*" action, *i.e.*, an action on behalf of its citizens, and that the citizens are the real party in interest. J&J Cross-Motion at 7. The argument is wrong. The State is not suing in the shoes of its citizens. It is bringing its own action. As the State showed in Section II above, it is proceeding under Wis. Stat. § 100.18(11)(d), which permits the State, and only the State, to bring an enforcement action to obtain civil penalties, injunctive relief, and restitution for persons who have been harmed by defendants' actions. The State, not its citizens, is the real party in interest. Private individuals must proceed under a separate statutory provision, section 100.18(11)(b)(2).

Although Wisconsin courts have not addressed the particular consequences that result from the State's independent right to bring its own suit, one Illinois appellate court has considered this issue under Illinois' Consumer Fraud Act ("ICFA"), whose structure, as shown above in Section II, is the same as the structure of §100.18. In *Illinois v. Lann*, 225 Ill.App.3d 236, 587 N.E.2d 521 (Ill. App. 1992), the Illinois Attorney General brought an action under the ICFA to recover restitution for consumers injured by defendant's unlawful conduct. The trial court entered an order imposing a duty on the Attorney General to act as counsel for individual consumers for whom restitution was sought and to treat them as party plaintiffs for discovery purposes. The trial court's order required the Attorney General to produce individual consumers for deposition and to answer interrogatories on behalf of consumers. The trial court also expressed concern that some of the consumers for whom the Attorney General sought restitution had filed their own lawsuits, creating the possibility of double liability for the defendant. The Appellate Court vacated the order and reversed the trial court.

First, the court concluded that when the Attorney General seeks restitution for individual consumers pursuant to the ICFA, he or she is bringing suit in the public interest, an interest separate and distinct from the interest of a private litigant:

An action filed by the Attorney General under the [Consumer Fraud] Act is essentially a law enforcement action designed to protect the public, not to benefit private parties...although restitution may benefit aggrieved consumers, the remedy flows from the basic policy that those who engage in proscribed conduct or practices surrender all profits flowing therefrom. Because the nature and object of the Act and its remedies are indisputably the protection of the public interest, we believe that the legislature intended the State to be the only real party in interest....

225 Ill.App.3d at 240-41. Second, the court found that when the Attorney General seeks restitution for consumers, no attorney-client relationship is created, even for discovery purposes. *Id.* at 241. This is because, among other things, the relationship lacks traditional attributes of an

attorney-client relationship: there is no mutual consent to enter the relationship; the Attorney General, not the consumer, initiates the action; the Attorney General has the power to direct the litigation without any input from aggrieved consumers; and the Attorney General owes primary responsibility to the public, not to any individual consumer. *Id.* Finally, the court rejected the argument that the existence of private lawsuits by the same consumers on whose behalf the Attorney General sought restitution precluded the Attorney General from maintaining its own suit because "[n]othing...precludes the [trial] court from fashioning an order diminishing the likelihood of double recovery." *Id.* at 244.

Similarly, Wisconsin has the right to bring its own lawsuit, independent of any lawsuit filed by its citizens. It is the State, not its citizens, that is the real party in interest in this case. Hence, the Wisconsin Medicaid Part B recipients who were class members in the MDL action are not "parties" to the present case. Judge Saris's judgment in the MDL in favor of Johnson & Johnson against a private class of consumers that included Wisconsin citizens cannot therefore act as a bar to Wisconsin's lawsuit because there is no identity between the parties.

Had Johnson & Johnson advanced a "privity" argument (it did not), it, too, would fail. "In order to be in privity with a party to a judgment, one must have such absolute identity of interests that the party to the earlier action represented the same legal interest as the non-party to that first action." *In re Paternity of Amber J.F.*, 205 Wis.2d 510, 516 (Wis. Ct. App. 1996); *see also Pasko v. City of Milwaukee*, 2002 WI 33, ¶ 16, 252 Wis.2d 1, 15 (Wis. 2002) ("[p]rivacy exists when a person is so identified in interest with a party to former litigation that he or she represents *precisely* the same legal right in respect to the subject matter involved.") (emphasis added); *State ex rel. Barksdale v. Litscher*, 2004 WI App 130, ¶ 14, 275 Wis.2d 493, 504 (Wis. Ct. App. 2004) ("Privity compares the interests of a party to a first action with a nonparty to

determine whether the first action protected the interests of the nonparty.”). As explained above, the class plaintiffs in the MDL did not represent the same legal interests as the State of Wisconsin.

Thus, the identity of parties or their privies requirement is not met, and claim preclusion does not apply to the State’s claims here.

This result is not only required by the law of claim preclusion, but is the just outcome. First, any other result would have been an intolerable, and arguably unconstitutional, intrusion into the State’s prerogatives. The State has critical interests at stake in the present lawsuit that neither were, nor could have been, asserted by the named plaintiffs in the MDL case. For example, one of the State’s key purposes in pursuing this case is to recover statutory penalties that are permitted by various provisions of the Wisconsin statutes. The private parties who represented the class in the MDL proceedings had no right to seek such penalties under the Wisconsin statutes in question, particularly §100.18. If the State could be foreclosed from seeking such penalties by the result of a case in which the State was not a party or participant, the result would be an intolerable example of the public-interest tail being wagged by the private-interest dog.

Second, it would be intolerable to allow the State’s prerogatives and remedies under its own statutes to be taken away from it as a result of litigation strategy decisions which were made by a private class in a case whose principal focus was a Massachusetts statute. As discussed earlier in this brief, the named plaintiffs in the MDL case tailored their litigation approach to the needs of the *Massachusetts* statute, with its requirement that they prove “egregious misconduct;” to the fact that they were predominantly highly sophisticated private insurance companies; and to the need to preserve the remarkable nationwide class that Judge Saris certified under the

consumer protection laws of all 50 states by embracing an “intent to deceive” requirement. All three of these factors led the named plaintiffs in the MDL case to assert a “lowest common denominator” legal theory, as discussed in Section V.J., *supra*, in which they conceded, through their expert, that they needed to prove that AWP was inflated by at least 30% before liability could attach under any state’s consumer fraud law.

The State had no role in the formulation of this “lowest common denominator” legal strategy and choice of expert, and does not agree that it is appropriate in an action by the State under Wis. Stat. §100.18. For present purposes, the important point is that the Wisconsin law of claim preclusion would never tolerate stripping the State of its prerogatives because of decisions made far away in another state by lawyers who did not represent the State’s interest and tailored their strategy to other factors having nothing to do with that interest.

Johnson & Johnson complains that if claim preclusion is not applied here, it will have defend itself against accusations similar to those in which it prevailed earlier. This point has no force. Claim preclusion is the exception, not the rule, when parties are different. As a result, nothing is more common than the same defendant having to litigate, in numerous different lawsuits, claims with a common nucleus of fact. For example, one of the defendants here, Merck, is having to litigate the legal issues associated with the properties of the drug Vioxx in hundreds of different cases across the country, because each different Vioxx plaintiff has significantly different interests than each other one does. Similarly, the State had entirely different interests than the private plaintiffs and class members had in the MDL proceedings.

In short, Johnson & Johnson’s claim preclusion argument has no merit. Ironically, the preclusive effect Judge Saris’s decision will help the *State*, not defendants. Under the doctrine of *issue* preclusion (formerly called collateral estoppel), factual findings made by Judge Saris in the

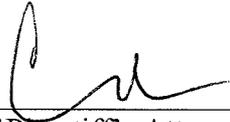
case may be used by the State against Johnson & Johnson, AstraZeneca, Schering-Plough/Warrick, and Bristol Myers-Squibb (BMS), who were parties in the trial. *See Northern States Power Co. v. Bugher*, 189 Wis.2d 541 (Wis. 1995). Judge Saris found that Johnson & Johnson reported AWP's that it knew were well above the actual average wholesale prices of its drugs. *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F. Supp.2d 20, 33 (D. Mass. 2007). She also found that Johnson & Johnson discounted its price below its published WAC, *id.* at 54-55, "there was serious concern that the government would find out about the spreads and take action to reduce the reimbursement amounts," *id.* at 55, and that despite these concerns Johnson & Johnson actively encouraged its sales representatives to "market the spread" by urging on providers their opportunity to make profits by selecting Johnson & Johnson's drugs. *Id.* at 55. She made similar findings as to defendants AstraZeneca, Schering-Pough/Warrick and BMS. *Id.* at 31 (AstraZeneca, Schering-Plough/Warrick, BMS), 50-54 & 102-103 (AstraZeneca), 59-70 & 104-108 (BMS), 70-75 & 108-109 (Schering-Plough/Warrick). These findings are binding on Johnson & Johnson, AstraZeneca, Schering-Plough/Warrick, and BMS under the doctrine of issue preclusion. Those findings therefore furnish yet additional reasons to enter summary judgment against Johnson & Johnson and AstraZeneca under §100.18 on the issue of liability, and to deny the cross-motions of Johnson & Johnson, AstraZeneca, and Schering-Plough/Warrick.

### **CONCLUSION**

The State respectfully requests that the Court (1) enter summary judgment on Counts I and II on the issue of liability against defendants AstraZeneca, Johnson & Johnson, Novartis, and Sandoz and set appropriate further proceedings to determine appropriate injunctive and damage

relief against them; (2) deny these defendants' cross-motions for summary judgment; and (3) deny the remaining defendants' cross-motion for summary judgment.

Dated this 7th day of March, 2008.



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