

Defendant Sandoz Inc. (“Sandoz”) respectfully submits this reply memorandum in further support of its Cross Motion for Summary Judgment. As shown below, the State’s Opposition fails to raise a genuine issue of material fact, and Sandoz is entitled to summary judgment as a matter of law.¹

INTRODUCTION

The State’s Opposition concedes the central facts supporting Sandoz’ Cross Motion. Among other things, the State concedes that its Maximum Allowable Cost (“MAC”) program played a central role in controlling reimbursements for generic drugs, and that MACs were set using transaction-based information obtained from the marketplace, not AWP or WACs. Indeed, for Sandoz in particular, the State concedes that MACs and provider supplied usual and customary charges, another measure not calculated using AWP or WACs, were used 96% of the time to reimburse for Sandoz drugs.

Further, for the few instances in which the State’s discounted AWP formula might have been relevant, the evidence shows that Sandoz’ AWP were precisely what the State and others expected them to be, benchmarks set based on AWP already existing in the marketplace to help identify Sandoz products as generics that would be priced as such in the marketplace.

To avoid the consequences of this devastating evidence, the State seeks to kick the can down the road and otherwise divert the Court’s attention from the facts showing Sandoz’ entitlement to summary judgment. Thus, the State claims that “causation” is irrelevant at this stage because the State is seeking injunctive relief. But the State ignores the fact that Sandoz’ motion is directed to dismissing its claims for pecuniary loss precisely because it can produce no evidence of causation. The State’s argument, shorn of rhetoric and misdirection, is that

¹ Sandoz also joins and incorporates by reference Defendants’ Reply (“Joint Reply”), AstraZeneca’s Reply and Novartis’ Reply.

causation should be addressed at some later point in the case. But if it cannot establish the existence of a question of material fact on causation in response to Sandoz' motion, there is no later phase necessary.

Likewise, the State's Opposition avoids Sandoz' central arguments, ignores the distinctions between the generic, self-administered pills sold by Sandoz and other drugs, such as brand name drugs or physician administered drugs, and otherwise improperly lumps "the Defendants" together. The State's sleight of hand cannot hide the flaws in its "plain meaning" argument or the failure to provide any evidence of an actionable statement made by Sandoz in Wisconsin.

We address these issues below in further detail, as well as the infirmities in the State's arguments regarding the statute of limitations.

ARGUMENT

I. HAVING ADMITTED THAT 96% OF ITS REIMBURSEMENTS FOR SANDOZ DRUGS WERE NOT BASED ON SANDOZ AWPS, THE STATE'S CLAIMS REGARDING SUCH REIMBURSEMENTS MUST BE DISMISSED

Sandoz' Cross Motion is directed in significant part at dismissal of the State's claims for pecuniary loss under Section 100.18. To be entitled to recover such pecuniary loss the State must be able to prove causation. In its moving papers, Sandoz demonstrated that the State's allegations regarding AWP and WAC were largely irrelevant because the State rarely used its discounted AWP formula to reimburse for Sandoz drugs, and never used WAC to reimburse for a Sandoz drug. The claims data provided by the State show that the vast majority – over 96% – of claims for Sandoz drugs were reimbursed at the State-created MACs (87%) or the provider-created usual and customary charges (9%). Less than 4% of the claims for Sandoz drugs were reimbursed on the discounted AWP formula, and not one was reimbursed on WAC. The State

does not dispute these facts. See Plaintiff's Response to Sandoz' Additional Proposed Undisputed Facts ("Pl. Resp. to SAPUF") ¶ 142 and Plaintiff's Response to Defendants' Joint Additional Proposed Facts ("Pl. Resp. to DAPUF") ¶ 45.

Moreover, with respect to its MAC program, the State concedes, among other things, that: (1) MACs were set at the discretion of State Medicaid (Pl. Resp. to SAPUF ¶¶ 146-47, 149, 155-58); (2) MACs were based on actual transaction prices in the marketplace obtained from retail buying groups or wholesalers, and were not based AWP or WAC (*id.* ¶¶ 153-58; 161-63); (3) MACs were set at levels to ensure that each retailer in the State would be able to purchase the product at or below the MAC, and thus provided a profit on the so-called "ingredient cost" (*id.* ¶¶ 155-58); and (4) AWPs were not used for setting MACs precisely because the State knew the selling prices were lower (Pl. Resp. to DAPUF ¶ 27). As the State put it, when a MAC is in place, the State "reimburses on the basis of MAC[] rather than AWP" to reduce the State's reliance on discounted AWPs for reimbursement. Opp. at 66.²

A claim for damages under Section 100.18 requires proof that defendant's "representation caused the plaintiff a pecuniary loss." *K & S Tool & Die Corp. v. Perfection Mach. Sales, Inc.*, 2007 WI 70, ¶ 19, 301 Wis. 2d 109, 122, 732 N.W.2d 792, 798 (Wis. 2007). These undisputed facts show no causal connection between the alleged wrongdoing – unfair, deceptive or misleading AWPs and WACs – and the State's claimed pecuniary loss, paying too much in reimbursement. Sandoz Br. at 60-62. Thus, at a bare minimum, the State's claims under Section 100.18 relating to reimbursements that were not paid using the State's discounted AWP formula should be dismissed.

² In fact, the State admits that its MACs were, on average, approximately 65% below AWP. Pl. Resp. to SAPUF ¶ 133.

Nothing in the State's Opposition saves its claims. First, the State claims that it is "irrelevant" that it did not use Sandoz AWP's for reimbursements based on State-created MACs or provider-created usual and customary charges because the State is seeking an injunction and thus is not required to show "causation" or pecuniary loss to establish "liability" under Section 100.18. Opp. at 10. Sandoz' Cross Motion, however, seeks dismissal of the State's claims for alleged pecuniary losses. The State consequently must establish "causation," as the remedial provisions for Section 100.18 clearly condition recovery of pecuniary losses on proof that the loss was suffered "because of" acts in violation of Section 100.18. See Wis. Stat. §§ 100.18(11)(d) and 100.18(11)(b)(2).³ Having failed on summary judgment to show causation of pecuniary loss, the State must suffer the consequences, dismissal.

In a companion argument buried in a hard to follow footnote, the State suggests that "[a]t the appropriate time" it will show how AWP's/WAC's affected reimbursements even when the State paid on the basis of a State-created MAC. See Opp. at 10-11, n.1. The State was required, however, to present such evidence (if it exists) in response to Sandoz' Cross Motion, or else suffer dismissal of its claims. See Wis. Stat. § 802.08(3); *Bantz v. Montgomery Estates, Inc.*, 163 Wis. 2d 973, 984, 473 N.W. 2d 506, 510 (Ct. App. 1991). Moreover, the State's speculation is flatly contradicted by the undisputed facts regarding the State's MAC program. See, e.g., Pl. Resp. to SAPUF ¶¶ 153-154 (MACs set without reference to AWP or WAC); *id.* ¶¶ 155-158 (MACs set at 10-25% above price at which all retailers presumably could purchase drug); Opp. at 66 (MACs used to reduce reliance on discounted AWP; for drugs with MACs, State reimbursed on basis of MAC rather than AWP).

³ The State's flawed arguments regarding the elements required for injunctive relief are addressed in Section II of the Joint Reply and Section 1 of Astra Zeneca's Reply.

Nor does the State's short affidavit from Ted Collins, the State's Pharmacy Consultant who was responsible for setting MACs at his discretion for the period from 1979-1984 and again from 1999 to the present, and who testified as the State's 804.05(2)(e) designee on issues relating to its MAC program, establish any question of fact. Although barely referenced in the State's brief, the Collins affidavit hypothesizes that "Wisconsin's MAC program is significantly impacted by defendants' AWP operationally" and speculates that had Collins received supposedly "true" AWP that were lower than the MACs he set, he might have used the "true" AWP. Opp., Ex. 4, ¶¶ 8, 10.

The Collins affidavit, which contains nothing but rank speculation, is a classic "sham" affidavit and cannot create a fact issue. *Yahnke v. Carson*, 2000 WI 74, ¶ 19, 236 Wis. 2d 257, 270, 613 N.W.2d 102, 108 (Wis. 2000) (adopting "sham" affidavit rule and finding affidavit which contradicted prior deposition testimony insufficient to create a genuine issue of fact). Indeed, Collins testified AWP played no role in setting Wisconsin MACs because he knew the selling prices he had access to were lower. Pl. Resp. to DAPUF ¶ 27. More importantly, he testified that he set MACs at a level 10-25% higher than the selling price he believed would at least be accessible to all retailers in the State. Pl. Resp. to SAPUF ¶¶ 155-158; 162-63. And the State admitted that it did not use pricing from certain sources because those prices might not have been available to all retail pharmacies. SAPUF ¶ 165. Collins cannot now speculate in response to Sandoz' motion that if he had different information regarding *average* prices at the retail level, he might have used such average prices to establish MACs, because average prices would not represent prices available to all retailers in the State. *See, e.g., Helland v. Kurtis A. Froedtert Mem'l Lutheran Hosp.*, 229 Wis. 2d 751, 756, 601 N.W.2d 318, 321 (Ct. App. 1999) (explaining that "[i]t is not enough to rely upon unsubstantiated conclusory remarks [or]

speculation” to defeat motion for summary judgment); *see also* Wis. Stat. § 802.08(3). In any event, the Collins affidavit provides no facts as to the Sandoz drugs (or any other company’s drug) at issue.

Lastly, there is no evidence to support the State’s conjecture that “pharmacies often use the defendants’ AWP as their usual and customary charges.” Pl. Resp. to SAPUF ¶ 135. The single witness (a Shopko representative) cited by the State testified that (1) individual Shopko stores set usual and customary charges based on market conditions; and (2) there is no direct relationship between AWP and usual and customary charges. Lori L. Neumann Tr. at 147:9-148:15 (attached hereto as Exhibit A). This of course makes sense, because Wisconsin requires each provider to submit as its usual and customary charge the provider’s charge for providing the same service to a private-pay patient. SAPUF ¶ 135. Again, the State has failed to provide any facts connecting a Sandoz AWP to the provider-submitted usual and customary charges that were used to reimburse Sandoz drugs on 9% of the claims at issue in this case. Nor could it, because the usual and customary charge in those instances must have been lower than the discounted AWP calculation, or else the usual and customary charge would not have been used as the basis of payment.

II. THE STATE’S OPPOSITION OTHERWISE FAILS TO SAVE ITS SECTION 100.18 CLAIMS

With respect to the few transactions in which Sandoz drugs may have been reimbursed based on the State’s discounted AWP formula, the State’s claims also fail. In its Opposition, the State does little more than seek to avoid its failure to come forward with evidence to support its supposedly “plain meaning” definition and divert attention from the undisputed facts regarding Sandoz.

For example, the State argues against a straw man, whether AWP is a “term of art,” something Sandoz did not argue and is not required to prove. What the State seeks to avoid is the substantial evidence regarding Sandoz’ practice for setting AWP’s and why those AWP’s were not untrue, deceptive or misleading, but instead were precisely what they were expected to be. The point of Sandoz’ argument was that under Section 100.18, statements must be examined in context, and Sandoz’ AWP’s were not unfair, deceptive or misleading when reviewed in proper context, with much of that context being the undisputed facts regarding the State’s MAC program,⁴ as well as information regarding AWP’s known by the State dating back to 1975. To this point, the State has no response.⁵

The State elsewhere seeks to shift the burden and divert attention by claiming that the “Defendants” fail to explain how AWP is a benchmark and are really claiming that AWP means “whatever figure we choose to provide to FDB.” Opp. at 18-19. The evidence shows, however, that Sandoz’ AWP’s were set at 85-90% of the already existing brand AWP, or were set at around the AWP’s for existing generic competition (not at whatever level Sandoz chose), in order to permit classification as a lower priced generic drug. See SAPUF ¶¶ 58-69 (discussing Sandoz’ practices and First DataBank indicators). The State admits a number of these facts. See Pl. Resp. to SAPUF ¶¶ 58-59, 63, 65, 67. As for the others, the State labels each as “disputed” because it allegedly is “[n]ot supported by record cite provided,” but nowhere provides an explanation for this position because there is none. See Pl. Resp. to SAPUF ¶¶ 60-62, 64, 66, 68-69. The facts are clear from the cited material.⁶

⁴ See, e.g., Section I, *supra*; Pl. Resp. to SAPUF ¶¶ 176-81 (admitting State received provider invoices showing both actual acquisition cost and AWP’s from wholesalers).

⁵ See Novartis’ Reply at Section A (discussing relevant case law).

⁶ Other examples of misdirection include: (1) The State continually misstates the federal requirements for receiving matching funds. Although the State concedes in responding to the Joint fact statement that the “estimated acquisition cost” measure in federal regulations does not apply to generic drugs for which CMS has set a “Federal Upper Limit” (see, e.g., Pl. Resp. to DAPUF at ¶ 73), the State’s brief repeatedly argues that federal law requires the

The State's reliance on Judge Saris' opinions in a private class action regarding Medicare Part B reimbursements likewise does nothing to support its claims as to Sandoz. Judge Saris' factual findings and legal rulings during a bench trial, *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F. Supp. 2d 20 (D. Mass. 2007) ("*AWP I*"), are not evidence in this case and have nothing to do with Sandoz or the drugs at issue here.⁷ Moreover:

- Sandoz was not a party in that case;
- No evidence about Sandoz or Wisconsin was presented;
- The trial addressed only physician administered drugs under Medicare Part B, not the self-administered drugs sold by Sandoz and reimbursed under Medicaid; and
- Generic drugs were excluded from the Class 3 claims because MACs were not calculated using AWP.

In re AWP II, 491 F. Supp. 2d at 39.⁸

Judge Saris' "plain meaning" interpretation of the phrase "average wholesale price" in the Medicare Part B statute, *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 460 F. Supp. 2d 277 (D. Mass. 2007) ("*AWP I*"), likewise offers no support to the State because, *inter alia*, Judge Saris herself later questioned that interpretation and, more importantly, did not

State to measure "estimated acquisition cost" for each drug. *See, e.g.*, Opp. at 1, 3-4. The State has it wrong, because that measure does not apply for FUL drugs, as the relevant regulations plainly explain. *See* 42 C.F.R. §§ 447.512, 514. Likewise, federal regulations do not require the State to pay the lower of FUL, estimated acquisition cost or usual and customary. *Id.* (2) The State asserts without citation that "[t]he prices the State paid providers were an arithmetic consequence of a formula in which AWP was the only variable" (Opp. at 11), which omits the generic drug MACs which were set at the discretion of the State based on information other than AWP, and the provider-submitted usual and customary charges. (3) The State discusses testimony from a Shopko witness (Opp. at 19), but that testimony does not relate to a Sandoz product, and the State's argument ignores both the central role of its MAC program in controlling costs by obtaining transaction prices from the marketplace as well as the witness' testimony (noted above) that Shopko's usual and customary charge is not connected to AWP.

⁷ Consequently, the State's factual arguments that rely on Judge Saris' findings are nothing more than naked assertions that fail to create genuine factual issues for trial. *See, e.g.*, Opp. at 21. The same holds true for the State's use of *In re Lorazepam and Clorazepate Antitrust Litig.*, 467 F. Supp. 2d 74 (D.D.C. 2006). *See, e.g.*, Pl. Resp. to SAPUF ¶ 78.

⁸ Additionally, in another AWP case, Judge Saris granted defendants' motion to dismiss MAIC drugs because the State (California) created its MAICs from marketplace transaction information, not AWP. *In re Pharm. Indus. Average Wholesale Price Litig.*, MDL No. 1456 (C.D. Cal. No. 03-CV-2238) (D. Mass. March 22, 2007). California's MAICs are roughly equivalent to Wisconsin MACs.

even follow that guidance at the trial of the class action claims. See *In re AWP II*, 491 F. Supp. 2d at 97 n.27; Novartis Reply, Section B.

The State's "plain meaning" argument simply fails when considered in the context of the State's reimbursement system, which for generic drugs relies heavily on MACs, and the information available regarding Sandoz. As addressed more completely in the moving papers, AWP cannot have a "plain meaning" of "actual average of wholesale prices" when (1) the State's own MAC program ignores it precisely because the State knew selling prices were lower (Pl. Resp. to DAPUF ¶ 27); (2) the State discounts the AWP when it is used in reimbursement, again precisely because it knows it is not an actual average; (3) the State had in its possession the AMP information for all of Sandoz' products, either directly from Sandoz or indirectly through the Unit Rebate Amounts ("URAs") received from CMS (SAPUF ¶¶ 113-15);⁹ (4) the State and other marketplace participants understood the nature of AWP and its use as a benchmark; and (5) the State's own source of information, First DataBank, called the information it received from Sandoz "Suggested Wholesale Price," which was not a transactional price (Pl. Resp. to DAPUF ¶ 231; Pl. Resp. to SAPUF ¶ 81).¹⁰

III. COUNTS III THROUGH V ARE TIME BARRED

Section V.A of the Joint Reply addresses the flaws in the State's response to Defendants' statute of limitations arguments. The State's Opposition fails to raise any fact issue with the Sandoz-specific evidence regarding what the State knew or should have known regarding Sandoz, making Sandoz' statute of limitations defense even more compelling.¹¹

⁹ The State's improper denial of these facts is addressed in Section III, *infra*.

¹⁰ Other infirmities in the State's "plain meaning" argument are addressed in Novartis' Reply. With respect to the State's failure of proof on the "In the State" and "Statement" requirements of Section 100.18, Sandoz relies upon AstraZeneca's Reply.

¹¹ The State does not contest that the limitations period for Sandoz started to run on November 1, 2004, the date the First Amended Complaint adding Sandoz was filed.

Sandoz provided Average Manufacturer Price (“AMP”) information for each Sandoz drug on a quarterly basis to the State beginning in 1991. SAPUF ¶ 115. The State’s only response to these facts is the naked assertion that they are “not based on admissible evidence.” No substantive explanation, however, is provided as to why Sandoz’ correspondence with the State would not be admissible to show the information the State received regarding Sandoz’ AMPs, because there is none.¹²

The State also received URAs for each Sandoz drug since 1991, from which the State knew it easily could calculate AMPs. SAPUF ¶¶ 113-114. The State’s citation of 42 U.S.C. § 1396r-8 and a letter from CMS, both of which address the use of such information, hardly count as “contrary evidence,” and are nonetheless contradicted by the State’s admission that in some instances it requested AMP information to help it set MAC prices.¹³ Pl. Resp. to SAPUF ¶ 164. The relevant question for statute of limitations purposes is whether the State knew or should have known the true nature of Sandoz’ AWP, and the Sandoz AMPs and URAs indisputably provided the State with substantial information regarding Sandoz’ transaction prices at the retail level. Whether or not the State could disclose such AMP information or use URAs to calculate “estimated acquisition cost” is beside the point.

CONCLUSION

For the foregoing reasons, Sandoz respectfully requests the Court grant Sandoz’ Cross Motion for summary judgment and dismiss the Second Amended Complaint in its entirety as to Sandoz or, in the alternative, grant partial summary judgment dismissing Counts I and II as to Sandoz for all claims not reimbursed on the discounted AWP formula.

¹² Contrary to the State’s assertion (Opp. at 39 n.5), the State also had the right to receive AMPs from CMS. SAPUF ¶ 112; 42 U.S.C. § 1396r-8(b)(3)(D). The State’s effort to “dispute” this fact is not well taken because it misreads the statute and ignores the cited evidence.

¹³ See, e.g., *Garrott v. Bd. of Regents of the Univ. of Wis. Sys.*, 381 F. Supp. 2d 927, 930 (W.D. Wis. 2005) (rejecting effort to dispute fact where party failed to cite evidence that put fact in dispute).

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