STATE OF WISCONSIN | CIRCUIT COURT Branch 9 | DANE COUNTY

STATE OF WISCONSIN, Plaintiff, v. AMGEN INC., *et al.*, Defendants.	))))))))))	Case No. 04-CV-1709

DEFENDANTS SCHERING-PLOUGH CORPORATION[1] AND WARRICK PHARMACEUTICALS CORPORATION'S REPLY MEMORANDUM TO STATE OF WISCONSIN'S SUPPLEMENTAL RESPONSE TO MOTION FOR SUMMARY JUDGMENT OF SCHERING-PLOUGH AND WARRICK

INTRODUCTION

The State's Supplemental Response ("State's Supplemental Response") to Defendants Schering-Plough Corporation ("Schering-Plough") and Warrick Pharmaceuticals Corporation's ("Warrick") Motion for Summary Judgment fails to cite a single piece of evidence for its assertions and, ultimately, fails to counter Schering-Plough and Warrick's arguments for summary judgment in their favor on Counts I and II of the Second Amended Complaint (the "Complaint"). The State's Supplemental Response focuses on the issues evidenced through the affidavit of Dr. Sumanth Addanki, which Schering-Plough and Warrick submitted in connection with their Motion for Summary Judgment. Despite having now engaged in discovery related to that affidavit, the State does not dispute any of the material facts that it establishes.

[1] As noted in Defendants Schering-Plough Corporation and Warrick Pharmaceutical Corporation's Motion for Partial Summary Judgment ("Motion for Summary Judgment"), Schering-Plough Corporation is a holding company that does not actually manufacture, market, or sell any of the drugs at issue in this case. Although this fact is not relied upon as a basis for the motion, it is a separate ground entitling Schering-Plough Corporation to summary judgment on all counts of the Complaint. Schering Corporation ("Schering"), a wholly-owned subsidiary of Schering-Plough, manufactures, markets, and sells the Schering-brand drugs at issue in this case.

ARGUMENT

I. WISCONSIN MEDICAID REIMBURSED MULTI-SOURCE DRUGS BASED UPON ITS MACs, WHICH WERE NOT INDUCED BY SCHERING OR WARRICK'S WACs OR AWPs.

As the State's Supplemental Response highlights, liability for multi-source drug reimbursement boils down to causation. Given this Court's recent summary judgment ruling and the Supreme Court's ruling on causation requirements under the Deceptive Trade Practices Act ("DTPA"), the State can no longer claim that causation does not matter in this litigation.[2] Because the State reimbursed multi-source drugs on the basis of MACs set through research into market prices and not based in any way on WACs or AWPs, *see* PUF, at ¶¶ 34-45, the State cannot show that WACs or AWPs reported by manufacturers had any effect on the State's reimbursement. Thus, no actions by Schering-Plough or Warrick caused any loss to the State, and the State's DTPA claims must fail.

Unable to muster any evidence in the record to support its position, the State raises two new theories of liability in its Supplemental Response. First, the State argues that the "misleading nature" of published prices "made it difficult" for Wisconsin to determine the acquisition cost of drugs and it "systematically guessed too high." *See* State's Supp. Resp., at 2. The State cites no evidence for this bald assertion. There is, in fact, no evidence that the State could cite to support this claim. The only evidence in the record on this point shows that there was no guessing involved. The State's consultant surveyed providers and wholesalers to obtain information about their actual transaction prices. *See* PUF, at ¶ 44. Indeed, the record evidence shows that the State's MAC program was wildly effective and reflected the State's knowledge

[2] *See* Decision and Order on Plaintiff's Motions for Partial Summary Judgment Against Defendants Novartis, AstraZeneca, Sandoz, and Johnson & Johnson, at 8 (May 20, 2008) (Niess, *J.*) ("Summary Judgment Order"); *Novell* v. *Migliaccio*, 2008 WI 44, at 19-20 (Feb. 29, 2008).

that price competition ensues when a brand-name drug loses its patent protection, which results in a drop-off in drug prices. *See* PUF, at ¶¶ 34-45.

Second, the State wrongly claims that "false prices" from defendants interfered with "the Medicaid processing system." *See* State's Supp. Resp., at 2. Again, however, the State cites absolutely no evidence for this assertion. The State now claims that Wisconsin's Medicaid Program was designed to pay pharmacists prescribing drugs the absolute lowest price for which those drugs could be acquired – regardless of whether a particular pharmacist actually paid that price for the drug and without providing a profit to the pharmacist on the drug cost. But, this claim is flatly contradicted by the record. The State's witness designated to testify about the MAC program explained that the State added a 10-25% mark-up to the lowest price for any drug to make sure that pharmacies serving Medicaid patients in Wisconsin would be able to acquire the drug for a price at or below the established MAC. *See* PUF, at ¶ 44.[3] Simply put, Wisconsin's MACs were as low and efficient as possible. Because Wisconsin Medicaid made such an affirmative choice in determining the level at which drugs reimbursed on the basis of a MAC would be paid, there is no genuine issue as to any material fact and this theory, too, is doomed to fail. Defendants are thus entitled to summary judgment on all claims reimbursed on the basis of MACs.

II. WISCONSIN ALSO CANNOT PROVE ITS CLAIM RELATING TO THE SCHERING-BRAND DRUGS AT ISSUE.

The record evidence demonstrates that published prices for Schering's brand-name drugs were in no way untrue, deceptive, or misleading and that Schering caused no harm to the State.

[3] Schering-Plough and Warrick have continued to emphasize this crucial fact – as their Reply Memorandum in Support of Their Motion for Partial Summary Judgment on Counts I and II of the Complaint ("Reply Memo.") notes, "the State does not dispute *the* critical paragraph in Schering-Plough and Warrick's Statement of Undisputed Facts. The State acknowledges the facts set forth in Paragraph 44 are undisputed – that, "in setting the MAC, [Mr. Collins] searched for the lowest price for the drug that was readily available in the marketplace" and "then added a 10-25% mark-up to that price to ensure that pharmacies serving Medicaid patients in Wisconsin would be able to acquire the drug for a price at or below the established MAC." *See* Reply Memo., at n.6.

The State's Supplemental Response does not dispute any of the facts in Dr. Addanki's affidavit – that the AWPs published by the pricing compendia for Schering's brand-name drugs reflected nothing more than the compendia's addition of a mark-up to Schering's reported WACs, and that Schering had significant sales at WAC. *See* Mot. for Summary Judgment, at 31-35. Instead, the State relies on statements of supposed fact that are either demonstrably false or have no support in the record.

Schering's WACs are not "untrue, deceptive, or misleading" under the DTPA but are instead "true" prices at which Schering made significant sales. *See* Mot. for Summary Judgment, at 34-35. The State now pretends, in its Supplemental Response, that WACs are irrelevant to this litigation. *See* State's Supp. Resp., at 4. Wisconsin claims that it "does not reimburse off the WAC so Schering's WAC is irrelevant." *Id.* This assertion is shocking given that the State's Complaint asserts that the State was duped by purportedly "misrepresented" and "inflated" WACs. *See* Complaint at ¶¶ 49, 53, 59. The State continues its parade of untrue facts by, next, asserting that "Schering sells virtually all of its products at a price below WAC," *see* State's Supp. Resp., at 4, despite the fact that, during the relevant time period, approximately 83% of the sales of Schering-brand drugs at issue were made at a price within 5% of WAC. *See* PUF, at ¶ 26. The State cannot meet its burden of proof in regard to the Schering-brand drugs and has not attempted to dispute the record evidence as it relates to Schering drugs.

In regard to the "spreads" that exist between WACs and AWPs, the State fails to consider this Court's summary judgment ruling that "context is relevant to the inquiry, as are any mutual understandings." *See* Summary Judgment Order, at 7. The term AWP, as it relates to brand-name pharmaceuticals, was understood in the industry to be a pricing benchmark typically 20-

25% above WAC.[4] *See* Mot. for Summary Judgment, at 32-33. As outlined in Schering-Plough and Warrick's Motion for Summary Judgment, Judge Saris examined extensive evidence on the industry understanding of the spread between AWP and WAC, and recognized the existence of a 30% "safe harbor" within which there can be no liability. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 91-92; Mot. for Summary Judgment, at 32-33. Plaintiff conveniently ignores this mutual understanding when it complains that defendants are arguing for a "normal range of falsity" in connection with the mark-up between WACs and AWPs. *See* State's Supp. Resp., at 3. In fact, the abundant record evidence shows that, in the context of the branded drug industry, AWP had a particular meaning as a pricing benchmark with a formulaic relationship to WAC. As outlined in Schering-Plough and Warrick's Motion for Summary Judgment, officials at Wisconsin Medicaid and the Wisconsin Legislature knew and understood that AWPs did not represent an actual average of transaction prices. *See* Mot. for Summary Judgment, at 35-38. For the Schering-brand drugs at issue in this case – with only a few limited exceptions – the Schering AWPs consistently fell within the "safe harbor" defined by industry expectations. *See* PUF, at ¶ 29.[5]

Finally, Plaintiff protests against Dr. Addanki's use of the Average Manufacturer Price or AMP as the baseline for his spread calculations, without providing any argument or evidence that the calculations are inaccurate. *See* State's Supp. Resp., at 3-4. However, AMP is a conservative baseline that may overstate spreads, but does not do the opposite. AMP is an average of the amount, after discounts and rebates, paid to a manufacturer by wholesalers for drugs distributed to the retail class of trade. *See* 42 U.S.C.§ 1396r-8(k)(1); PUF, at ¶ 19. AMP represents a conservative baseline because Medicaid providers, on average, pay more than AMP

[4] Mark-up percentages used by the compendia varied by the compendium and time period.

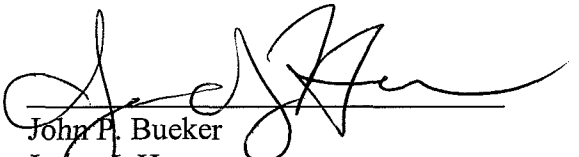
[5] As noted in Schering-Plough and Warrick's initial summary judgment brief, defendants do not mean to suggest that there should be liability for spreads in excess of 30%.

to acquire drugs. Many (if not most) Medicaid providers purchase drugs through wholesalers, which typically add a mark-up to the price at which they acquire the drug from the manufacturer or, at least, do not pass along the customary prompt pay discount extended by the manufacturer, which, during the relevant time, would have been reflected in the manufacturer's AMP. *See* PUF, at ¶ 19. The State does not provide any argument or evidence about any supposed problems with Dr. Addanki's use of AMPs. The record evidence demonstrates that the Schering-brand AWPs at issue in this case consistently fell within the "safe harbor" based on industry and Wisconsin Medicaid expectations. *See* PUF, at ¶ 29. Thus, Schering's AWPs and WACs did not cause the State any harm.

RELIEF SOUGHT

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

Respectfully submitted,



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Dated: June 9, 2008

Counsel for Defendants Schering-Plough Corporation and Warrick Pharmaceuticals Corporation

CERTIFICATE OF SERVICE

I hereby certify that on June 9, 2008, a true and correct copy of the foregoing document was served upon all counsel of record via Lexis-Nexis File and Serve.

Renée A. Coshin