

COPY

STATE OF WISCONSIN

CIRCUIT COURT
Branch 9

DANE COUNTY

STATE OF WISCONSIN,

Plaintiff,

v.

AMGEN, INC., et al.,

Defendants.

Case No. 04-CV-1709

Unclassified - Civil: 30703

**THE JOHNSON & JOHNSON DEFENDANTS' MEMORANDUM OF LAW IN
OPPOSITION TO THE STATE OF WISCONSIN'S AMENDED MOTION FOR
PARTIAL SUMMARY JUDGMENT ON LIABILITY WITH RESPECT TO COUNTS I
AND II OF WISCONSIN'S COMPLAINT, AND IN SUPPORT OF DEFENDANTS'
JOINT CROSS-MOTION FOR SUMMARY JUDGMENT**

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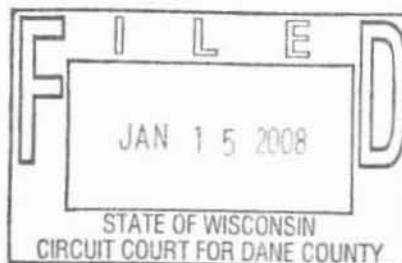


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Defendants Johnson & Johnson, Janssen L.P., McNeil-PPC, Ortho Biotech Products L.P. and Ortho McNeil Pharmaceutical, Inc. (collectively, the "J&J Defendants") respectfully submit this Memorandum of Law in Opposition to the State of Wisconsin's Amended Motion for Partial Summary Judgment On Liability Against Johnson & Johnson and its Subsidiaries With Respect to Counts I and II Of Wisconsin's Complaint.

The J&J Defendants join in and incorporate by reference the Defendants' Joint Response to Plaintiffs' Partial Motions for Summary Judgment Against AstraZeneca, Johnson & Johnson, Novartis and Sandoz & Defendants' Joint Cross Motion for Summary Judgment and Supporting Memorandum ("Defendants' Joint Response"), including the Defendants' Joint Additional Proposed Undisputed Facts ("DAPUFs") and all related exhibits and submissions.¹

There is no dispute regarding the parties or the procedural facts.

¹ The J&J Defendants have also moved separately for summary judgment on certain of the State's *parens patriae* claims based on the Judgment entered in their favor in the United States District Court in *In re Pharm. Indus. Average Wholesale Price Litig.* (hereinafter "*In re AWP*"), 491 F. Supp. 2d 20 (D. Mass. 2007).

SECTION I

INTRODUCTION AND SUMMARY OF ARGUMENT

Wisconsin says “there is no question” that the term “Average Wholesale Price” or “AWP” means “exactly what it says: the average price paid for goods for resale.” In fact, that is not what AWP means, and no one in the pharmaceutical industry who uses the term AWP – including the agency responsible for administering Wisconsin’s Medicaid program – uses it to refer to an actual transaction price, or to an average of such prices. Nevertheless, because AWP exceeds “the actual price pharmacies are generally paying” for drugs, the State would have this Court conclude that it is undisputed that “J&J has lied about what its average wholesale prices are.”²

Nothing could be further from the truth. Wisconsin’s case is premised on a lawyer-created fiction that bears no relation to reality. Within the pharmaceutical industry, the term “AWP” refers to a reimbursement benchmark that is calculated by adding a standard markup (usually 20% to 25%) to the undiscounted list price at which brand name manufacturers sell their drugs to wholesalers; AWP does not refer to an average of the prices at which wholesalers sell drugs to pharmacies and physicians. See In re AWP, 491 F. Supp. 2d at 40. This is true for every brand name drug sold in the United States, not just those brand name drugs sold by the J&J Defendants.³ (See Johnson & Johnson Defendants’ Proposed Undisputed Facts (“JJPUF”) ¶¶ 12-13, 18-23; DAPUF ¶¶ 1-30).

² See Memorandum in Support of State of Wisconsin’s Amended Motion for Partial Summary Judgment On Liability Against Johnson & Johnson and its Subsidiaries With Respect to Counts I and II Of Wisconsin’s Complaint (“Pl.’s J&J Mot.”) at 6 and 8-9.

³ The pricing conventions applicable to brand name drugs are not always the same for multi-source or “generic” drugs. Relevant differences are discussed by Sandoz Inc. in its separate opposition to the State’s motion for summary judgment against Sandoz.

The specialized meaning of AWP is well-understood. For example, the federal agency that administers the Medicaid program advised state Medicaid agencies in 1994 that AWP “is not ... a direct measure of true acquisitions costs” but rather a “suggested wholesale list price to the pharmacy. ... [W]holesalers compete with each other by offering pharmacies discounts from AWP.” (DAPUF ¶ 7, fn. 5). Similarly, Wisconsin’s Legislative Fiscal Bureau explained in 1999 that “AWP is the manufacturer’s suggested wholesale price of a drug and is analogous to a ‘sticker price’ of a car. It does not reflect the actual cost of acquiring the drug.” (DAPUF ¶ 10).

The fact that brand name pharmaceutical manufacturers, private insurance companies and state Medicaid agencies all use the term “Average Wholesale Price” or “AWP” to refer to a reimbursement benchmark calculated as a markup over the manufacturer’s list price (which price is commonly referred to as the “Wholesale Acquisition Cost” or “WAC”), rather than to an average of the wholesalers’ selling prices, does not make the term “untrue, deceptive or misleading” under Wisconsin law. To the contrary, a manufacturer’s use of the term “AWP” to refer to a standard markup over WAC is no more unlawful than a baker’s use of the term “Danish pastry” to refer to sweet rolls baked in the United States.

Wisconsin’s understanding of AWP’s industry-specific meaning is firmly established in the record. The very reimbursement formulas used by Wisconsin and other payors demonstrate, on their face, that AWP does not refer an average price paid by retailers. Entities that pay for drugs, such as Medicaid agencies and private insurers, routinely reimburse pharmacies and physicians at relatively steep discounts below AWP. (DAPUF ¶¶ 37-38). For example, Wisconsin’s Medicaid program has reimbursed pharmacies at discounts ranging from AWP minus 10% to AWP minus 13%. (DAPUF ¶¶ 41, 43). This practice would be nonsensical

if Wisconsin thought AWP was an average of actual wholesale prices, as it would mean that the State believed for decades that its pharmacies were losing money when they dispensed drugs to Medicaid patients. Wisconsin's practice of paying pharmacies less than AWP shows that Wisconsin understood that the term AWP does not refer to "the average price paid for goods for resale."

The State's claim that AWP is meant to refer to an actual average of wholesale prices is also belied by other features of the pharmaceutical market. For example, various Wisconsin State agencies, along with thousands of other purchasers such as hospitals, pharmacies, nursing homes, and pharmacy benefits managers, purchase drugs directly at prices well below AWP. (DAPUF ¶¶ 24-25). The fact that the State had first-hand knowledge of pharmaceutical pricing proves that it knew what AWP was (and was not) when it elected to reimburse pharmacies at a discount from AWP. The State also received countless reports from the federal government and others explaining that retail pharmacies purchase brand name drugs from wholesalers at a discount from AWP, and typically at prices very near to the published WAC prices. (See, e.g., DAPUF ¶¶ 7-30, 78-79, 145, 164). These WAC prices appear side-by-side with the AWPs in the price reporting compendia. (JJPUF ¶ 43). Indeed, in the case of the J&J Defendants, the State received WAC prices directly. (JJPUF ¶ 16).

The State's knowledge of AWP's meaning is reflected in numerous internal planning and policy documents. (DAPUF ¶¶ 1-30, 105-191). Despite this knowledge, Wisconsin's Medicaid agency, and the executive and legislative branches of the Wisconsin government, repeatedly decided not to cut the Medicaid reimbursement rate to less than AWP minus 10% or AWP minus 13%. (DAPUF ¶¶ 105-191). This evidence is fatal to Wisconsin's legal claims, because it shows beyond question that the State's use of AWP in its Medicaid

reimbursement formula was knowing and deliberate, and was not caused by defendants' allegedly untrue, misleading or deceptive statements concerning AWP.

Wisconsin's Medicaid officials do not deny that they made a knowing and deliberate choice to use AWP as a reimbursement benchmark. The State's lawyers, however, ask the Court to find that the State's knowing and deliberate use of AWP is irrelevant, because a manufacturer's non-literal use of the term is per se unlawful under Wis. Stat. § 100.18. See Pl.'s J&J Mot. at 16-17. They press this point even though the agency charged with administering Wisconsin's Medicaid program, and the legislative and executive branches of Wisconsin's government, all used the term AWP in exactly the same way that manufacturers used it.

Wisconsin law does not require such an outlandish result. Wis. Stat. § 100.18 does not prohibit parties from using standard industry terminology simply because the words "average," "wholesale" and "price" are defined differently in the dictionary. Were that the case, the Milwaukee County Zoo could not lawfully advertise an exhibit featuring "Koala Bears," because marsupials are not "bears" as defined in the dictionary.

The State also maintains that its knowing and deliberate decision to use AWP is irrelevant, because the State's employees cannot acquiesce in a violation of Wisconsin law. See Pl.'s J&J Mot. at 18-19. This argument is misplaced. The J&J Defendants do not argue that Wisconsin is barred from suing because its Medicaid officials somehow "acquiesced" in defendants' allegedly unlawful use of the term AWP. Rather, as Wisconsin's own documents and witnesses confirm, everyone used and understood the term AWP to mean the same thing. (DAPUF ¶¶ 1-30, 63-191; JJPUF ¶¶ 12-13, 18-23). Since manufacturers and payors, including the Wisconsin Medicaid agency, were speaking the same language when they used the term AWP, its use was not "untrue, deceptive or misleading" under Wis. Stat. § 100.18.

The only court that has considered AWP's meaning in the context of pharmaceutical reimbursement has expressly rejected the State's contentions. The Hon. Patti Saris has spent years handling AWP-related claims in a class action pending in federal court in Boston. After a three-week bench trial, Judge Saris rejected the argument that a manufacturer violates state consumer protection statutes by reporting an AWP that is not a "true" average of wholesale prices. See In re AWP, 491 F. Supp. 2d at 32 (rejecting plaintiffs' theory that defendants acted "unfairly and deceptively by having any spread between the published AWP and the true average of prices charged to providers"). As Judge Saris noted, from at least 1990 onwards, "most knowledgeable insiders understood that AWP did not reflect the average sales price to providers, but that it bore a formulaic relationship to WAC of a 20 to 25 percent markup." Id. at 40. Nor did payors believe that actual "spreads" were limited to the published difference between WAC and AWP: "payors were aware that there was some discounting from WAC." Id. Indeed, standard industry markups between WAC and AWP have existed for brand name drugs since the 1960's. Id. at 32, 91.

Johnson & Johnson was a defendant in that trial, and the AWP claims against Johnson & Johnson and its subsidiaries were dismissed, because the spreads on the Johnson & Johnson drugs "never substantially exceeded the range of what generally was expected by the industry and government." Id. at 31. Judge Saris did find liability as to certain brand name drugs, but only as to those with so-called "secret mega-spreads far beyond the standard industry markup." Id. at 95. Judge Saris also ruled that the Federal Trade Commission's "wholesale price" precedents, which the State relies upon in its brief, were inapplicable to defendants' AWPs, because those guidelines are directed to protecting the "consuming public" from

“misleading prices,” whereas drug manufacturers “are not advertising prices to the consuming public.” *Id.* at 84.

In sum, the State’s motion for summary judgment, like its case as a whole, is based on a legal artifice that bears no connection to reality. Some of Wisconsin Medicaid’s employees apparently agree. When asked to comment on the State’s claim, one responded that: “some here view [this] suit as baseless because it has been generally known for years that ‘AWP’ does not truly reflect a manufacturer’s average wholesaler price.” (DAPUF ¶ 23). Plaintiff’s motion must be denied.

SECTION II

RESPONSE TO CLAIMS

The J&J Defendants incorporate by reference the Responses To Claims in the Defendants’ Joint Response.

SECTION III

ELEMENTS OF DEFENSES

The J&J Defendants incorporate by reference the Elements of Defenses in the Defendants’ Joint Response.

SECTION IV

RESPONSE TO PROPOSED UNDISPUTED FACTS

A. Responses to Plaintiff’s Proposed Undisputed Facts

1. Disputed in part based on the State’s mischaracterization of the word

“purchase.” Wisconsin’s Medicaid program “reimburses” for drugs; it does not “purchase” drugs. See In re: Rezulin Prods Liab. Litig., 390 F. Supp. 2d 319, 333 (S.D.N.Y. 2005); In re AWP, 491 F. Supp. 2d at 84.

2. Not disputed.
3. Not disputed.
4. Disputed based on contrary evidence.

The J&J Defendants have reported a “list price” (also called a “direct distributor price” or “Wholesale Acquisition Cost”) for their drugs, together with an “AWP” or a “Suggested AWP” for their drugs based on an industry-standard markup between list price and AWP. The J&J Defendants did not send documents to anyone purporting to state actual averages of wholesaler prices for their drugs. (See Affidavit of William Parks (“Parks Aff.”) ¶¶ 3-5, 13).

5. Disputed based on contrary evidence.

The J&J Defendants’ “AWPs” are “true” AWP’s because they reflect the standard markup over the J&J Defendants’ list price to wholesalers, and were so understood by the pricing compendia, wholesalers and payors, including the State of Wisconsin. (See Parks Aff. ¶¶ 8-14; see also DAPUF ¶¶ 1-23).

6. Not disputed.
7. Disputed in part based on contrary evidence.

There is no evidence that the J&J Defendants ever represented to anyone that AWP was the price retailers paid to acquire drugs from wholesalers or any J&J Defendant. (See Parks Aff. ¶ 13).

8. Not disputed.
9. Disputed in part based on contrary evidence.

The J&J Defendants did not send documents to anyone purporting to state actual averages of wholesaler prices for their drugs. They used the terms “AWP” or “suggested AWP,” which do not denote actual averages of wholesaler prices. (See Parks Aff. ¶¶ 3-14).

10. Disputed based on contrary evidence.

The J&J Defendants did not understand that AWP was “intended to represent the average price at which wholesalers sell drugs” and, indeed, understood that AWP was not intended to represent the average price at which wholesalers sell drugs. The inaccurate description of AWP quoted in the State’s motion was copied verbatim from a report available on the internet by a group called the National Health Policy Forum, and was so cited in the email quoted by the State. It does not represent the views of the J&J Defendants. (See Parks Aff. ¶¶ 3-14; February 6, 2007 deposition of Diane Ortiz at 73:17-76:4, 172:8-173:3).

B. Defendants’ Joint Additional Proposed Undisputed Facts

11. The J&J Defendants join, adopt and incorporate as if fully set forth herein the Defendants’ Joint Additional Proposed Undisputed Facts as set forth in Defendants’ Response.

C. The J&J Defendants’ Proposed Undisputed Facts

(i) Brand Name Pharmaceutical Pricing Conventions

12. Nearly all brand name pharmaceuticals sold in the United States, including those sold by the J&J Defendants, have a published wholesale list price (sometimes referred to as “wholesale acquisition cost” or “WAC”) and a published “average wholesale price” or “AWP.” (See In re AWP, 491 F. Supp. 2d at 32-33; Parks Aff. ¶¶ 2, 5; Affidavit of Gregory Bell (“Bell Aff.”) ¶¶ 11, 13).

13. Since the 1960’s, there has been an “industry standard markup” between the WAC price and the AWP for brand name drugs of 20-25%. In re AWP, 491 F. Supp. 2d at 32-33, 91. This means that, for nearly all brand name drugs, not just those manufactured by the J&J Defendants, the published AWP is either 20% or 25% higher than the published WAC price. (Parks Aff. ¶ 4-5; Bell Aff. ¶ 13).

14. The J&J Defendants typically sell their drugs to wholesalers at or about the published WAC price, usually offering a small “prompt payment” discount of 2% if the

wholesaler pays within 30 days. (See Parks Aff. ¶ 7; see also May 16, 2007 Hearing Tr. at 22:8-16 (recording a colloquy in which MDL plaintiffs' counsel agrees with the Court's assessment that there are other "bona fide" and "routine[]" discounts, such as the prompt-pay discount, over and above the 20-25% mark-up, that are not indicative of any "kind of problem" or "violat[ion]")).

15. Wholesalers in turn typically resell brand name drugs to retail pharmacies at a small markup over what they pay to acquire the drugs from the manufacturer, *i.e.*, at a price at or within a few percentage points of the published WAC price. (See [REDACTED]; [REDACTED]; PSW_00010530-531 at 531; *In re AWP*, 491 F. Supp. 2d at 33).

16. WACs and AWP for virtually all brand name drugs are available from the national pricing compendia, including First DataBank and Red Book, and are sometimes provided to Wisconsin Medicaid directly by the J&J Defendants. (See August 27, 2007 deposition of Patricia Kay Morgan ("Morgan Tr.") at 29:4-11; Parks Aff. ¶¶ 2-4; September 15, 2006 deposition of William Parks ("Parks Tr. ") at 193:18-194:6).

17. Because the relationship between WAC and AWP is usually fixed at 20% or 25%, the price that retailers pay wholesalers can be expressed, in percentage terms, either as a markup over the WAC price, or as a discount from the AWP. For example, if the AWP for a given drug is 20% above the WAC price, the discount from the AWP to the WAC price is 16 2/3%. Similarly, if the AWP is 25% above WAC, the discount to the WAC price is 20%. (Parks Aff. ¶¶ 4-5; Bell Aff. ¶ 13).

18. Wisconsin's Medicaid agency, and the executive and legislative branches of the Wisconsin government, know that pharmacists typically purchase brand name drugs at

prices approximating the reported WAC prices, not at the reported AWP. (See, e.g., DAPUF ¶¶ 78-79, 145, 164; see generally DAPUF ¶¶ 9-30).

19. Wisconsin's Medicaid agency, and the executive and legislative branches of Wisconsin's government, recognize that the difference between the Medicaid reimbursement rate and the pharmacists' acquisition cost represents "profit" to the pharmacist. (See, e.g., DAPUF ¶¶ 74, 78-81, 104, 145).

20. Wisconsin's Medicaid agency, and the executive and legislative branches of the Wisconsin government, intend the AWP-based reimbursement formula to provide a profit margin to pharmacists to ensure that a sufficient number of pharmacists participate in Medicaid to meet federal access guidelines. (See DAPUF ¶¶ 63-104).

(ii) The J&J Defendants' Pricing Reporting Practices Are Consistent with Industry Norms

21. The historical markup between WAC and AWP for the J&J Defendants' drugs was consistent with industry practice and norms. (Parks Aff. ¶ 4).

22. The J&J Defendants do not know precisely how much wholesalers charge retail pharmacies for the J&J Defendants' drugs. Hence they could not have calculated a precise average of the wholesalers' prices to retailers. Any attempt by the J&J Defendants to report "average" prices paid by retailers as "AWPs" would have been confusing and misleading to payors, who, like Wisconsin Medicaid, base their reimbursement formulas on the expectation that AWP is systematically higher than the average price charged by wholesalers. (See Parks Aff. ¶¶ 9-14).

23. The J&J Defendants never told Wisconsin or anyone else that AWP represents the wholesalers' actual average selling price to retail pharmacies. (See Parks Aff. ¶ 13).

(iii) Pharmacies in Wisconsin Lose Money Dispensing Some of the J&J Defendants' Drugs

24. Reimbursement for filling Medicaid prescriptions takes two forms:

(i) reimbursement for acquiring the drug based on a formula of AWP minus 13%, and (ii) a dispensing fee. (See DAPUF ¶¶ 40-41). Since at least 1990, Wisconsin Medicaid has paid pharmacies a dispensing fee which it knows is inadequate to cover the pharmacies' actual dispensing costs. (See DAPUF ¶¶ 82-104).

25. Some pharmacies in Wisconsin, including [REDACTED] [REDACTED]. (See Affidavit of Eric Gaier ("Gaier Aff.") ¶¶ 8-11).

26. Even making conservative assumptions as to the true cost of dispensing, [REDACTED] [REDACTED]. (Gaier Aff. ¶ 8).

27. [REDACTED] [REDACTED] [REDACTED]. (Gaier Aff. ¶ 9)

28. [REDACTED] [REDACTED], further cuts in the drug reimbursement amount (e.g., to AWP minus 15%), without a compensating increase in dispensing fees could, if the same pattern holds true for other drugs, produce even greater disincentives to fill Medicaid prescriptions. (Gaier Aff. ¶¶ 10-11).

(iv) The J&J Defendants Pay Rebates to the State that Lower the State's Net Reimbursement Costs Below Even Pharmacy Acquisition Costs

29. In 1990, Congress passed the Omnibus Budget Reconciliation Act

("OBRA '90"). That statute set up a mechanism whereby any pharmaceutical manufacturer seeking to have Medicaid cover its drugs had to enter into a contract with the federal government providing for the payment of rebates proportional to state Medicaid programs' utilization of their drugs. See 42 U.S.C. §1396r-8(a).

30. OBRA '90, by establishing this rebate program, made it possible for the states to pay the pharmacists at some percentage over their acquisition cost and enable them to make a profit, which would encourage their participation in the Medicaid program, while simultaneously enabling the Medicaid program to recoup a substantial proportion of that money from the manufacturers through rebates. (November 14, 2007 deposition of Theodore Marmor ("Marmor Tr.") Tr. at 412:1-413:1).

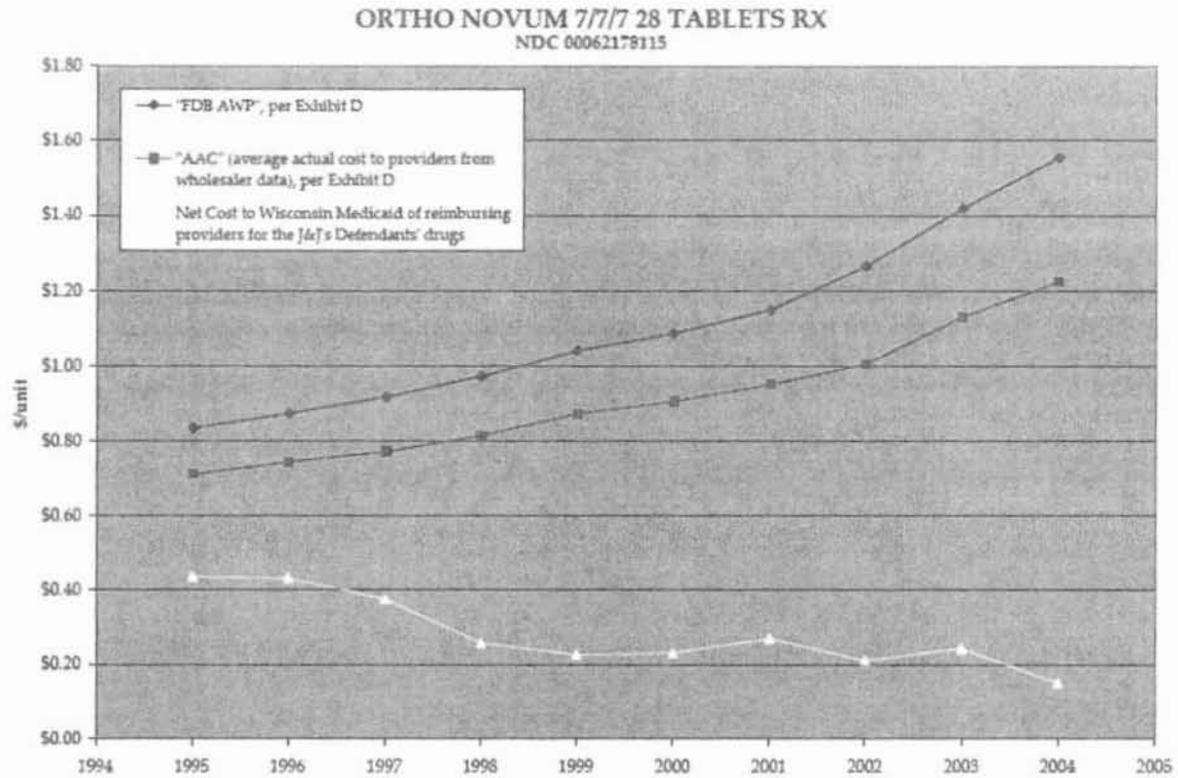
31. The J&J Defendants pay rebates to Wisconsin Medicaid pursuant to OBRA '90. (See WI-JJ00019288 through WI-JJ00019681 (rebate contracts); Affidavit of Jayson Dukes (Dukes Aff.) ¶ 6).

32. The rebates paid by the J&J Defendants ensure that Wisconsin's net cost of reimbursing providers is less than the total payments that Wisconsin makes to Medicaid providers. In effect, the rebates subsidize Wisconsin's Medicaid program by lowering its net reimbursement cost. (Marmor Tr. 416:12-417:3; see also In re AWP, 457 F. Supp. 2d 65, 74-75 (D. Mass. 2006) (damages allegedly incurred due to excessive payments to providers "will necessarily be reduced by the rebates the state received," and, therefore, "may play a role in determining the correct amount of damages in the case"))).

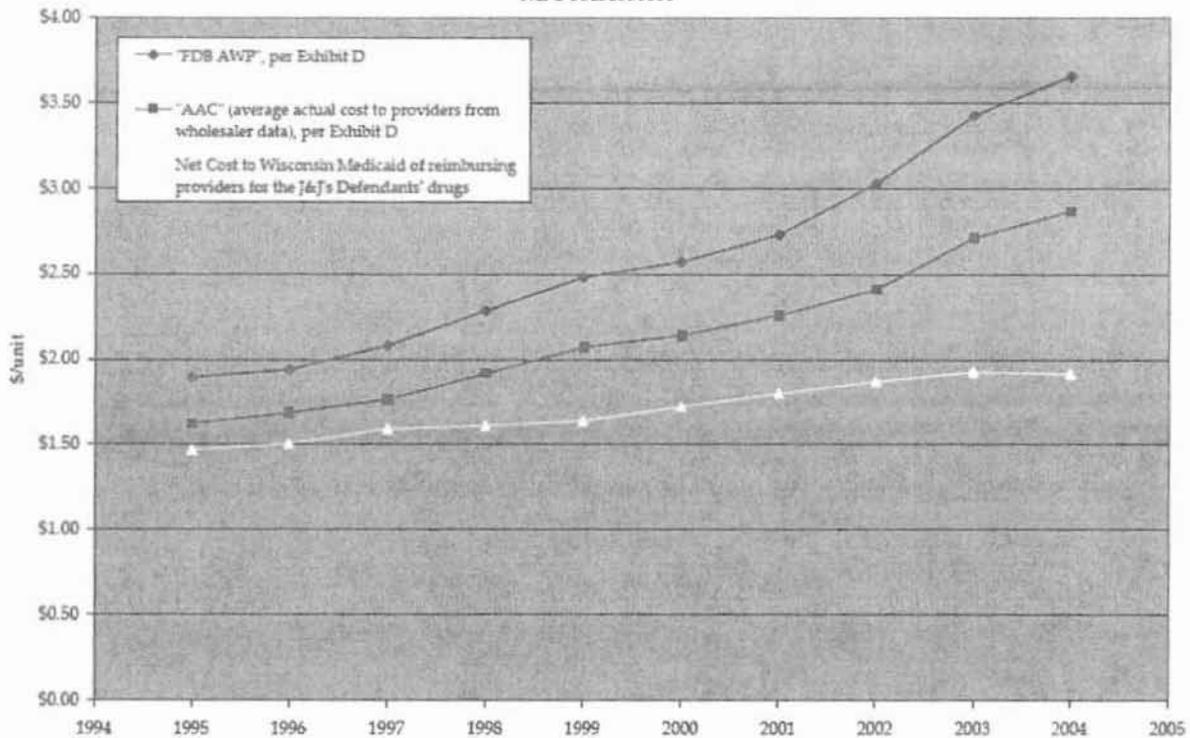
33. The net cost to Wisconsin Medicaid of reimbursing for the J&J Defendants' drugs is almost always lower than the price paid by pharmacies to purchase those drugs in the market. (Dukes Aff. ¶ 16; Dukes Aff. Ex. 2).

34. The following two examples illustrate how rebates from the J&J

Defendants lower the State's net cost of reimbursement (Dukes Aff. Ex. 2 at 24, 39):



RISPERDAL 1MG
NDC 50458030006



35. This scenario is common for the J&J Defendants' drugs paid for under the Wisconsin Medicaid program. (Dukes Aff. ¶ 16; Dukes Aff. Ex. 2).

(v) **The J&J Defendants Do Not Control the AWP's Published by First DataBank and Utilized by Wisconsin Medicaid**

36. Wisconsin purchases AWP's from First DataBank, an independent pharmaceutical price-reporting service. (Wis. Sec. Amend. Compl. ¶ 34).

37. Patricia Kay Morgan, Manager, Product Knowledge-based Services at First DataBank, has testified that First DataBank during the relevant period published at least two AWP-based pricing benchmarks for a given drug: a "Suggested Wholesale Price," which First DataBank receives from the manufacturer, and a "Blue Book" AWP, which it determines by surveying wholesalers to find out what markup they apply to the pharmaceutical company's products. (Morgan Tr. 45:2-9, 201:21-202:4).

38. Wisconsin relies on the Blue Book AWP, which First DataBank obtains

from the wholesaler, rather than the Suggested Wholesale Price, which First DataBank obtains from the manufacturer. (September 27, 2007 deposition of Carrie Gray ("Gray Tr.") at 128:11-17; Morgan Tr. 45:2-9, 201:21-202:4; MMIS RFP Q&A 9/12/90 at 39; see also DAPUF ¶¶ 229-235).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

40. Beginning in 2002, without giving advance notice to the J&J Defendants, First DataBank unilaterally raised the Blue Book AWP's it published for the J&J Defendants' drugs from 20% to 25% over the WAC price. (Parks Aff. ¶¶ 15-17).

41. When a representative of Johnson & Johnson inquired about the change, he was advised by First DataBank that the Blue Book AWP's that First DataBank published were based on the markups reported by the wholesalers. (Parks Aff. ¶ 18).

42. Beginning in 2004, the J&J Defendants stopped sending AWP's or Suggested AWP's to the wholesalers, to the price reporting services, or to anyone else. Nevertheless, the price reporting services have continued to publish AWP's on the J&J

Defendants' drugs at either WAC plus 20% or WAC plus 25%. (Parks Aff. ¶¶ 18-20).

43. First DataBank and other pricing compendia publish AWP and WAC side by side. As such, the formulaic markup between the two is readily apparent to anyone looking at the data. (Morgan Tr. 28:23-29:11, 98:4-18).

SECTION V

THE LEGAL STANDARD

The J&J Defendants incorporate by reference the Legal Standard in the Defendants' Joint Response.

SECTION VI

ARGUMENT

I. THE STATE'S MOTION FOR PARTIAL SUMMARY JUDGMENT ON ITS § 100.18(1) CLAIM MUST BE DENIED

A. The State Motion Must Be Denied Because It Has Not Proven the Elements Necessary to Establish Liability Under § 100.18(1)

Wis. Stat. § 100.18(1) requires proof of the following elements:

1. "[W]ith the intent to induce an obligation, the defendant made a representation to 'the public.'" K&S Tool & Die Corp. v. Perfection Mach. Sales, Inc., 301 Wis. 2d 109, 121-22, 732 N.W.2d 792, 798 (2007).
2. "[T]he representation was untrue, deceptive or misleading." Id.
3. "[T]he representation caused the plaintiff a pecuniary loss." Id.

The State cannot possibly prove any of these elements with respect to the J&J Defendants, let alone all three of them. At a bare minimum, summary judgment must be denied because the facts pertaining to each of these elements are disputed.

(i) **The State Offers No Evidence that the J&J Defendants Represented AWP's to the Public With the Intent to Induce An Obligation.**

The State's J&J-specific motion is silent with respect to the first element the State must prove to establish liability under Wis. Stat. § 100.18(1). Not one of the 10 supposedly "indisputable facts" listed in the State's J&J-specific motion demonstrates that the J&J Defendants' AWP's are disseminated with the intention of inducing an obligation by the State. See Pl.'s J&J Mot. at 3-5. Summary judgment must be denied on that basis alone.

As set forth in Section VI.C.3 of the Defendants' Joint Response, Section 100.18 only applies to parties who were induced or were in a position to be induced by a false or misleading representation into an obligation. The State never specifies what obligation it was allegedly induced to make by reason of the J&J Defendants' allegedly false AWP's. It does not claim, for example, that the J&J Defendants' AWP's induced it to purchase the J&J Defendants' drugs. Indeed, the State Medicaid program does not purchase the J&J Defendants' drugs; it only reimburses for drugs purchased by Wisconsin's Medicaid providers. See In re: Rezulin Prods. Liab. Litig., 390 F. Supp. 2d 319, 333 (S.D.N.Y. 2005) (insurer paid for drugs but was not a purchaser of drugs); In re AWP, 491 F. Supp. 2d at 84 (same).

Nor does the State submit evidence that Wisconsin's Medicaid providers were induced to purchase the J&J Defendants' drugs by reason of the drugs' allegedly false AWP's. There is no proof that Medicaid providers, such as retail pharmacies, purchased the J&J Defendants' drugs because they mistakenly believed that AWP meant an actual average of wholesale prices. Indeed, the Medicaid providers who purchased the J&J Defendants' drugs

knew they were not paying AWP, a fact they reported to Wisconsin Medicaid. (DAPUF ¶¶ 13-15). Nor is there proof that the State was induced to reimburse Medicaid providers for the J&J Defendants' drugs based on the drugs' allegedly false AWP. Today, almost four years after this lawsuit was filed and six years after the filing of the MDL case, Wisconsin Medicaid continues to reimburse based on AWP. (DAPUF ¶¶ 9-49, 105-191).

The deficiencies in the State's proof with respect to its Section 100.18 claim are discussed more fully in Section VI.D of the Defendants' Joint Response, which section is incorporated by reference as if set forth fully herein.⁴ (See also AstraZeneca Response Section IV.C; Novartis Response Section IV.D.3-4; Sandoz Response Section III.)

(ii) The State Cannot Prove that the J&J Defendants' AWP Were Untrue, Deceptive or Misleading.

The J&J Defendants' AWP were not "untrue, deceptive or misleading," because the term AWP, as used in the context of the brand name pharmaceutical industry, refers to a reimbursement benchmark which typically is 20% to 25% above WAC. (JJPUF ¶¶ 13, 18-23).

⁴ As noted above, the State's reliance on certain FTC cases from the early 1960s regarding list prices (Pl.'s J&J Mot. at 10), is misplaced, because those precedents were aimed at protecting the "consuming public" from "misleading prices," whereas drug manufacturers "are not advertising prices to the consuming public." *In re AWP*, 491 F. Supp. 2d at 84. In any event, the State fails to point out that the cases were overruled by the FTC's Guides Against Deceptive Pricing (the "FTC Guides"), promulgated in 1964, which provide that a list price "will not be deemed fictitious if it is a price at which substantial (that is, not isolated or insignificant) sales are made . . ." 16 C.F.R. § 233.3(d). Contrary to what the State suggests, those Guides do not provide standards for determining whether a list price "is impermissible" (Pl.'s J&J Mot. at 11); rather, they delineate a safe harbor in which list prices will not be deemed fictitious if they satisfy the test. Furthermore, the FTC has not brought a case under the Guides since 1979. According to former FTC Chair Robert Pitofsky, the FTC has concluded that "enforcement actions in this area do more harm than good," because they discourage discounting. Pitofsky, *et al.*, "Pricing Laws Are No Bargain For Consumers," *Antitrust* (Summer 2004), at 62. Enforcement actions in this area are limited to situations in which consumers (not businesses or sophisticated State agencies) may in fact be deceived. *Id.* Indeed, the FTC has taken the position that pharmaceutical manufacturers should not be required to disclose discounted prices because it would "chill the willingness" of companies to offer them. (Letter from S. Creighton to Assemblyman Aghazarian, dated Sept. 7, 2004, at 10). If Wisconsin were to adopt a rule that is inconsistent with that federal policy, it would violate the commerce clause of the United States Constitution. See, e.g., *Pharmaceutical Research & Mfrs. of America v. District of Columbia*, 406 F. Supp. 2d 56, 70 (D. D.C. 2005) (holding unconstitutional an act that required companies doing business nationwide to provide special prices for the District of Columbia).

The J&J Defendants' AWP's were "true" because they were exactly that. (JJPUF ¶ 21). Moreover, it is absolutely clear that the J&J Defendants' AWP's were not "deceptive or misleading," because Wisconsin admittedly was not deceived or misled. (DAPUF ¶¶ 1-30, 63-191). This is consistent with Judge Saris' finding that the AWP's for the J&J Defendants' drugs at issue in the MDL trial were not "deceptive or unfair" because they "never substantially exceeded the range of what was generally expected by the industry and government." In re AWP, 491 F. Supp. 2d at 31, 104.

The other defendants' briefs, including the Defendants' Joint Response at Sections IV, VI.C & VI.D, the Novartis Response at Section IV.A.2-4, and Section IV.C of the AstraZeneca Response, discuss the record evidence and law applicable to this element of plaintiff's claim in greater detail. Those discussions are incorporated herein by reference. As Judge Saris recognized, the fundamental problem with the State's per se liability theory is that it would improperly extend liability to an entire category of specialized industry terms that can only be considered "untrue" if they are ripped from the context in which they are actually used and understood by industry and government, including Wisconsin Medicaid.

It is hardly unusual for the parlance of a particular industry to depart from dictionary definitions. The scrap steel industry provides several apt illustrations:

In the scrap trade, "barley" is the lariat-thick copper wire that is used for high-voltage electrical transmission in railroad signals, for example—the best kind of copper scrap; "honey" is copper with brass in it; and "candy" is No. 1 copper tubing, which is used for household plumbing. The bushy copper coiling that makes up the heart of an electrical motor is called "meatball." The terms were coined in the early twentieth century in order to conduct business by telegrams—short words were cheaper.

John Seabrook, "American Scrap: An Old-School Industry Globalizes," The New Yorker, Jan. 14, 2008, at 46, 49.

Under Wisconsin's *per se* liability theory these industry-specific uses of the words "barley," "honey," "candy," and "meatball" would be unlawful, because, according to the dictionary, they do not "express things exactly as they are." Pl.'s J&J Mot. at 9. The answer, of course, is that they do express things exactly as they are, when viewed in the specialized context in which they are used.

The pharmaceutical industry's use of the term "AWP" is no different. AWP's are reimbursement benchmarks used by private health insurers and government agencies who understand that they do not refer to an average of transaction prices charged by wholesalers. The State's Medicaid formula of AWP minus 13% proves the point. AWP's are not disseminated to unsuspecting consumers in Wisconsin who might be induced into believing they are paying "wholesale prices" when they are not. Wisconsin's consumer protection law is simply inapplicable to specialized industry terms such as AWP.

(iii) The State Cannot Prove that the J&J Defendants' AWP's Caused It To Suffer a Pecuniary Loss.

As discussed at greater length in the Section VI.D of the Defendants' Joint Response and Section IV.D.4 of the Novartis Response, which discussions are incorporated by reference, Wisconsin cannot prevail unless it proves that the J&J Defendants' AWP's caused it to suffer a pecuniary loss. *K & S Tool & Die Corp. v. Perfection Mach. Sales, Inc.*, 732 N.W.2d at 802 ("To prevail on [a section 100.18(1)] claim, the plaintiff must prove . . . that the representation caused the plaintiff a pecuniary loss."); Wis. JJ-Civil 2418 (requiring causation).

Wisconsin cannot prove this element of its claim for at least four reasons.

First, Wisconsin knows that the term AWP does not mean an actual average of wholesale transaction prices, yet it continues to this day to use AWP in its reimbursement formula because it wants Wisconsin's pharmacies to earn a reasonable profit when servicing

Medicaid patients. (DAPUF ¶¶ 9-30, 63-104). In fact, it has been an express goal of the State since at least 1975 to allow providers who participate in Medicaid to earn a reasonable profit on the drugs dispensed to Medicaid patients. (DAPUF ¶¶ 74-81). Since that time, the State considered and rejected a number of alternatives to AWP-based reimbursement, including the providers' actual acquisition costs. (DAPUF ¶¶ 105-191). It also rejected numerous proposals to adopt even deeper discounts from AWP. (See e.g., DAPUF ¶¶ 142-173, 176-186). Even now, long after its attorneys filed suit alleging that AWPs are "phony" and "inflated," the State continues to base pharmacy reimbursement on AWP, because its AWP-based formula functions as intended. (DAPUF ¶¶ 43, 191).

In short, there is no evidence that Wisconsin based its reimbursement rate on the false assumption that AWP equaled an average of provider acquisition costs, or that Wisconsin would have paid its pharmacies any less if defendants' AWPs had been different.

Second, Wisconsin's reimbursement rates are based on the "Blue Book" AWPs published by First DataBank, not on the AWPs or Suggested AWPs that the J&J Defendants sent to the pricing compendia, wholesalers and, in some instances, directly to the Wisconsin Medicaid agency. (JJPUF ¶¶ 36-39). The AWPs that First DataBank forwards to EDS for use by Wisconsin Medicaid are based on the markups provided by the wholesalers (DAPUF ¶¶ 200-235; JJPUF ¶ 37-38), and [REDACTED] [REDACTED] [REDACTED]. (JJPUF ¶ 39). In short, the J&J Defendants' AWPs, which Wisconsin did not even use, had no affect on the level of reimbursement Wisconsin paid to Medicaid providers.

Third, [REDACTED]

[REDACTED]

In many instances they actually lose money because of Wisconsin's meager dispensing fee. (JJPUF ¶¶ 24-28; DAPUF ¶¶ 82-104). There is no evidence that Wisconsin suffered a pecuniary loss caused by the J&J Defendants' AWP.

Fourth, the J&J Defendants' AWP did not cause a pecuniary loss because the State's payments to Medicaid providers were heavily subsidized by the rebates the State received from the J&J Defendants. (JJPUF ¶¶ 29-35). These rebates substantially reduced Wisconsin's reimbursement costs. After accounting for rebates, Wisconsin actually paid less for the J&J Defendants' drugs than the Wisconsin's pharmacies paid for them. (Id.) Indeed, that is the purpose of the rebate program. As Judge Saris noted in another AWP-based Medicaid case, any alleged overcharge incurred by the states as a result of alleged overpayments based on AWP, "will necessarily be reduced by the rebates the state received." In re AWP, 457 F. Supp. 2d at 74-75.

In addition, as discussed in Section IV.C of the AstraZeneca Response, which point is incorporated by reference, Wisconsin's long-standing contractual relationship with First DataBank/EDS affirmatively shows the absence of causation between defendants' AWP and the State's alleged loss.

In sum, the State's motion for summary judgment on its Section 100.18(1) must be denied because it cannot prove any the elements necessary to establish its claim. At a bare minimum, the material facts are disputed.

B. The State’s Motion Must Be Denied Because Wisconsin Medicaid Is Not a Member of the “Public.”

The J&J Defendants join, adopt and incorporate as if fully set forth herein the arguments made in Section IV.D.2 of the Novartis Response.

C. The State’s Motion Must Be Denied Because § 100.182, and Not § 100.18(1), Applies to Conduct Relating to Drugs.

The J&J Defendants join, adopt and incorporate as if fully set forth herein the arguments made in Section VI.C.1 of the Defendants’ Joint Response.

D. The State’s Motion Must Be Denied Because § 100.18(1) Does Not Apply to Drugs.

The J&J Defendants join, adopt and incorporate as if fully set forth herein the arguments made in Section VI.C.2 of Defendants’ Joint Response.

II. THE STATE’S MOTION FOR PARTIAL SUMMARY JUDGMENT ON ITS § 100.18(10)(b) CLAIM MUST BE DENIED.

The J&J Defendants join, adopt and incorporate as if fully set forth herein the arguments made in Section VI.E of Defendants’ Joint Response.

RELIEF SOUGHT

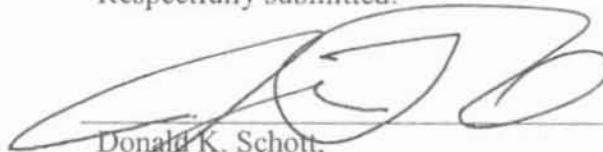
The J&J Defendants respectfully request that the Court issue an order denying the State of Wisconsin's Motion for Partial Summary Judgment on Liability With Respect to Counts I and II of Wisconsin's Complaint.

The J&J Defendants join in Defendants' Joint Cross Motion for Summary Judgment, and respectfully request that the Court grant summary judgment against all of the State's claims

In addition, the J&J Defendants have moved separately for summary judgment on certain of the State's parens patriae claims based on the Judgment entered in favor of the J&J Defendants in the United States District Court in In re AWP.

Dated: January 15, 2008

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