

STATE OF WISCONSIN

CIRCUIT COURT  
Branch 9

DANE COUNTY

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STATE OF WISCONSIN, )  
 )  
 Plaintiff, )  
 ) Case No.: 04 CV 1709  
 ABBOTT LABORATORIES, INC., et. al. )  
 )  
 Defendants. )

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**RESPONSE OF DEFENDANT NOVARTIS PHARMACEUTICALS  
CORPORATION TO PLAINTIFF'S MOTION FOR PARTIAL SUMMARY  
JUDGMENT, AND CROSS MOTION FOR SUMMARY JUDGMENT OF  
DEFENDANT NOVARTIS PHARMACEUTICALS CORPORATION SEEKING  
DISMISSAL OF THE SECOND AMENDED COMPLAINT  
IN ITS ENTIRETY**

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## **I. INTRODUCTION**

Defendant Novartis Pharmaceuticals Corporation (“Novartis”) submits this Response to Plaintiff’s Motion for Partial Summary Judgment against Novartis as to Counts I and II of the Second Amended Complaint (the “Complaint”) in this action and Cross-Motion for Summary Judgment dismissing Counts I and II of the Complaint. Novartis also adopts and incorporates Defendants’ Joint Response to Plaintiff’s Partial Motion for Summary Judgment against AstraZeneca, Johnson & Johnson, Novartis, and Sandoz & Defendants’ Joint Cross-Motion for Summary Judgment and Supporting Memorandum and asks, for the reasons set forth therein, for dismissal of the entire Complaint. Plaintiff’s Motion sets forth no procedural facts in its Introduction and, therefore, there are none to dispute. Plaintiff purports to bring this action as a “civil enforcement action” to recover for alleged overpayments made to retail pharmacies and physicians – money it readily admits was never paid to Novartis either by it or by the recipients – for Novartis branded prescription drugs dispensed to Medicaid beneficiaries. As shown below, Plaintiff’s purported “civil enforcement action” mischaracterizes Wisconsin consumer protection statutes in an attempt to mislead the Court into ignoring reality.

### **Summary of Argument**

Plaintiff’s motion, like Plaintiff’s claims, rests on two deceptively simple, and demonstrably false, premises: First, that “Average Wholesale Price” and “AWP” – terms used by, and which have a specific meaning to, those involved in the manufacture, sale, and reimbursement of pharmaceuticals – instead should be interpreted to mean an average of actual transaction prices paid by retailers to wholesalers for brand name prescription drugs. Second, that “Wholesale Acquisition Cost” and “WAC” – terms broadly understood in the industry to be a manufacturer’s list price to wholesalers before prompt pay or other discounts earned by

wholesalers – are “false” if they do not convey the precise transaction prices paid by wholesalers to manufacturers, net of discounts. These premises are indisputably false.

As shown below, the undisputed facts demonstrate that AWP and WAC are terms with accepted meaning to those who manufacture, distribute and pay or reimburse for brand name prescription drugs and that, at all relevant times, (i) Novartis’s reporting of its prices was fully consistent with those meanings, and (ii) Plaintiff, including the Wisconsin Medicaid agency on whose behalf Plaintiff purports to sue, understood that those terms have the same meaning understood by everyone else in the industry. AWP is a term broadly understood by all participants in pharmaceutical markets to be a benchmark, which, for brand name prescription drugs, is generally 20 to 25 percent above manufacturers’ list prices to wholesalers, and it has been so understood for at least 25 years. It is similarly broadly known that WAC (a price Plaintiff never used for drug reimbursement) is a manufacturer list price, and that wholesalers may earn discounts for prompt payment or receive occasional allowances to stock new products.

As a result, Plaintiff’s central premises are false, and its after-the-fact attempt to ascribe wholly different meanings to AWP and WAC, and on that basis now claim that Novartis (and every other brand name pharmaceutical company) misled it, should be rejected by the Court.

Plaintiff’s motion also rests on a series of erroneous legal and factual assumptions that are either disputed or directly contrary to undisputable facts. Thus, Plaintiff purports to seek summary judgment that Novartis violated the Wisconsin Deceptive Trade Practices Act (“WDTPA”), which requires first that there be an “advertisement, announcement, statement or representation” that could be deceptive or misleading. Yet, Plaintiff wholly fails to offer in support of its motion any specific “advertisement, announcement, statement or representation” published or caused to be published by Novartis in Wisconsin. Nor does it offer any admissible

evidence describing such advertisement or representation with any precision (*e.g.*, content or date of publication in Wisconsin). As a consequence of failing to identify an “advertisement, announcement, statement or representation,” Plaintiff also fails to (i) identify the allegedly “untrue, deceptive or misleading statement” in the advertisement or statement, (ii) show exactly how it was “untrue, deceptive or misleading,” and (iii) establish that Novartis made the statement “with intent to induce the public in any manner to enter into any contract or obligation relating to the purchase . . . of any real estate, merchandise, securities, employment or service.” Yet these are all elements of the claim *identified by Plaintiff in its motion*. (See Pl.’s Br. at 4-5.) As a result, Plaintiff asks the Court to render, in the form of summary judgment, an advisory opinion that, *if* Novartis made or caused to be made an advertisement in Wisconsin that included an AWP or WAC that did not equal the average of transaction prices paid by retail pharmacies to wholesalers or precise transaction prices paid by wholesalers to Novartis for Novartis products, it might somehow be liable under WDTPA. This abject failure by Plaintiff to identify a single specific allegedly deceptive or misleading “advertisement, announcement, statement or representation” requires denial of Plaintiff’s motion.

Plaintiff also asserts – with no supporting evidence – that Wisconsin Medicaid “relied” on Novartis AWPs in setting reimbursements to pharmacies. The evidence shows, however, that Wisconsin Medicaid never used Novartis AWPs for any purpose. Instead, Wisconsin Medicaid used AWPs created by First DataBank, an independent company that has testified that it never used Novartis AWPs to create its published AWPs. Moreover, Wisconsin Medicaid never “relied” on such AWPs; it reimbursed pharmacies based on a discount it applied to the AWPs, reflecting its understanding both that AWPs were higher than what pharmacies paid wholesalers

for drugs and of the political and economic realities of setting reimbursement rates for Wisconsin pharmacies.

Finally, Plaintiff here may not rely on WDTPA because Wisconsin is not a consumer under that Act. WDTPA was enacted to protect consumers from being misled or deceived by sellers who typically have more power and control in their particular seller-buyer relationships. It was not enacted to “protect” a government agency that both fully understands the markets in which it participates and has the power to demand information from virtually any participant in it. Moreover, the myriad contracts among Wisconsin Medicaid, the federal government, First DataBank, manufacturers, and others define the relationships among those parties and preclude application of WDTPA to those relationships.

Because Plaintiff’s motion is legally and factually deficient, it should be denied. Because Plaintiff’s consumer protection claims in Counts I and II rest on a manufactured set of assumptions that are contrary to undisputed material facts, Novartis’s cross-motion for summary judgment on Counts I and II should be granted, and Counts I and II of the Complaint should be dismissed as to Novartis.

## **II. RESPONSE TO CLAIMS**

Plaintiff seeks summary judgment as to Counts I and II of the Complaint. Novartis opposes Plaintiff’s motion for summary judgment and requests summary judgment in its favor dismissing Counts I and II of the Complaint.

### **A. Count I – Wisconsin Stat. § 100.18(1)**

Novartis disputes the elements of Wis. Stat. § 100.18(1) as stated in Plaintiff’s Motion. The Wisconsin Supreme Court has ruled that 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.* To prove causation, the plaintiff must show that the representation “materially induced” it to act differently. *Id.* at 129, 802.

B. Count II – Wisconsin Stat. § 100.18(10)(b)

Novartis does not dispute that Plaintiff has accurately quoted the text of Wis. Stat. § 100.18(10)(b). Novartis disputes Plaintiff’s characterization of Wis. Stat. § 100.18(10)(b) as providing a separate cause of action. Subsection (10)(b) merely provides a statutorily defined example of one type of conduct that the legislature has deemed “deceptive” under Wis. Stat. § 100.18(1), and therefore there are no separate “elements” of this claim as set forth in Plaintiff’s motion.

**III. RESPONSE TO PROPOSED UNDISPUTED FACTS AND NOVARTIS’S ADDITIONAL PROPOSED UNDISPUTED FACTS**

A. Response to Proposed Undisputed Facts

1. Disputed as incomplete and inaccurate. Contrary evidence.

Plaintiff: Novartis was created in 1997 as a result of the merger of Ciba-Geigy Pharmaceuticals and Sandoz Pharmaceuticals. Transcript of June 23, 2006 deposition of Novartis corporate designee Michael Conley, Executive Director for U.S. Managed Markets, Trade Corporate Accounts, and Customer Service (“Conley Tr.”), at 68.

Novartis: Novartis began its operations in its current form on January 1, 1997 as a result of the U.S. merger of Sandoz Corporation, which was the ultimate U.S. parent of Sandoz Pharmaceuticals Corporation, with Ciba-Geigy Corporation. Affidavit of Gary Rosenthal, Novartis’s Vice President of Finance and Administration, dated July 10, 2007 (“Rosenthal Aff.”) at ¶ 5 (Affidavit of Kim

Grimmer, dated January 15, 2008 (“Grimmer Aff.”)<sup>1</sup>, Ex. 1). Novartis is the successor to Sandoz Pharmaceuticals Corporation, to which the assets of Ciba-Geigy Corporation’s Pharmaceuticals Division were contributed in early 1997 by Novartis Corporation, then its parent company. *Id.*

2. Not disputed.

3. Disputed. Not supported by record cite provided.

4. Not disputed.

5. Not disputed.

6. Not disputed.

7. Disputed. (a) Not an evidentiary fact, but rather a legal conclusion; (b) not based on admissible evidence (no foundation for the competence of testimony cited by Plaintiff as the witness was not designated to testify as to Novartis’s “duties” and such “duties” are not within his job description or expertise); and (c) contrary evidence.

Plaintiff: By choosing voluntarily to participate in the Medicaid program, Novartis has a duty or obligation to familiarize itself with the federal Medicaid rules and regulations. Conley Tr. at 15.

Novartis: Novartis employees are required to familiarize themselves with the laws and regulations governing Novartis’s business. *See* Novartis Pharmaceuticals Corporation Code of Employee Conduct, dated September 2001, NPC-AGC009469092-107 (Grimmer Aff., Ex. 2); “Overview of Legal Issues” Training Seminar, dated November 15, 2001, NPC-AGC010903051-082 (Grimmer Aff., Ex. 3); “Important Limitations Regarding Discussions of Reimbursement Information,” NPC-AGC009005245-248 (Grimmer Aff., Ex. 4); Novartis Business Ethics and Compliance Program presentation, NPC-AGC009451750-779 (Grimmer Aff., Ex. 5). There are federal Medicaid rules and regulations “that have nothing to do with how Novartis acts or how they do business with Medicaid.” Transcript of August 21, 2007 deposition of Novartis corporate designee Stephen P. Byler, Senior Associate Director, U.S. Managed Markets, Medicaid (“Byler Tr.”), at 34-35 (Grimmer Aff., Ex. 6). Whether Novartis has an obligation to familiarize itself with specific rules and regulations of the federal Medicaid program is a legal question. Byler Tr. at 89-90 (Grimmer

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<sup>1</sup> The Affidavit of Kim Grimmer and the attached exhibits were submitted as a separately bound appendix.

Aff., Ex. 6). Rules and regulations relating to states' chosen reimbursement methodologies are not relevant to Novartis's business. Transcript of September 26, 2007 deposition of Novartis corporate designee Gary Rosenthal, Vice President of Finance and Administration ("9/26/07 Rosenthal Tr."), at 189-90 (Grimmer Aff., Ex. 7).

8. Disputed. (a) Not an evidentiary fact, but rather a legal conclusion; and (b) not based on admissible evidence (no foundation for the competence of testimony cited by Plaintiff as the witness was not designated to testify as to Novartis's "duties," and such "duties" are not within his job description or expertise).

9. Not disputed.

10. Not disputed.

11. Not disputed.

12. Not disputed.

13. Not disputed.

14. Disputed in part. (a) Not based on admissible evidence (no foundation for the competence of testimony cited by Plaintiff as the witness was not designated to testify as to the operation of the Wisconsin Medicaid program, which is not within his job description or expertise); and (b) contrary evidence.

Plaintiff: The retail pharmacy would fill the Diovan prescription, but because the person was eligible for Wisconsin's Medicaid program, the person would not pay for the drug. Conley Tr. at 12.

Novartis: Wisconsin Medicaid has a patient co-pay of \$3 for brand name drugs. Transcript of December 11, 2006 deposition of Pharmacy Society of Wisconsin corporate designee Christopher J. Decker, Executive Director ("Decker Tr."), at 167-68 (Grimmer Aff., Ex. 8); Transcript of December 12, 2006 deposition of Marshland Pharmacy corporate designee Susan L. Sutter ("Sutter Tr.") at 41 (Grimmer Aff., Ex. 9).

15. Disputed. Not based on admissible evidence (no foundation for the competence of testimony cited by Plaintiff as the witness was not designated to testify as to the operation of the Wisconsin Medicaid program, which is not within his job description or expertise).

16. Disputed. Not based on admissible evidence (no foundation for the competence of testimony cited by Plaintiff as the witness was not designated to testify as to the operation of the Wisconsin Medicaid program, which is not within his job description or expertise).

17. Disputed in part. First sentence not disputed. Second sentence disputed; not an evidentiary fact, but rather a legal conclusion based on an incomplete quotation of the cited statute, which provides that Wisconsin Medicaid's payment to pharmacies for branded drugs dispensed to Medicaid beneficiaries not exceed the estimated acquisition cost of the drug plus a reasonable dispensing fee, *in the aggregate*, or the pharmacy's usual and customary charge, whichever is lower. *See* 42 C.F.R. § 447.512(b).

18. Disputed. Not based on admissible evidence (no foundation for the competence of testimony cited by Plaintiff as the witness was not designated to testify as to Novartis's understanding of regulations that do not apply to Novartis's business; the regulations apply to how states may choose to pay pharmacies for drugs dispensed to Medicaid beneficiaries, which is not within the witness's job description or expertise).

19. Disputed. Not an evidentiary fact. Incorrect legal citation.

20. Disputed. (a) Not an evidentiary fact, but rather a legal conclusion; (b) not based on admissible evidence (no foundation for the competence of testimony cited by Plaintiff as the witness was not designated to testify as to the meaning of federal regulations that do not apply to Novartis's business, and the meaning and interpretation of federal regulations are not within the witness's job description or expertise); and (c) contrary evidence.

Plaintiff: “Estimated acquisition cost” means the price the retail pharmacy paid to acquire the drug from whomever it purchased it from. Conley Tr. at 17-18.

Novartis: EAC is Wisconsin’s best estimate of prices generally and currently paid by providers for pharmaceuticals. The states have a certain amount of discretion to determine the appropriate level of payment and Wisconsin determines its EAC based on its review of various reports, including federal OIG reports, what other states are paying, and information from private payers. Transcript of August 16, 2007 deposition of Wisconsin Medicaid designee James Vavra, Bureau Director, Division of Healthcare Financing (“8/16/07 Vavra Tr.”), at 57-61, 68, 98-99 (Grimmer Aff., Ex. 10).

21. Disputed. Not based on admissible evidence (no foundation for the competence of testimony cited by Plaintiff as the witness was not designated to testify as to Novartis’s understanding of regulations that do not apply to Novartis’s business; the regulations apply to how states may choose to pay pharmacies for drugs dispensed to Medicaid beneficiaries, which is not within the witness’s job description or expertise).

22. Not disputed.

23. Not disputed.

24. Disputed in part as incomplete. Novartis is aware that some states use AWP as the starting point for calculating reimbursements to pharmacies for brand name drugs dispensed to Medicaid beneficiaries and that, in recognition of such states’ understanding that AWP exceeds pharmacies’ actual acquisition cost of such drugs, all such states apply discounts to the AWP to calculate such reimbursements. Byler Tr. at 37, 111-13 (Grimmer Aff., Ex. 6).

25. Disputed. Not based on admissible evidence (no foundation for the competence of testimony cited by Plaintiff as the witness was not designated to testify as to the operation of the Wisconsin Medicaid program, which is not within his job description or expertise).

26. Not disputed.

27. Not disputed.

28. Disputed in part. Contrary evidence.

Plaintiff: Since 1997, Novartis has reported pricing information, including average wholesale price (“AWP”) and wholesale acquisition cost (“WAC”), for its drugs to First DataBank and Red Book. Conley Tr. at 22, 114-115.

Novartis: Novartis stopped reporting AWP in 2005. Transcript of June 23, 2006 deposition of Novartis corporate designee Michael Conley, Executive Director of U.S. Managed Markets Trade (“Conley Tr.”), at 23-24 (Grimmer Aff., Ex. 11); 9/26/07 Rosenthal Tr. at 34-35 (Grimmer Aff., Ex. 7).

29. Disputed as incomplete. Novartis reports prices to First DataBank because Novartis is aware that many participants in the pharmaceutical industry use First DataBank’s databases for information, and that many private and public payers use its pricing information as a component in calculating their reimbursements to pharmacies for drugs dispensed to their beneficiaries. 9/26/07 Rosenthal Tr. at 38-39, 71 (Grimmer Aff., Ex. 7).

30. Not disputed.

31. Not disputed.

32. Disputed. Not supported by record cite provided. Contrary evidence.

Plaintiff: Between 1997 and July 2002, Novartis understood that First DataBank would publish the identical AWP’s that Novartis reported to First DataBank. Conley Tr. at 25-26.

Novartis:

Q. Now, since 1997, when Novartis has reported AWP’s [sic] to First DataBank for its -- the targeted drugs, Novartis intended for First DataBank to publish those AWP’s, correct?

A. We would provide the information. It was up to them to do with it as they saw fit.

Q. Well, my question is whether Novartis intended First DataBank to report the AWP’s [sic] -- strike that. My question’s whether Novartis intended that the AWP’s [sic] they reported to First DataBank would be published by First DataBank identically.

A. We would provide the information to First DataBank. They would publish . . . what they considered AWP based on surveys they did with wholesalers.

Q. My question’s a little different. My question was about what Novartis intended at the time they reported the AWP’s [sic]. So let me try again. Did

Novartis intend that when it reported these AWP's [sic] to First DataBank, that First DataBank would in fact publish those very same AWP's [sic] in its publications?

A. Again I -- I can't speak to our intention. We published the number. But I'm not aware of any intention of us to -- to have First DataBank report that number.

Conley Tr. at 25 (Grimmer Aff., Ex. 11). First DataBank does not ask Novartis to verify or approve the prices that it is going to publish. Conley Tr. at 99-100 (Grimmer Aff., Ex. 11).

33. Disputed. Contrary evidence.

Plaintiff: Novartis knows the WACs and AWPs for its drugs that are published by First DataBank because Novartis purchases pricing information from First DataBank regarding Novartis's drugs. Conley Tr. at 100.

Novartis: Novartis has access to the pricing information First DataBank publishes for its products, but it generally does not monitor that information. Conley Tr. at 100 (Grimmer Aff., Ex. 11); 9/26/07 Rosenthal Tr. at 71 (Grimmer Aff., Ex. 7).

34. Not disputed for purposes of this motion.

35. Not disputed for purposes of this motion.

36. Not disputed.

37. Not disputed.

38. Not disputed.

39. Not disputed.

40. Disputed. Contrary testimony.

Plaintiff: Novartis defines WAC or wholesale acquisition cost as the price that direct purchasers pay to Novartis. Conley Tr. at 74.

Novartis: WAC is Novartis's list price at which it makes its products generally available to wholesalers. 9/26/07 Rosenthal Tr. at 28-29, 43-44 (Grimmer Aff., Ex. 7).

41. Not disputed.

42. Disputed in part as containing disputed inferences and characterizations rather than evidentiary facts. Novartis does not dispute that its published WAC is a list price exclusive of prompt pay discounts or other allowances (such as initial stocking allowances to encourage wholesalers to stock a new drug before prescriptions begin to be written for it) available to wholesalers. 9/26/07 Rosenthal Tr. at 55-58 (Grimmer Aff., Ex. 7). Novartis disputes Plaintiff's inference that this fact renders the published WAC not a "true" price when it is, in fact, a true list price consistent with the understanding of all of the participants in the prescription drug market, including third party payors such as Wisconsin Medicaid. 8/16/07 Vavra Tr. at 133-34 (Grimmer Aff., Ex. 10).

43. Disputed in part as incomplete. Novartis's AWP's are reference points for its drugs, which are determined by applying a mathematical formula to Novartis's WAC price for a drug, generally 1.2 times WAC. 9/26/07 Rosenthal Tr. at 44, 88, 113-14 (Grimmer Aff., Ex. 7).

44. Disputed. Contrary evidence. The so-called Novartis Pharmacy Benefit Reports are published by Emron, an independent research firm, for Health Maintenance Organization ("HMO") professionals, to provide them with relevant information they can use for planning and benchmarking, with funds provided by Novartis. See Pl.'s Motion, Declaration of Charles Barnhill, dated October 29, 2007, Ex. 3 at NOV/WIS000100444 and Ex. 4 at NOV/WIS000100494. The Reports state on their very first pages that the included content and data:

are prepared and edited by Emron, and are based on independently conducted research, information contributed by experts in the health care industry, and government and industry publications. Any statements and opinions contained herein are not necessarily those of Novartis. *Id.*

45. Not disputed.

46. Not disputed.

47. Not disputed.

48. Not disputed as to the present time. Disputed as to the entire period covered by the Complaint, as cited testimony does not support an inference that wholesaler margins have been consistent over time.

49. Disputed (a) as to the entire period covered by the Complaint, as cited testimony does not support an inference that wholesaler margins have been consistent over time; and (b) as incomplete. Novartis does not have knowledge of the prices that retail pharmacies pay wholesalers for Novartis drugs. Conley Tr. at 53, 56 (Grimmer Aff., Ex. 11).

50. Not disputed.

51. Disputed in part. First sentence not disputed. Second sentence not supported by record cite. Contrary evidence.

Plaintiff: Novartis knows that when it sells its drugs directly to retail pharmacies such as Walgreens, CVS, Rite-Aid, Eckert, and Long's Drugs Stores, the most the retail pharmacies pay for those drugs is the WAC. Because Novartis's AWP's have always been at least 20% higher than Novartis's WACs, these customers never paid a price equal to or greater than AWP for Novartis's drugs. Conley Tr. at 34-36.

Novartis: Novartis has, on occasion, sold its drugs directly to warehousing retail chains, *i.e.*, retail organizations that use warehouses to distribute to their own pharmacies. 9/26/07 Rosenthal Tr. at 54 (Grimmer Aff., Ex. 7). In those circumstances, Novartis sells its drugs to the warehousing retail chains at WAC. Conley Tr. at 34 (Grimmer Aff., Ex. 11). Novartis does not know the price paid by these warehousing retail chains when they purchased Novartis's drugs from another source, such as a wholesaler, instead of directly from Novartis. Conley Tr. at 34, 73 (Grimmer Aff., Ex. 11); 9/26/07 Rosenthal Tr. at 191 (Grimmer Aff., Ex. 7). Novartis does not know whether these warehousing retail pharmacies or any other retail pharmacies ever paid a price equal to or greater than AWP for Novartis's drugs. Conley Tr. at 34, 47-49, 73 (Grimmer Aff., Ex. 11); 9/26/07 Rosenthal Tr. at 191 (Grimmer Aff., Ex. 7).

B. Novartis's Additional Proposed Undisputed Facts

52. Novartis is a research-based manufacturer of brand name prescription drugs. When first introduced into the market, Novartis drugs are patented and, therefore, are available only from Novartis. Rosenthal Aff. at ¶ 6 (Grimmer Aff., Ex. 1).

53. The vast majority of Novartis products are self administered drugs, products that are prescribed by doctors, dispensed by pharmacies and taken by patients on their own. Transcript of September 26, 2007 deposition of Novartis corporate designee Francis J. Arena, Vice President, Sales Operations (“Arena Tr.”), at 40 (Grimmer Aff., Ex. 12).

54. When a doctor prescribes a branded self administered drug, and the patient presents such a prescription to the pharmacy, the pharmacy can only dispense that drug, and may not substitute an alternative product. Rosenthal Aff. at ¶¶ 10, 13 (Grimmer Aff., Ex. 1).

55. Consequently, retail pharmacies have little or no influence over which branded prescription drug is dispensed to patients and, therefore, little or no ability to affect the market share of a branded drug versus that of its branded competitors. Rosenthal Aff. at ¶¶ 10, 20 (Grimmer Aff., Ex. 1).

56. Because retail pharmacies have no significant influence over whether a Novartis drug will be prescribed, Novartis generally does not offer retailers discounts or financial incentives in connection with the sale of its products. Rosenthal Aff. ¶ 20 (“Because retail pharmacies must provide to patients what doctors prescribe . . . [Novartis] generally does not offer incentives, financial or otherwise, in connection with the sale of its patented drugs to retail pharmacies.”) (Grimmer Aff., Ex. 1).

57. Novartis provides discounts and financial incentives to entities that have the ability to influence prescribing decisions and maintain formularies, such as Wisconsin Medicaid,

private third party payers, and prescription drug benefit managers. Rosenthal Aff. ¶ 18 (Grimmer Aff., Ex. 1).

58. The entities described in paragraph 57, *supra*, do not buy or sell drugs, and are not reimbursed for them; rather, they are the reimbursers. Rosenthal Aff. ¶ 18 (Grimmer Aff., Ex. 1). Novartis also reduces prices for hospitals, public health clinics, and other facilities that maintain pharmacies that dispense drugs because they, too, can influence prescribing choices made by affiliated doctors. *Id.* at ¶ 19.

59. Novartis sells its products to wholesalers, who in turn sell them to retailers. Transcript of June 24, 2004 deposition of Novartis corporate designee Gary Rosenthal, Vice President of Finance and Administration (“6/24/04 Rosenthal Tr.”), at 70-71, 211-12 (Grimmer Aff., Ex. 13); Rosenthal Aff. at ¶ 15 (Grimmer Aff., Ex. 1).

60. Wholesalers, like retailers, have little to no ability to determine what branded drugs will be prescribed and, therefore, dispensed. Consequently, they too have little to no ability to affect the market share of a branded drug versus that of its branded competitors. Rosenthal Aff. at ¶¶ 10, 20 (Grimmer Aff., Ex. 1).

61. Novartis sells its products to wholesalers at what is known in the industry as Wholesale Acquisition Cost or WAC, which is Novartis’s list price to wholesalers. Rosenthal Aff. at ¶ 15 (Grimmer Aff., Ex. 1); 9/26/07 Rosenthal Tr. at 28-29, 43-44 (Grimmer Aff., Ex. 7). It offers such wholesalers a small “prompt-pay” discount of approximately two percent off of WAC if the wholesalers pay within a specified period of time. 9/26/07 Rosenthal Tr. at 56 (Grimmer Aff., Ex. 7); 6/24/04 Rosenthal Tr. at 141 (Grimmer Aff., Ex. 13); Rosenthal Aff. at ¶ 20 (Grimmer Aff., Ex. 1).

62. When Novartis launches a new product, wholesalers may also be offered a one-time “stocking allowance” to ensure that the new product is available on the market to meet demand. 9/26/07 Rosenthal Tr. at 56-57 (Grimmer Aff., Ex. 7).

63. Retail drug stores purchase Novartis products from wholesalers at whatever prices the wholesalers are willing to sell them to such retailers. Rosenthal Aff. at ¶ 20 (Grimmer Aff., Ex. 1).

64. At the time of his deposition in June 2006, Michael Conley was Executive Director of U.S. Managed Markets Trade. In that position, he was responsible for (i) the customer service department, which handles the direct purchasing order processing from Novartis’s direct customers, as well as returns that come in from various customers, (ii) the account management team that calls on the headquarters of large retail chains and wholesalers, and (iii) communications with third party publishers of pharmaceutical information, such as First DataBank. Conley Tr. at 63-66 (Grimmer Aff., Ex. 11).

65. Novartis designated Mr. Conley to testify about the following four topics only:

1. The evidence or information, if any, about which [Novartis] is aware, which shows that any of the drugs listed on Exhibit A to this notice of deposition (“targeted drugs”) were purchased by retail pharmacies at a price equal to or greater than the then current Average Wholesale Price (“AWP”) published by either First DataBank or the Red Book . . . .

2. The evidence or information, if any, about which [Novartis] is aware, which shows, or which Novartis believes may tend to show, that the published AWP was higher than the price pharmacies were actually paying for any of the targeted drugs in each year . . . .

3. What contacts Novartis, or its subsidiaries, have had with First DataBank or the Red Book about any of the targeted drugs.

4. Whether Novartis, or any of its subsidiaries, ever communicated to First DataBank or the Red Book that the published Average Wholesale Price was neither a price that was

actually an average of wholesale prices, nor a price that was actually paid by the retail classes of trade, and if so, when such communications took place and of what they consisted.

Letter from C. Neagle to R. Libman, dated June 1, 2006 (Grimmer Aff., Ex. 14); Notice of Deposition to Defendant Novartis Pharmaceuticals Corporation, dated March 23, 2006 (Grimmer Aff., Ex. 15).

66. Wisconsin Medicaid's principal source of published AWP's has for many years been a company called First DataBank, a subsidiary of the Hearst Corporation that creates and maintains an extensive drug database that includes a wide variety of information about virtually every drug sold in the United States, including pricing information. Complaint at ¶ 35; Transcript of September 27, 2007 deposition of State of Wisconsin designee Carrie L. Gray, Pharmacy Program Policy Analyst ("Gray Tr."), at 51, 112-13, 119-20 (Grimmer Aff., Ex. 16); Transcript of August 15, 2007 deposition of State of Wisconsin designee Kimberly A. Smithers, Business Automation Specialist Senior ("Smithers Tr."), at 32-33 (Grimmer Aff., Ex. 17); Transcript of August 27, 2007 deposition of Patricia Kay Morgan, former Manager of Editorial Services at First DataBank ("Morgan Tr."), at 28, 150 (Grimmer Aff., Ex. 18).

67. First DataBank does not publish information to "the public." Rather, it provides information to sophisticated industry participants who purchase it. Morgan Tr. at 71-72, 110-11 (Grimmer Aff., Ex. 18).

68. Wisconsin Medicaid used First DataBank's published AWP information in its drug reimbursement formulas. Gray Tr. at 112-13, 119-20 (Grimmer Aff., Ex. 16).

69. Wisconsin Medicaid does not contract directly with First DataBank for pricing information. Rather, First DataBank contracts with and supplies pricing information to Wisconsin's fiscal agent, Electronic Data Systems Corporation ("EDS"). Smithers Tr. at 32-33 (Grimmer Aff., Ex. 17); Transcript of December 19, 2007 deposition of EDS corporate designee

Mark Gajewski, EDS Account Manager for Wisconsin Medicaid (“Gajewski Tr.”), at 115-17, 127-28, 146-47 (Grimmer Aff., Ex. 19); May 6, 1991 Master Purchase Agreement Between EDS and First DataBank, and Amendments, WIS-AWP 000001-027 (Grimmer Aff., Ex. 20).

70. After receiving weekly pricing data from First DataBank, EDS applies a pricing algorithm depending on the type of drug (*e.g.*, brand vs. generic), as well as various filters, and then loads this information into a reference file, which Wisconsin Medicaid can then use. Smithers Tr. at 36-37, 46-47 (Grimmer Aff., Ex. 17).

71. Wisconsin Medicaid generally does not have access to First DataBank’s data until after these filters and pricing algorithms are applied. However, certain individuals employed by Wisconsin Medicaid have access to unfiltered First DataBank data through the “Data Warehouse,” which is maintained by EDS. Information contained in this “Data Warehouse” is used solely for analysis and not for purposes of reimbursement. Smithers Tr. at 47-52 (Grimmer Aff., Ex. 17).

72. At all relevant times, First DataBank set the AWP’s it published to its customers based on information it obtained from periodically surveying a varying number of national wholesalers, and those reported AWP’s accurately reflected First DataBank’s understanding of the markups those wholesalers were using to set their *list* prices to retailers. Morgan Tr. at 38-39, 89, 201-02 (Grimmer Aff., Ex. 18).

73. First DataBank’s published AWP – the “Blue Book” AWP – is derived from this survey of national wholesalers conducted from time to time by First DataBank. Morgan Tr. 38-39, 89, 201-02 (Grimmer Aff., Ex. 18).

74. First DataBank's survey does not collect wholesaler-to-retailer transaction prices; rather, it collects the wholesaler's internal markup used to create the wholesaler's list price to retailers. Morgan Tr. at 38-39 (Grimmer Aff., Ex. 18).

75. First DataBank published the AWP's reported by Novartis in its data field labeled SWP (for "Suggested Wholesale Price"). Morgan Tr. at 45 (Grimmer Aff., Ex. 18).

76. Wisconsin Medicaid uses the Blue Book AWP for reimbursement, rather than the Suggested Wholesale Price. First DataBank/EDS State of Wisconsin Functional Specifications, Version 2.0, FDB/Wisconsin 00393-00412 (Grimmer Aff., Ex. 21); First DataBank/EDS State of Wisconsin Functional Specifications, Version 2.1, FDB/Wisconsin 01823-01843 (Grimmer Aff., Ex. 22).

77. Around July 2002, Novartis learned from one of its managed care accounts that First DataBank's published AWP's for many Novartis branded drugs were higher than the AWP's that Novartis reported to First DataBank. Conley Tr. at 27 (Grimmer Aff., Ex. 11); 9/26/07 Rosenthal Tr. at 72-73 (Grimmer Aff., Ex. 7).

78. After discovering this, Novartis contacted First DataBank to get an explanation. Conley Tr. at 27, 29, 102 (Grimmer Aff., Ex. 11); 9/26/07 Rosenthal Tr. at 73-74 (Grimmer Aff., Ex. 7); July 23, 2002 e-mail from Hank Slomkowski to Kay Morgan, NPC-AGC003630729-731 at 729 (Grimmer Aff., Ex. 23).

79. First DataBank's response confirmed that First DataBank did not rely on Novartis's published AWP's to set the AWP's that First DataBank displayed in its database for use by its customers. July 23, 2002 e-mail from Kay Morgan to Hank Slomkowski, NPC-AGC003630729-731 at 729 (Grimmer Aff., Ex. 23); Conley Tr. 29, 31, 103 (Grimmer Aff., Ex. 11); 9/26/07 Rosenthal Tr. at 72-75 (Grimmer Aff., Ex. 7).

80. The document that First DataBank sent to Novartis in response describes how AWP is set and defined by First DataBank:

First DataBank surveys national wholesalers to ascertain what they use as a price basis in their AWP files. [First DataBank] contact[s] the wholesalers to determine what the markup should be for a new company or to confirm that the markup that [First DataBank is] applying is current . . . .

The markup that First DataBank utilizes is representative of wholesalers on a national level. Because individual wholesalers may mark up each manufacturer differently, a weighted average, not a consensus average, is calculated . . . . We also consider the manufacturer's suggested wholesale price (SWP) in our determination.

Many are under the impression that the manufacturer sets the AWP. [First DataBank] considers the wholesale price suggested by the manufacturer a "Suggested Wholesale Price (SWP)" . . . . Frequently, the SWP and AWP are the same; however we are having more instances where they are differing. We will populate the SWP with the new mark-up, but will survey the national wholesalers to determine AWP . . . .

July 23, 2002 e-mail from Kay Morgan to Hank Slomkowski and attachment, NPC-AGC003630729-731 at 730 (Grimmer Aff., Ex. 23).

81. First DataBank continued to publish AWP's for Novartis drugs that were 25% higher than the WACs for those drugs, even though Novartis generally reported AWP's that were set at 20% above WAC for its drugs. Conley Tr. at 30-31 (Grimmer Aff., Ex. 11); 9/26/07 Rosenthal Tr. at 88-89 (Grimmer Aff., Ex. 7).

82. Novartis sets its WAC price – its list price to wholesalers – as do most manufacturers of products, and it accurately reports that price to its customers and to First DataBank. 9/26/07 Rosenthal Tr. at 28-29, 33, 43, 45, 48, 58-60, 87-88 (Grimmer Aff., Ex. 7).

83. Novartis did not set, or cause to be published, the AWP that First DataBank provided to Wisconsin Medicaid during the relevant period. Morgan Tr. at 38 (Grimmer Aff., Ex. 18); July 23, 2002 e-mail from Kay Morgan to Hank Slomkowski and attachment, NPC-AGC003630729-731 (Grimmer Aff., Ex. 23).

84. From 2002 to 2005 (when Novartis stopped reporting AWP's altogether), the AWP's listed by First DataBank for Novartis drugs were in all but a few instances different from – and higher than – those reported by Novartis. Affidavit of Gregory K. Bell, Ph.D., Executive Vice President, CRA International, dated July 13, 2007, at ¶ 13 (Grimmer Aff., Ex. 24).

85. Novartis reported an AWP for its drugs on its own price lists sent to its customers, and to third party publishers, for their reference use. 9/26/07 Rosenthal Tr. at 45, 48-49, 70 (Grimmer Aff., Ex. 7); *see also, e.g.*, July 10, 1997 letter from Novartis to Third Party Journal attaching updated price list, NPC-AGC 005717087-098 (Grimmer Aff., Ex. 25); October 26, 1998 letter from Novartis to Third Party Journal attaching updated price list, NPC-AGC 005718215-226 (Grimmer Aff., Ex. 26); October 15, 1999 letter from Novartis to Third Party Journal attaching updated price list, NPC-AGC 005717473-483 (Grimmer Aff., Ex. 27); July 5, 2000 letter from Novartis to Third Party Journal attaching updated price list, NPC-AGC 005716810-819 (Grimmer Aff., Ex. 28); November 1, 2001 letter from Novartis to Third Party Journal regarding price adjustments to Desferal, NPC-AGC 005717298 (Grimmer Aff., Ex. 29); May 9, 2002 letter from Novartis to Third Party Journal regarding price adjustments for various products, NPC-AGC 005918146-148 (Grimmer Aff., Ex. 30).

86. Novartis stopped reporting AWP on its price lists in 2005. 9/26/07 Rosenthal Tr. at 34-35 (Grimmer Aff., Ex. 7).

87. Between 1997 and 2005, it was Novartis's policy to include the following explanatory statement about AWP on all external communications – including communications to First DataBank – that contained AWP information:

As used in this letter, the term AWP or Average Wholesale Price constitutes a reference for each Novartis product, and in keeping with current industry practices, is set as a percentage above the price at which the product is offered generally to wholesalers. Notwithstanding the inclusion of the term price in

Average Wholesale Price, AWP is not intended to be a price charged by Novartis for any product to any customer.

Arena Tr. at 26 (Grimmer Aff., Ex. 12); 9/26/07 Rosenthal Tr. at 33, 45, 151-53 (Grimmer Aff., Ex. 7); *see also, e.g.*, July 10, 1997 letter from Novartis to Third Party Journal attaching updated price list, NPC-AGC 005717087-098 (Grimmer Aff., Ex. 25); October 26, 1998 letter from Novartis to Third Party Journal attaching updated price list, NPC-AGC 005718215-226 (Grimmer Aff., Ex. 26); October 15, 1999 letter from Novartis to Third Party Journal attaching updated price list, NPC-AGC 005717473-483 (Grimmer Aff., Ex. 27); July 5, 2000 letter from Novartis to Third Party Journal attaching updated price list, NPC-AGC 005716810-819 (Grimmer Aff., Ex. 28); November 1, 2001 letter from Novartis to Third Party Journal regarding price adjustments to Desferal, NPC-AGC 005717298 (Grimmer Aff., Ex. 29); May 9, 2002 letter from Novartis to Third Party Journal regarding price adjustments for various products, NPC-AGC 005918146-148 (Grimmer Aff., Ex. 30).

88. Although the exact language of the explanatory statement varied slightly over time, the statement that Novartis's AWP's were "set as a percentage above the price at which each product is offered generally to wholesalers" was always included. *Id.*; 9/26/07 Rosenthal Tr. at 33, 45, 151-53 (Grimmer Aff., Ex. 7).

89. Wisconsin Medicaid's designee testified that no one from Novartis ever misrepresented anything to her, and she had no reason to believe that Novartis would not have provided truthful information about its AWP's if asked. Gray Tr. at 174 (Grimmer Aff., Ex. 16).

90. Novartis does not sell drugs to Wisconsin Medicaid. Rosenthal Aff. at ¶ 14 (Grimmer Aff., Ex. 1).

91. The Secretary of the U.S. Department of Health and Human Services (the "Department") signed Medicaid rebate agreements with Novartis's predecessor companies,

Sandoz Pharmaceuticals Corporation and Ciba-Geigy Corporation, in February 1991 and December 1992, respectively, on behalf of the Department and all states that participate in Medicaid. Sandoz Pharmaceuticals Corporation Rebate Agreement, NPC-AGC006228674-685 (Grimmer Aff., Ex. 31); Ciba-Geigy Rebate Agreement, NPC-AGC00957784-795 (Grimmer Aff., Ex. 32). These agreements set forth Novartis's responsibilities as a manufacturer participating in state Medicaid programs. *Id.* at NPC-AGC006228679-80 and NPC-AGC009577887-88.

92. Wisconsin Medicaid contracts with Provider Synergies through its fiscal agent, EDS, to administer Wisconsin Medicaid's Preferred Drug List ("PDL") and negotiate with pharmaceutical manufacturers on its behalf. Transcript of January 24, 2007 deposition of Wisconsin Medicaid designee James Vavra, Bureau Director, Division of Healthcare Financing ("1/24/07 Vavra Tr."), at 111-12 (Grimmer Aff., Ex. 33); Transcript of September 27, 2007 deposition of Wisconsin designee James J. Vavra, Bureau Director, Division of Healthcare Financing ("9/27/07 Vavra Tr."), at 598 (Grimmer Aff., Ex. 34).

93. Provider Synergies solicits pricing information from pharmaceutical manufacturers in connection with the administration of Wisconsin's Medicaid PDL. 1/24/07 Vavra Tr. at 111 (Grimmer Aff., Ex. 33).

94. Starting in 2004, Novartis has entered into supplemental Medicaid rebate agreements with the Wisconsin Department of Health and Family Services ("DHFS"). Byler Tr. at 67-68 (Grimmer Aff., Ex. 6); Supplemental Rebate Agreement between DHFS and Novartis, NOV-WIS000106544-556 (Grimmer Aff., Ex. 35); Amendment No. 1 to Supplemental Rebate Agreement, NOV-WIS000106540-543 (Grimmer Aff., Ex. 36); Amendment No. 2 to Supplemental Rebate Agreement, NPC-AGC003806244-246 (Grimmer Aff., Ex. 37);

Amendment No. 3 to Supplemental Rebate Agreement, NOV-WIS000106649-651 (Grimmer Aff., Ex. 38); Amendment No. 4 to Supplemental Rebate Agreement, NOV-WIS000106520-522 (Grimmer Aff., Ex. 39); Amendment No. 5 to Supplemental Rebate Agreement, NOV-WIS000106645-648 (Grimmer Aff., Ex. 40); Amendment No. 6 to Supplemental Rebate Agreement, NOV-WIS000106505-507 (Grimmer Aff., Ex. 41). Provider Synergies uses Novartis's WAC prices in its supplemental rebate determinations. Supplemental Rebate Agreement between DHFS and Novartis at NOV-WIS000106556 (Grimmer Aff., Ex. 35); Amendment No. 1 at NOV-WIS000106542 (Grimmer Aff., Ex. 36); Amendment No. 2 at NPC-AGC003806245 (Grimmer Aff., Ex. 37); Amendment No. 3 at NOV-WIS000106651 (Grimmer Aff., Ex. 38); Amendment No. 4 at NOV-WIS000106522 (Grimmer Aff., Ex. 39); Amendment No. 5 at NOV-WIS000106648 (Grimmer Aff., Ex. 40); Amendment No. 6 at NOV-WIS000106507 (Grimmer Aff., Ex. 41).

#### **IV. ARGUMENT<sup>2</sup>**

It is beyond dispute that AWP is a pricing term commonly used in pharmaceutical markets that, when applied to brand name prescription drugs, is understood by manufacturers, wholesalers, retailers and third party payors to describe a price that is 20-25% higher than published WAC, and often as much as 30% higher than retailers' actual acquisition cost. *See, e.g., In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20 (D. Mass. 2007) (*In re AWP IP*); (DAPUF ¶¶ 1-8.).<sup>3</sup> It is also beyond dispute that Wisconsin Medicaid, a

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<sup>2</sup> Novartis adopts and incorporates by reference the arguments set forth in the Responses of AstraZeneca, Johnson & Johnson, and Sandoz to Plaintiff's Motions for Partial Summary Judgment, to the extent they are applicable to the claims against Novartis.

<sup>3</sup> References to Defendants' Additional Proposed Undisputed Facts, which Novartis adopts and incorporates by reference, are cited as "(DAPUF ¶ \_\_)."

sophisticated participant in those markets, shared that understanding. (DAPUF ¶¶ 9-23.) Plaintiff asks the Court to ignore this reality and interpret AWP and WAC devoid of context, using meanings that only Plaintiff ascribes. Without any evidentiary basis, Plaintiff asks the Court to define AWP as *an average of transaction prices actually paid by retailers to wholesalers* and WAC as *a transaction price actually paid by wholesalers to manufacturers*. (Pl.'s Br. at 2.) Based on those newly minted definitions, Plaintiff asks the Court to issue an advisory opinion that publishing AWP and WACs that do not comport with its asserted definitions violates WDTPA. Moreover, Plaintiff seeks summary judgment against Novartis, without having presented to the Court a single advertisement, announcement, statement, or representation made by or on behalf of Novartis in Wisconsin, much less one that Wisconsin Medicaid saw or relied upon.

The terms AWP and WAC have particular meanings to the parties who use them – including Wisconsin Medicaid – and whether they have been properly used must be measured against those meanings, not against artificial meanings constructed by Plaintiff. No provision of WDTPA allows Plaintiff to lift commonly used industry terms entirely out of context and redefine them retrospectively to manufacture a claim, as it attempts to do here. No precedent supports Plaintiff's remarkable request for a judgment of liability for alleged false statements that does not rest on a specific "advertisement, announcement, statement, or representation" by Novartis made at a specific time, within or to Wisconsin, so that the Court can determine, in context, whether it was deceptive or misleading and whether anyone was damaged by it. Plaintiff's failure to identify any such specific advertisement or statement mandates denial of its motion.

A. Factual Background

1. Novartis and Its Business

Novartis is a research-based manufacturer of brand name prescription drugs. (NAPUF ¶ 52.)<sup>4</sup> When first introduced into the market, Novartis drugs are patented and, thus, are available only from Novartis. (NAPUF ¶ 52.) The vast majority of Novartis products are self administered drugs that are prescribed by doctors, dispensed by pharmacies, and taken by patients on their own. (NAPUF ¶ 53.) A small number of its products are physician administered, meaning that a doctor or healthcare professional must administer the drug to a patient. (NAPUF ¶ 53.) Novartis sells its products to wholesalers at what is known in the industry as WAC, which is Novartis’s list price to wholesalers. (NAPUF ¶ 61.) Such wholesalers may deduct approximately two percent off the invoiced amount if they pay Novartis within a specified period of time. (NAPUF ¶ 61.) When Novartis launches a new product, wholesalers may also be offered a one-time “stocking allowance” to ensure that the new product is available on the market to meet demand. (NAPUF ¶ 62.) Retail drug stores (and physicians who buy physician administered drugs) typically purchase Novartis products from wholesalers at whatever prices wholesalers are willing to sell them to such retailers. (NAPUF ¶ 63.) Because retail pharmacies have no significant influence over whether a Novartis brand drug will be prescribed, Novartis generally does not offer retailers discounts or financial incentives in connection with the sale of its products. (NAPUF ¶ 56.)

Novartis provides rebates to reduce prices paid by entities like Wisconsin Medicaid, private third party payers, and prescription drug benefit managers because those entities can

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<sup>4</sup> References to Novartis’s Additional Proposed Undisputed Facts are cited as “(NAPUF ¶ \_\_).”

affect what drugs are prescribed for the patients they cover, similar to consumer product companies giving coupons to consumers to encourage them to choose their products over those of competitors when they go shopping. (NAPUF ¶ 57.) Novartis also reduces prices for hospitals, public health clinics, and other facilities that maintain pharmacies that dispense drugs because they, too, can influence prescribing choices made by affiliated doctors. (NAPUF ¶ 58.) Plaintiff has proffered no evidence that such rebates or discounts affect the prices paid by Wisconsin pharmacies that dispense Novartis drugs to Medicaid patients.

## 2. AWP and WAC

While AWP may have once been equal to an actual average of the prices paid by retailers to wholesalers, by at least the mid-1980s, AWP had become a benchmark or reference price that everyone – including those in the federal government and the state Medicaid agencies – understood did not reflect the average of the prices paid by retailers to wholesalers. (DAPUF ¶ 5.) Because WAC is known to be a list price that does not account for prompt-pay or other discounts, it has long been widely known that the published AWP of brand name drugs is often as much as 30% higher than the price a retailer might pay to a wholesaler for a drug. *See In re AWP II*, 491 F. Supp. 2d 20 (D. Mass. 2007). Put another way – as it was stated repeatedly in numerous federal government reports provided periodically to Wisconsin Medicaid from 1984 through 2005 – retailers were often able to acquire brand name drugs from wholesalers at discounts of at least 16% to 20% less than the AWP. (DAPUF ¶¶ 7-8, 11, 145.)

## 3. First DataBank and Its Role

Wisconsin Medicaid's principal source of drug pricing information has been First DataBank, a subsidiary of the Hearst Corporation. (NAPUF ¶ 66.) First DataBank creates and maintains an extensive drug database that includes a wide variety of information about virtually every drug sold in the United States, including pricing information. (NAPUF ¶ 66.) At all

relevant times, First DataBank independently set the AWP's it reported to its customers based on information it obtained from a varying number of national wholesalers and those published AWP's accurately reflected First DataBank's understanding of the markups those wholesalers were using to set their *list* prices to retailers, not the transaction prices ultimately paid by the retailers. (NAPUF ¶¶ 72-74, 80.)

Thus, Novartis did not set, or cause to be published, the AWP's that First DataBank provided to Wisconsin Medicaid during the relevant period. Rather, Novartis provided AWP's for its drugs on Novartis's price lists sent to its customers, for their reference use. (NAPUF ¶ 85.) First DataBank's undisputed testimony demonstrates that AWP's provided by Novartis had no influence whatsoever on the AWP's published by First DataBank. (NAPUF ¶¶ 72-74, 83.) This testimony is confirmed by evidence that from 2002 to 2005 (when Novartis stopped reporting AWP's altogether), the AWP's listed by First DataBank for Novartis drugs were in all but a few instances different from – and higher than – those reported by Novartis. (NAPUF ¶ 84.)

4. Wisconsin Medicaid Understood Pricing Terminology and Set Its Reimbursement Rates Based on That Understanding

Throughout the relevant period, Wisconsin Medicaid – like every other pharmaceutical market participant – fully understood that published AWP's did not represent Wisconsin Medicaid providers' actual drug acquisition costs. (DAPUF ¶¶ 9-23.) Wisconsin Medicaid used that knowledge to purposefully design its reimbursement system for brand name drugs in a way that worked best for it. (DAPUF ¶¶ 63-191.)

Indeed, even today, Wisconsin continues to utilize AWP in its Medicaid drug reimbursement formula for certain drugs, as it has for many years. (DAPUF ¶¶ 41, 43.)<sup>5</sup> That is Wisconsin's choice, as no federal statute or regulation requires it to use AWP. (DAPUF ¶¶ 33-36.) On the contrary, for more than twenty years, the federal government has discouraged using AWP as a component of drug reimbursement (DAPUF ¶¶ 121-23) – advice which Wisconsin has chosen to disregard.

Wisconsin's informed decision to use a discounted AWP in its reimbursement formula was intended to provide a profit to pharmacists to ensure that a sufficient number of pharmacists would participate in Medicaid, enabling Wisconsin to meet federal access to care requirements. (DAPUF ¶¶ 65, 74-79.) Wisconsin has, over the years, considered and rejected several proposals to increase the percentage discount it applied to AWP and thus bring the ingredient cost component of its reimbursement formula more in line with pharmacists' actual acquisition costs. (DAPUF ¶¶ 142-60, 167-73, 176-91.)

These choices were not made out of ignorance. In 1975, long before Wisconsin began applying a discount to AWP in its reimbursement formula, it considered changing to an actual acquisition cost methodology based on pharmacy invoices, because it considered AWP to be a “highly suspect . . . figure,” which overstated actual drug costs by 15%. (DAPUF ¶¶ 109-14.) Wisconsin nonetheless chose at that time to continue reimbursing at 100% of AWP. (DAPUF ¶ 116.)

In 1984, the Office of Inspector General (“OIG”) of the United States Department of Health and Human Services issued a report concluding that “pharmacies do not purchase drugs at

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<sup>5</sup> Wisconsin has never used WAC as a basis for drug reimbursement under its Medicaid program. (DAPUF ¶ 45.)

the AWP published in the ‘Bluebook’ [First DataBank’s publication], ‘Redbook,’ or similar publications. Thus AWP cannot be the best – or even an adequate – estimate of the prices providers generally are paying for drugs.” (DAPUF ¶ 122.) After receiving the report, Wisconsin again considered changing its reimbursement methodology, but chose to continue reimbursing at 100% of AWP, citing the potential impact on Wisconsin provider participation. (DAPUF ¶¶ 124-26.)

In 1989, the Health Care Financing Administration (“HCFA”), the federal agency responsible for overseeing the Medicaid program at that time, issued a directive to states that “absent valid documentation to the contrary, a published AWP level as a State determination of EAC without a significant discount being applied is not an acceptable estimate of prices generally and currently paid by providers.” (DAPUF ¶ 127.) In response, Wisconsin considered various reimbursement methodologies, including “actual acquisition cost” and “wholesale cost [WAC] plus” but ultimately chose a discounted AWP methodology (AWP minus 10%), a “middle ground” that “might be acceptable to HCFA” and would be “more acceptable to providers since it would allow higher reimbursement for higher cost drugs.” (DAPUF ¶¶ 129-32.) Apparently, that “middle ground” was insufficient for providers and, in response to their protests, the Wisconsin legislature increased providers’ dispensing fees in order to offset the reduced reimbursement rate. (DAPUF ¶¶ 133-35.)

Throughout the 1990s and to the present, Wisconsin continued to receive information from the federal government and other sources confirming that AWP exceeded pharmacists’ actual costs by as much as 20%. (DAPUF ¶¶ 7-8, 11, 161-62, 174.) Several times Wisconsin proposed reducing its reimbursement rate. (DAPUF ¶¶ 113, 129, 131, 136, 142, 153, 167, 176.) It also received information and conducted its own studies finding that dispensing fees it paid

were insufficient to cover providers' actual dispensing costs, and each proposal to reduce the ingredient cost reimbursement met with provider resistance. (DAPUF ¶¶ 82-83, 87, 89, 91, 93.) Consequently, each proposal to reduce reimbursement rates was either rejected or modified to reflect a smaller rate reduction, in recognition of the need to provide pharmacies with sufficient reimbursement to earn a profit (and to offset low dispensing fees) so that Wisconsin could maintain adequate participation in Medicaid. (DAPUF ¶¶ 97-103, 132-35, 137-41, 143-45, 156-60, 171-73.)

B. Legal Standard for Summary Judgment

To prevail on its motion for summary judgment, Plaintiff must prove that no issues of material fact exist. *See e.g., Nielsen v. Spencer*, 287 Wis. 2d 273, 281, 704 N.W.2d 390, 394 (Ct. App. 2005). Thus, Plaintiff must show undisputed material facts supporting each element required to be proved. *See Metro. Ventures, LLC v. GEA Assocs.*, 291 Wis. 2d 393, 407, 717 N.W.2d 58, 65 (2006) (stating, “summary judgment is appropriate only when there is no dispute over facts that would affect the outcome of the case”). And, “if the inferences to be drawn from credible evidence are doubtful and uncertain, the motion for summary judgment should be denied.” *Frewe v. Dupons Constr. Co.*, 37 Wis. 2d 676, 681, 155 N.W.2d 595, 598 (1968). As shown below, Plaintiff's motion at best raises disputed material issues of fact on which Plaintiff must prevail to prove its claims. Therefore, its motion should be rejected.

To avoid summary judgment in favor of Novartis on its cross-motion, Plaintiff has “the ultimate burden of demonstrating that there is sufficient evidence . . . to go to trial at all.” *See Kaufman v. State Street Ltd. P'ship*, 187 Wis. 2d 54, 58-59, 522 N.W.2d 249, 251 (Ct. App. 1994) (citation omitted). Because the undisputed evidence demonstrates that the meaning of AWP on which Plaintiff's claim rests is at odds with reality, Plaintiff has not and cannot produce

evidence showing that any person to whom AWP was published was deceived or misled. Consequently, Plaintiff's WDTPA claims should be dismissed.

C. Plaintiff's Motion and WDTPA Claims Rest on Fabricated Definitions of Industry Terms Contrary to the Understanding of Wisconsin Medicaid and, Therefore, Fail for Lack of Admissible Evidence that Novartis's AWP and WACs Were Untrue, Deceptive, or Misleading

The undisputed factual record demonstrates how Wisconsin Medicaid, along with the other participants in the market for brand name pharmaceuticals, used and understood the terms AWP and WAC, rather than the different meanings Plaintiff now proffers for them. The record itself warrants rejection of Plaintiff's motion.

The central premise of Plaintiff's claims is that AWP means the "true average [transaction] price[] charged by wholesalers," and that WAC means "the true price[] paid by wholesalers to [Novartis] to acquire [Novartis's drugs]" *after* deducting "rebates, discounts, chargebacks, and similar items that reduce wholesalers' true cost to purchase [Novartis's] drugs." (Pl.'s Br. at 2.) Plaintiff contends that because Novartis's AWP and WACs do not conform to Plaintiff's definitions, they are "untrue, deceptive, and misleading" in violation of Wis. Stat. section 100.18(1). Plaintiff has not, however, produced undisputed evidence to support its definitional premise. To the contrary, the undisputed evidence demonstrates the unreasonableness of that premise and highlights the absurdity of defining these terms according to their so-called "plain meaning."

Indeed, the undisputed evidence shows that AWP is broadly understood by the market in which it is used to be a benchmark which, in the case of branded drugs like Novartis's, is generally 20-25% above manufacturers' list prices to wholesalers, and that it has been so understood since at least the early 1980s. The undisputed evidence further shows that WAC is a manufacturer's list price to wholesalers and is broadly understood by the market in which it is

used not to include discounts, rebates, or any other factors that could, in any particular sale, reduce a wholesaler's actual purchase price below the list price. Against this backdrop, Plaintiff has not met its burden of showing, by undisputed evidence, that Novartis's AWP and WACs are "untrue, deceptive, or misleading."

1. Context Is Relevant and Should Be Considered

Remarkably, Plaintiff contends that whether a particular statement is "untrue, deceptive or misleading" should be determined in a vacuum, without the benefit of context – including knowledge and sophistication of the target audience – and without reference to accepted industry usage. Ignoring Judge Learned Hand's oft-cited admonition that "it is one of the surest indexes of a mature and developed jurisprudence not to make a fortress out of the dictionary," *Cabell v. Markham*, 148 F.2d 737, 739 (2d Cir. 1945), *aff'd*, 326 U.S. 404, 66 S. Ct. 193, 90 L. Ed. 165 (1945), Plaintiff argues that the Court should accept its definition of AWP and WAC based solely on a literal, dictionary-based interpretation of their component words, and without reference to the context in which they were used and understood within the markets for brand name drugs, including by Plaintiff's own Medicaid officials. Plaintiff's argument, however, is wholly unsupported by any Wisconsin or federal<sup>6</sup> case law, and defies common sense.

Federal case law construing analogous provisions of the Federal Trade Commission Act and the Lanham Act specifically caution against "the tyranny of literalness" and admonish that "[f]undamental to any task of interpretation is the principle that text must yield to context." *Avis*

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<sup>6</sup> Wisconsin courts are guided by federal cases interpreting analogous consumer protection statutes, particularly where, as here, Wisconsin cases have not addressed the issue. *State v. Am. TV & Appliance of Madison, Inc.*, 146 Wis.2d 292, 301, 430 N.W.2d 709 (1988) (relying on federal cases construing Federal Trade Commission Act and Lanham Act claims); *see also* Pl.'s Br. at 17 (citing *Tim Torres Enters., Inc. v. Linscott*, 142 Wis.2d 56, 66-67, 416 N.W.2d 670, 674 (Ct. App. 1987)).

*Rent A Car Sys., Inc. v. Hertz Corp.*, 782 F.2d 381, 385 (2d Cir. 1986) (holding that statements were not false and stating that “[i]n his determination to ‘go by the written word’ and to ignore the context in which the words were used, the district judge . . . failed to heed the familiar warning of Judge Learned Hand that ‘[t]here is no surer way to misread any document than to read it literally’” (citation omitted)); *see also, e.g., Labware, Inc. v. Thermo Labsystems, Inc.*, 2005 WL 1541028, \*9 (E.D.Pa. 2005) (“A determination of literal falsity rests on an analysis of the message in context.”) (quoting *Johnson & Johnson-Merck Consumer Pharms. Co. v. Rhone-Poulenc Rorer Pharms., Inc.*, 19 F.3d 125, 129 (3d Cir. 1994)); *cf. Gallego v. Wal-Mart Stores, Inc.*, 288 Wis. 2d 229, 239, 707 N.W.2d 539, 544 (Ct. App. 2005) (although dictionary definition of “merchandise” may include articles of food, “statutory background” of Wis. Stat. section 100.18(1) indicates a different meaning in context); *State ex rel. Kalal v. Cir. Ct. for Dane County*, 271 Wis. 2d 633, 663, 681 N.W.2d 110, 124 (2004) (“Context is important to meaning . . . . Therefore, statutory language is interpreted in the context in which it is used; not in isolation but as part of a whole; in relation to the language of surrounding or closely-related statutes; and reasonably, to avoid absurd or unreasonable results.”) (citations omitted).

Federal cases repeatedly emphasize the importance of context to determining the truth of a statement or its capacity to mislead, particularly where, as here, “the target of the [statement] is not the consuming public *but a more well informed and sophisticated audience. . . .*” *Plough, Inc. v. Johnson & Johnson Baby Prods. Co.*, 532 F.Supp 714, 717 (D. Del. 1982) (emphasis added); *see also, e.g., Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 229-30 (3d Cir. 1990) (“a target audience’s special knowledge of a class of products is highly relevant to any claim that it was misled by an advertisement for such a product”).

In *Plough*, the court held that the term “sunscreen” in the context of comparative statements in trade advertising (*i.e.*, advertising directed at merchants, such as wholesalers and retailers, as opposed to the consuming public) was not literally false because the “merchants to whom the parties address themselves are more likely to interpret ‘sunscreen’” in a way that does not render the statement false. 532 F.Supp at 718; *see also Am. Home Prods. Corp. v. Abbott Labs.*, 522 F.Supp. 1035, 1042-44 (S.D.N.Y 1981) (stating that “context determines the meaning of words” and observing that similarly worded phrases could have different meanings in different commercial contexts). In *Princeton Graphics Operating, L.P. v. NEC Home Electronics (U.S.A.), Inc.*, the court defined the term “compatibility” according to its “common and well-defined” meaning within the particular target group (“the ‘retail channel’ of sophisticated users”) to whom the advertising was directed. 732 F.Supp. 1258, 1262, 1266 (S.D.N.Y. 1990). Although the court held that the advertisement was literally false because “the performance of the [advertised product] did not come within the parameters of that definition,” *id.* at 1266, it specifically found that dictionary and glossary definitions “were of little probative value” because the relevant audience was the “‘retail channel,’” rather than the “general population.” *Id.* at 1262 n.11.

These precedents recognize that virtually every trade or industry, including the pharmaceutical industry, has a language used by the industry participants. The industry terms that make up these languages do not always mean what they might appear to mean to a non-participant in the particular market at issue. Rather, such industry terms have meanings to those who take part in that industry, and those particular meanings are well-known within the

industry.<sup>7</sup> For those who manufacture, distribute and pay for branded pharmaceuticals, the terms “AWP” and “WAC” have a meaning, and literal dictionary definitions are unhelpful in determining that meaning.<sup>8</sup>

Plaintiff’s reliance on Judge Saris’s decision, ascribing a “plain meaning” to the phrase “average wholesale price” as used by Congress in a specific Medicare statute at a particular moment in time, is misplaced. (Pl.’s Br. at 15-16 (citing *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d 277, 278, and 287-88 (D. Mass. 2006) (“*In re AWP. I*”).) There, the court was asked to determine what Congress understood the words to mean when adopting them for use in a federal statute setting reimbursement to providers of drugs under the Medicare Part B program at “95 percent of the average wholesale price.” 42 U.S.C. § 1395u(o). Judge Saris assumed that Congress – which is not composed of participants in the market for pharmaceuticals – used each word “average,” “wholesale,” and “price” not as a term of art used in the market but as a layman might use them. *See In re AWP. I*, 460 F. Supp. 2d at 287-88.

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<sup>7</sup> Words that are ambiguous or subject to more than one interpretation cannot be deemed “false.” *See, e.g., Time Warner Cable, Inc. v. DirectTV, Inc.*, 497 F.3d 144, 158 (2d Cir. 2007) (“if the language . . . is susceptible to more than one reasonable interpretation, the advertisement cannot be literally false”); *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 586 (3rd Cir. 2002) (“only an unambiguous message can be literally false”).

<sup>8</sup> Similarly, how “[o]ther courts” defined the phrase “wholesale price” in completely different contexts is entirely irrelevant to determining the meaning of the terms at issue here. *See* Pl.’s Br. at 16 (citing *Federated Nationwide Wholesalers Serv. v. FTC*, 398 F.2d 253, 256 n.3 (2d Cir. 1968) (upholding FTC’s findings that seller’s representation to consumers that its actual prices were “wholesale prices” was deceptive and misleading where its actual prices exceeded the prices retailers paid for the items) and *Guess v. Montague*, 51 F. Supp. 61, 65 (D. S.C. 1942) (in deciding whether the defendant’s business was a “retail” establishment for purposes of the wages paid to employees under the Fair Labor Standards Act, court noted that “wholesale” and “retail” take on distinct and entirely different meanings depending on context)).

Even if that assumption were correct, Judge Saris did not purport there to define AWP as used by participants in the market, such as First DataBank and third party payors, including Wisconsin Medicaid. In a later opinion following a lengthy bench trial in which she received evidence of the understanding of all such market participants, she confirmed that (i) all market participants shared the understanding of AWP that Novartis proffers here, and (ii) publishing AWPs consistent with that understanding is neither deceptive nor misleading as a matter of consumer protection law. *See In re AWP II*, 491 F. Supp. 2d 20, 94 (D. Mass. 2007) (specifically holding that “[a]dherence to industry standards or customs is one factor that supports a finding of no unfairness under [the Massachusetts Consumer Protection Act] Chapter 93A”).<sup>9</sup> Based on an extensive record of public information provided to the marketplace – including a long history of government reports and other information provided directly to Wisconsin Medicaid and sister state agencies from the 1980s forward – Judge Saris determined that the prescription drug marketplace has long been aware that WAC is an undiscounted list price and that the AWP of branded drugs is 20-25% above WAC. *Id.* at 97. Accordingly, Judge Saris held that a defendant is not liable for “unfair” or “deceptive” conduct if the alleged spreads between AWP and actual retail acquisition cost for that defendant’s drugs were equal to or less than 30%. *See id.* at 92, 95, 101-04.

Indeed, in *AWP II*, Judge Saris stated that the well known industry practice of calculating AWPs by applying a 20-25% markup from WAC is “arguably relevant in construing the

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<sup>9</sup> The Massachusetts Consumer Protection Act, ALM GL ch. 93A, prohibits “unfair or deceptive acts or practices in the conduct of any trade or commerce.” Massachusetts courts, like Wisconsin courts, apply the Federal Trade Commission’s standard that an act is “deceptive” if it has “a capacity or tendency to deceive.” *Tim Torres Enterprises, Inc. v. Linscott*, 142 Wis. 2d 56, 66-67, 416 N.W.2d 670, 674 (Wis. Ct. App. 1987); *Leardi v. Brown*, 474 N.E.2d 1094, 1099 (Mass. 1985).

meaning of the statutory term AWP.” *Id.* at 97 & n.72. She further acknowledged that she had not considered the industry practice question prior to issuing her decision in *AWP I* construing AWP in the context of a federal Medicare statute. *Id.* Her earlier decision – on which Plaintiff erroneously relies – must be read in light of, and limited by, her later holdings.

2. Market Knowledge and Understanding Is Relevant

Based on its misreading of a single Wisconsin case, Plaintiff argues incorrectly that “what the public, the State or any other purchaser understood about [Novartis’s] AWP’s is irrelevant to the determination of truthfulness under [section 100.18(1)].” (Pl.’s Br. at 16 (citing *Tim Torres Enters., Inc. v. Linscott*, 142 Wis. 2d 56, 66, 416 N.W.2d 670, 674 (Ct. App. 1987).) In *Linscott*, the court upheld a jury determination that advertisements for the sale of frozen custard were literally false, concluding “that there was sufficient credible evidence upon which the jury could find that the statements were untrue.” *Id.* at 65. Notably, that evidence included not only the advertisements themselves; it also included evidence pertaining to the *context* in which the advertisements were made, such as “various agreements, the advertisements, the timing of the appearance of the advertisements, and [the defendants-appellants’] admissions.” *Id.* at 69. Although the court held that “a determination of untruthfulness does not *require* proof of public reaction,” *id.* (emphasis added), the court did not suggest – let alone hold – that such proof would be *irrelevant* to a determination of untruthfulness.

To the contrary, the *Linscott* court’s own words confirm that the impression a statement will make on its target audience must be considered in determining whether the statement is false or deceptive. *Id.* at 67 (“the cardinal factor is the probable effect which the advertiser’s handiwork will have upon the eye and mind of the reader”) (quoting *FTC v. Sterling Drug, Inc.*, 317 F.2d 669, 674 (2d Cir. 1963)). This is also consistent with the federal case law on which *Linscott* relied. Thus,

While actual consumer confusion is not necessary to assert a claim of literal falsity, *the perspective of the relevant consumer population is necessary in determining whether an advertisement could be viewed as false*. Thus, in order to assess whether an advertisement is literally false, the Court must analyze the message conveyed within the full context of the advertisement. *Making such a determination as to the full context requires the Court to look at the audience.*

*Utah Med. Prods., Inc. v. Clinical Innovations Assocs., Inc.*, 79 F. Supp. 2d 1290, 1309 (D. Utah 1999) (emphasis added).

Applying this standard of inquiry in *Utah Medical*, the court rejected the plaintiff's expert's testimony because he reviewed the defendant's advertisement, describing its intrauterine catheter as "sensor tipped," in isolation. *Id.* at 1310. The court held as a matter of law that the advertisement was not literally false, finding that:

[P]laintiff's argument does not take into account the proper context of the statement. Furthermore, plaintiff's expert offers no insight into how an educated and skilled labor and delivery clinician could [be] misled into believing that there is a pressure transducer in the . . . catheter tip when the product literature repeatedly states that the external transducer is located in the reusable cable.

*Id.* Plaintiff's motion asks this Court to ignore context. A multitude of state and federal consumer protection and false advertising law exposes the error in that request. Plaintiff's effort to deny reality should be rejected.

### 3. Novartis's AWP's and WAC's Are Not Untrue

Plaintiff asserts that Novartis's AWP's and WAC's were disseminated to a sophisticated and knowledgeable target audience of third party payors, including Wisconsin Medicaid and other entities with specialized knowledge of the pharmaceutical industry. (Complaint ¶¶ 35, 70; NAPUF ¶¶ 29, 67, 82, 85; DAPUF ¶¶ 2-5.) The undisputed evidence further shows that the entire pharmaceutical market knew and expected, that AWP's for branded drugs would be set at 20-25% above WAC, and that the market also knew and expected WAC to be a list price, *before* discounts, rebates, and other items that may in any given transaction reduce the net price paid by

wholesalers. (DAPUF ¶¶ 2-7, 46-49, 145.) Finally, Novartis specifically disclosed on its price announcements that, as used by Novartis, “the term AWP or Average Wholesale Price constitutes a reference for each [Novartis] product, and in keeping with current industry practices, is set as a percentage above the price at which each product is offered generally to wholesalers.” (NAPUF ¶¶ 87-88.)

There is simply no evidence that the message conveyed by Novartis was – as Plaintiff alleges without proof – that its AWPs represented an actual average of what retailers pay to wholesalers for Novartis’s drugs. Nor is there any evidence that the message conveyed by Novartis’s WACs was that they represented the net price paid by wholesalers for Novartis’s drugs, *after* deducting all discounts, rebates, chargebacks, and other items that reduce the price paid by a wholesaler in a given transaction. Rather, Novartis’s AWPs and WACs were entirely consistent with market norms and, in fact, conformed exactly to the understanding and expectation of Plaintiff and others who sought the information to use in whatever manner they saw fit. Thus, Plaintiff has failed to meet its burden of proof to establish that Novartis’s AWPs and WACs were “untrue,” because the undisputed evidence shows that Novartis’s AWPs and WACs “express[ed] things exactly as they are.” *Linscott*, 142 Wis. 2d at 65 n.3.

#### 4. Novartis’s AWPs and WACs Are Not Deceptive or Misleading

For the same reasons, Plaintiff has also failed to meet its burden of proof to establish that Novartis’s AWPs and WACs were “deceptive or misleading.” A statement is deceptive or misleading if it has “a capacity or tendency to deceive, *i.e.*, when there is a likelihood or fair probability that the reader will be misled.” *Id.* at 66-67. Thus, what Wisconsin Medicaid and others in the industry knew and understood about AWP and WAC is obviously relevant to determining the likelihood or fair probability that they would be misled. *See, e.g., Utah Med. Prods.*, 79 F. Supp. at 1310 (noting that plaintiff could not have prevailed on a claim that the

advertisement was misleading, because there was no factual basis to show that “from the perspective of the *relevant* consumer the advertisements as a whole could be viewed as false”) (emphasis added). Yet, Plaintiff does not – nor can it – point to a single undisputed fact showing a likelihood or fair probability that Novartis’s AWP’s and WAC’s would mislead Wisconsin Medicaid or anyone else in Wisconsin who was likely to use them for any purpose. *See Madcap I, LLC. v. McNamee*, 284 Wis. 2d 774, 793-94. 702 N.W.2d 16, 25-26 (Ct. App. 2005) (summary judgment improper where there are reasonable conflicting inferences about meaning of allegedly false or misleading statements under section 100.18(1)); *see also Ball v. Sony Elecs. Inc.*, 2005 WL 2406145, at \*3 (W.D. Wis. Sept. 28, 2005) (dismissing section 100.18 claim, finding that troubleshooting section of the defendant’s website, which allegedly contained the untrue, deceptive or misleading statements, “includes nothing that could be deemed false, deceptive or misleading”); *Uebelacker v. Paula Allen Holdings, Inc.*, 464 F. Supp. 2d 791, 805 (W.D. Wis. 2006) (dismissing section 100.18 claim, finding that the “statements” when “read in the context of the documents of which they are a part . . . contradict the allegation that the statements are either deceptive or misleading”).<sup>10</sup>

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<sup>10</sup> Plaintiff’s reliance on early 1960s FTC cases regarding list prices (Pl.’s Br. at 18-19), and the subsequently issued FTC Guides Against Deceptive Pricing (the “Guides”), promulgated in 1964, is quite misplaced. First, all relate only to consumer transactions, which are not at issue here. Second, the Guides overruled the cases by creating a safe harbor for list prices “at which substantial (that is, not isolated or insignificant) sales are made . . . .” 16 C.F.R. § 233.3(d). The Guides do not provide that a list price “is unlawful” (Pl.’s Br. at 17) if it is not within the “safe harbor.” Therefore, the Guides themselves do not reflect FTC agreement with the Plaintiff’s theory here, as the FTC itself has made clear. Rather, 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 (Grimmer Aff., Ex. 43). Enforcement actions in this area are limited to situations in which consumers (not businesses or sophisticated state agencies) may in fact be deceived. *Id.* The FTC has stated 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  
(continued...)

In light of the overwhelming undisputed evidence proving that Wisconsin Medicaid and the rest of the pharmaceutical industry knew and understood exactly what AWP and WACs did and did not represent, and that Novartis's AWP and WACs conformed to that knowledge and understanding, there exists no genuine issue of material fact as to whether Novartis's AWP and WACs were untrue, deceptive, or misleading. They were not. Consequently, not only should Plaintiff's motion for summary judgment be denied, but Plaintiff's WDTPA claims as to Novartis should be dismissed.

D. Plaintiff's Motion Fails Because It Has Not Proffered Admissible Evidence to Satisfy the Elements of Wis. Stat. § 100.18(1)

Even if the Court were to allow Plaintiff to proceed on the theory that a jury could be permitted to ignore context entirely in determining whether terms used are misleading or deceptive, Plaintiff is not entitled to summary judgment because it has failed to produce competent, admissible undisputed evidence establishing each element of its WDTPA claims.<sup>11</sup>

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Assemblyman Aghazarian, dated September 7, 2004, at 10 (Grimmer Aff., Ex. 44). A Wisconsin rule inconsistent with that federal policy would violate the commerce clause of the United States Constitution. *See, e.g., Pharm. Research & Mfrs. of Am. 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).

<sup>11</sup> Plaintiff supports its motion almost entirely with snippets of testimony from one Novartis witness – Michael Conley – whose job description makes clear that he is not competent to testify to the matters as to which Plaintiff now wishes to rely on his testimony, nor was Mr. Conley designated by Novartis to testify about those subjects. Mr. Conley was Executive Director of Managed Markets Trade. In that position, he was responsible for (i) the customer service department, which handles the order processing for Novartis's direct customers, as well as returns that come in from various customers, (ii) the account management team that calls on the headquarters of large retail chains and wholesalers, and (iii) communications with third party publishers of pharmaceutical information, such as First DataBank. (NAPUF ¶ 64.) Not surprisingly, Plaintiff left Mr. Conley's job description out of the portions of his deposition attached to its motion, as well as Novartis's statement concerning the subject matters about which Mr. Conley was designated to testify. (NAPUF ¶ 65.) Had they been included, the Court could readily see that Mr. Conley's speculation as to Wisconsin Medicaid's actions and

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1. Plaintiff Has Proffered No Admissible Evidence of a Single Advertisement, Announcement, Statement, or Representation by Novartis in Wisconsin

Plaintiff concedes that both subparts of WDTPA under which it seeks partial summary judgment require it to establish, as a predicate to any liability, an “advertisement, announcement, statement or representation” made, or caused to be made by, Novartis. (*See* Pl.’s Br. at 4-5.) Yet, Plaintiff’s motion proffers no admissible evidence of any specific “advertisement, announcement, statement or representation” in Wisconsin by or on behalf of Novartis. This evidentiary failure alone dooms its motion.

Plaintiff’s “evidence” consists of four exhibits: excerpts from two depositions of Novartis employees and two iterations of a publication by Emron, a subsidiary of IMS Health, entitled *Pharmacy Benefit Report*, which is published with financial support from Novartis. Plaintiff does not assert that the *Pharmacy Benefit Report* includes any allegedly false prices, and does not offer the *Pharmacy Benefit Report* as a false “advertisement, announcement, statement or representation” of any price. Plaintiff cites no admissible deposition testimony that identifies a specific “advertisement, announcement, statement or representation” of any kind made in Wisconsin by or on behalf of Novartis, let alone one that included a price for any one or more of Novartis’s brand name drugs. Plaintiff, therefore, provides no evidence whatsoever that such “advertisement, announcement, statement or representation” was untrue, deceptive or misleading and made with the intent to induce the public to buy any merchandise, and no evidence on which the Court could actually enter a judgment under the WDTPA.

The most that Plaintiff offers is generalized testimony to the effect that:

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decisions, Novartis’s alleged legal duties to Wisconsin Medicaid, or the meaning of federal reimbursement regulations is not admissible evidence to establish any of those matters.

- Novartis sent price lists to its customers (wholesalers, warehousing retail chains) and to certain publishers of drug information (i.e., First DataBank). (PUF ¶ 28; NAPUF ¶¶ 82, 85.)
- Those price lists ordinarily included an AWP and WAC for each Novartis drug on the list. (PUF ¶ 28; NAPUF ¶¶ 82, 85.)
- The WAC was a list price to wholesalers. (PUF ¶ 43; NAPUF ¶¶ 40, 61, 82.)
- The AWP – as stated on the price lists themselves – is a mathematical extension of the WAC. (PUF ¶ 43; NAPUF ¶¶ 87-88.)

From there, Plaintiff asks the Court to infer that every Novartis price list published over a period of years was necessarily “untrue, deceptive or misleading” and – because Plaintiff never used Novartis’s prices – that First DataBank merely republished Novartis’s listed prices, despite First DataBank’s sworn testimony to the contrary. To obtain summary judgment establishing liability for making “untrue, deceptive or misleading” statements, Plaintiff must provide the statements, and specify the time, place, and manner in which they were made.<sup>12</sup> It may not rely upon a cascade of inferences that leaves the Court with no specific statements on which to enter judgment.

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<sup>12</sup> On Defendants’ motion to dismiss Plaintiff’s First Amended Complaint, this court found that Plaintiff had failed to articulate what it considers to be the threshold for fraud. The court wondered, “[w]ould a few cents difference from the AWP and the actual sales price meet that definition? A few dollars? Is the State limiting this case to the drugs mentioned in Exhibits A & B attached to the Complaint or is it including the 65,000 different drugs referenced several times in that pleading?” (Judge Krueger’s April 3, 2006 Partial Decision and Order [on Defendants’ Motions to Dismiss] at 13.) Thus, in order to maintain its causes of action, this court ordered Plaintiff to re-plead them, giving as many specifics as it can and identifying “which of its drugs are involved and what (name, date) publication of AWP is false, and the actual price that should have been published.” *Id.* Nearly two years and tens of millions of pages of discovery later, Plaintiff still has not done so. *See e.g., Butler v. Advanced Drainage Sys., Inc.*, 294 Wis. 2d 397, 411, 717 N.W.2d 760, 767 (Wis. 2006) (“Every decision on a motion for summary judgment begins with a review of the complaint to determine whether, on its face, it states a claim for relief.”) In light of that failure, its claims should be dismissed.

*Peterson v. Cornerstone Property Development, LLC*, 294 Wis. 2d 800, 822, 720 N.W.2d 716, 727 (Wis. Ct. App. 2006), illustrates this point. In *Peterson*, the Wisconsin Court of Appeals affirmed summary judgment for the defendant seller of a condominium, in part because the plaintiff purchaser “continually states only that [defendant] made ‘representations and omissions’ that entitle her to relief under Wis. Stat. § 100.18(1)” but “because [plaintiff] failed to identify the representations that she alleges were false, she cannot now allege false advertising.” *Id.* The same is true here. Plaintiff proffers no evidence of a single “advertisement, announcement, statement or representation” made in Wisconsin by or on behalf of Novartis on which the Court could enter a judgment finding liability. Neither the language of WDTPA nor any case cited by Plaintiff permits entry of a judgment in the absence of such evidence.

In the absence of any proof that Wisconsin Medicaid relied on a Novartis published AWP for any purpose, and conceding that Medicaid only used First DataBank AWP, Plaintiff seeks judgment against Novartis based solely on the assumption that Novartis somehow set and controlled AWP *published by First DataBank*, an independent drug information provider, which Wisconsin Medicaid is alleged to have used (Complaint at ¶ 35).<sup>13</sup> That assumption is conclusively refuted by the testimony of Patricia Kay Morgan, the former Manager of Editorial Services for First DataBank. Ms. Morgan testified that First DataBank derived its published

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<sup>13</sup> Plaintiff cites to PUF ¶¶ 26-39 in an attempt to support its baseless statement that “Novartis admits that it sets and controls the AWP and WACs that First DataBank publishes.” (Pl.’s Br. at 20.) Novartis disputes several of Plaintiff’s proposed facts because they are not supported by the record cite or because there is evidence to the contrary. (*See* III.A, *supra*.) In addition, the proposed undisputed facts on which Plaintiff relies are wholly irrelevant to – and, therefore, not supportive of – any such “admission” by Novartis. For example, PUF ¶¶ 26-27 merely state that First DataBank and RedBook (which is not at issue in this case) publish a variety of pharmaceutical pricing information about Novartis’s and other manufacturers’ drugs. Clearly, these facts do not support an admission by Novartis that it sets and controls the AWP published by First DataBank.

AWPs from surveys that it conducted of wholesalers to determine the “markup [wholesalers] applied to [a] manufacturer[’s]” line of products, and not from AWP’s that manufacturers reported to First DataBank. (NAPUF ¶¶ 72-74, 83.) Significantly, beginning in 2002, the AWP’s that First DataBank set and published for Novartis drugs generally were different from – and greater than – the AWP’s that Novartis reported to First DataBank. As a result, for almost the entire relevant period,<sup>14</sup> Wisconsin Medicaid’s reimbursements to providers for nearly all of the Novartis drugs at issue here were based on AWP’s that were different from the AWP’s on Novartis’s price lists. Given that it is undisputed that First DataBank alone made the “advertisement, announcement, statement or representation” to Wisconsin Medicaid, Plaintiff’s motion for summary judgment should be denied. Moreover, because that undisputed evidence negates an inference essential to Plaintiff’s WDTPA claims, those claims must be dismissed.

Recognizing that it has no evidence that Novartis controlled First DataBank, Plaintiff is reduced to arguing that it is “of no moment” that AWP’s published by First DataBank bore no resemblance to those that Novartis provided to First DataBank, because Novartis “expected, indeed knew,” that First DataBank was setting its AWP’s by applying a 25% markup to the WAC that Novartis reported for its drugs. (Pl.’s Br. at 20-23.) This is both factually and legally incorrect.

The facts establish only that Novartis learned in 2002 that First DataBank AWP’s for Novartis drugs reflected a 25% markup over WAC where most had previously reflected a 20% markup, and it was told that First DataBank determined its markups by surveying wholesalers. (NAPUF ¶¶ 77-81.) Novartis did not know what the final number would end up being because it

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<sup>14</sup> Judge Krueger’s May 18, 2006 decision on Defendants’ motion to dismiss held that Plaintiff’s WDTPA claims accruing prior to June 16, 2001 are barred because of the applicable statute of repose. (Judge Krueger’s May 18, 2006 Partial Decision and Order at 9.)

was First DataBank’s survey (emphasis added). (NAPUF ¶¶ 72-74, 80.) The only reasonable inference from these facts is that Novartis knew what First DataBank’s AWP’s were in 2002 when First DataBank published them and that First DataBank claimed that they were the result of its wholesaler surveys. Because First DataBank claimed to set its AWP’s based upon wholesaler surveys, Novartis could hardly predict what First DataBank’s surveys would show in the future.

Moreover, Plaintiff offers no authority for the proposition that Wisconsin law – or any law – imposed a duty on Novartis to monitor and control what is published by First DataBank, an independent entity over which Novartis had demonstrably no control. It certainly offers no authority for the proposition that Novartis’s “failure” to monitor and attempt to influence First DataBank’s independently published data somehow transformed that data into an “advertisement, announcement, statement or representation” made by Novartis.<sup>15</sup>

In the absence of any authority that requires a manufacturer to control or correct statements made about its products by independent publishers such as First DataBank, Plaintiff relies on cases holding manufacturers liable where they clearly controlled offending representations to the public by distributors or retailers of those manufacturers’ products, a role wholly different from that of an independent information services provider. For example,

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<sup>15</sup> Plaintiff mistakenly relies on *In re AWP II*, 491 F. Supp. 2d 20 (D. Mass. 2007) to support its proposition that expectation and knowledge of First DataBank’s practices on the part of Novartis could rise to the level of “effective[] control[]” over First DataBank. (Pl.’s Br. at 23.) The court in that case – which was not decided under WDTPA and to which Novartis was not a party – concluded that another manufacturer could affect and, at times, control the First DataBank AWP for its drugs. *Id.* at 60-61. That factual determination rested on the court’s interpretation of evidence of that manufacturer’s interaction with First DataBank. *Id.* Even if that factual determination was correct as to that manufacturer’s relationship with First DataBank – a matter that manufacturer disputes – Plaintiff has identified no evidence regarding Novartis’s relationship with First DataBank that would establish as a matter of undisputed fact that Novartis controlled First DataBank’s AWP’s, as it must to obtain summary judgment.

Plaintiff relies on cases in which manufacturers placed deceptive labels on their own products or created products that physically resembled a better-known brand, and provided those products to middlemen who resold them to consumers in the same form. *See FTC v. Winsted Hosiery Co.*, 258 U.S. 483 (1922) (labels on garments); *Coca Cola Co. v. Gay-Ola Co.*, 200 F. 720 (6th Cir. 1912) (packaging and color of soft drink); *Von Mumm v. Frash*, 56 F. 830 (2d Cir. 1893) (deceptive labels on champagne).<sup>16</sup> Here, Novartis provided no labeled products to First DataBank for resale, it provided information. The evidence demonstrates that First DataBank did not simply republish that information as its AWP, but instead created its own AWP based on other information. (NAPUF ¶¶ 72-75, 77-81, 83-84.)

Plaintiff also relies on cases in which manufacturers were held liable for providing distributors and retailers with fictitious prices for their use in reselling the manufacturer's goods. In these cases, while the distributors and retailers chose whether to use these prices, any fictitious prices they used came from the manufacturer alone. *See e.g., Baltimore Luggage Co. v. FTC*, 296 F.2d 608 (4th Cir. 1961); *Clinton Watch Co. v. FTC*, 291 F.2d 838 (7th Cir. 1961). The liability in these cases derived from the resellers' use of the fictitious prices set by the manufacturer, not from their rejection of the prices. Even accepting Plaintiff's erroneous argument that AWP are fictitious, the undisputed evidence from First DataBank is that it never published a Novartis-provided AWP as a First DataBank AWP to Wisconsin Medicaid; First DataBank did not transmit Novartis's AWP to Wisconsin Medicaid, and Wisconsin Medicaid

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<sup>16</sup> *Idaho v. Master Distributors, Inc.*, 101 Idaho 447 (1980), is similarly inapposite because there was no real question that anyone but the manufacturer controlled the false representations. The defendant manufacturer hired and trained the distributor's sales personnel and created and had daily involvement with the distributor's sales program.

never used them.<sup>17</sup> Consequently, none of these cases even remotely suggests that Novartis can be held liable under Wis. Stat. § 100.18(1) for instances in which its allegedly false AWP's were not used.

Plaintiff also cites *FTC v. Windward Marketing, Ltd.*, 1997 WL 33642380 (N.D. Ga. Sept. 30, 1997) for the unremarkable proposition that “[a]wareness of fraudulent practices and failure to act within one’s authority to control such practices is sufficient to establish liability.” (Pl.’s Br. at 20.) Plaintiff ignores that the *Windward Marketing* court found “authority to control” in circumstances wholly unrecognizable here: It held that the owner/CEO of a closely-held corporation and the person who handled the corporation’s day-to-day affairs, by virtue of their positions, had direct authority over their small corporation’s illicit conduct. *Windward Mktg.* at \*\*4-5, 14. Glaringly absent from Plaintiff’s submission is any evidence indicating that Novartis had the “authority to control” First DataBank, as *Windward Marketing* requires. In fact, the Proposed Undisputed Facts Plaintiff identified pertaining to Novartis’s interactions with First DataBank are limited to the fact that Novartis has reported AWP's and WAC's for its drugs to First DataBank. In contrast, First DataBank’s uncontradicted evidence establishes that it was never controlled by Novartis.

No doubt cognizant of the absence of any evidence that Novartis could “control” First DataBank, Plaintiff seems to suggest that Novartis had some duty to publicly correct information published by First DataBank – assuming it was inaccurate – or warn Wisconsin Medicaid not to use First DataBank’s data. (Pl.’s Br. at 20-23.) The suggestion that Novartis had some sort of duty to inject itself in the relationship between First DataBank and Wisconsin Medicaid is

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<sup>17</sup> Thus, it is not First DataBank’s independent judgment that breaks the chain (as was argued in *Baltimore Luggage* and *Clinton Watch*).

contrary to established Wisconsin law.<sup>18</sup> Wisconsin courts have made clear that “[s]ilence – an omission to speak – is insufficient to support a claim under Wis. Stat. § 100.18(1). The DTPA does not purport to impose a duty to disclose . . . .” *Tietsworth v. Harley Davidson, Inc.*, 270 Wis. 2d 146, 169-70, 677 N.W.2d 233, 245 (2004) (holding that plaintiffs failed to state a claim under Wis. Stat. § 100.18 because, *inter alia*, “nondisclosure is not an ‘assertion, representation or statement of fact’ for purposes of the DTPA”); *see also Wisconsin v. McGuire*, 735 N.W.2d 555, 564 (Wis. Ct. App. 2007) (citing *Tietsworth* and stating that “§ 100.18 prohibits only affirmative assertions, not a failure to disclose” and “the DTPA . . . provides no remedy for omissions of material facts”).

The undisputed evidence demonstrates that the core inference sought – that First DataBank’s AWP, on which Plaintiff claims Wisconsin Medicaid relied, were controlled by Novartis – is unreasonable. The evidence also shows that First DataBank claimed that its AWP were the product of its independent survey efforts (NAPUF ¶¶ 72-74, 79-80, 83), a claim Novartis would be in no better position than Plaintiff to verify, even if it had a duty to police First DataBank’s publication. Under Wisconsin law, Novartis had no such duty.

Plaintiff’s demand for summary judgment is based on inference and argument rather than evidence and should be rejected. And Plaintiff’s failure to provide proof of even a single specific “representation” in Wisconsin made by or on behalf of Novartis alone requires denial of its motion.

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<sup>18</sup> Notably, the cases cited by Plaintiff in the section of its brief addressing First DataBank are not Wisconsin cases.

2. WDTPA Does Not Apply Because Wisconsin Medicaid Is Not a Member of the “Public”

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None of the representations of which Plaintiff complains was made to the public, as WDTPA requires. *See, e.g., Tietsworth v. Harley-Davidson, Inc.*, 270 Wis. 2d 146, 169, 677 N.W.2d 233, 245 (2004) (to state a claim under Wis. Stat. § 100.18(1), plaintiff must allege that a defendant has “made an ‘advertisement, announcement, statement or representation . . . to the public’ . . .”) (citations omitted) (emphasis added).

Wisconsin courts “have declined to conclude that the term [public] means everyone.” *Uniek, Inc. v. Dollar Gen. Corp.*, 474 F. Supp. 2d 1034, 1038 (W.D. Wis. 2007). It is well settled that the existence of a “particular relationship” between two parties precludes the application of section 100.18(1) to representations made between the parties. *Wisconsin v. Automatic Merchandisers of Am.*, 64 Wis. 2d 659, 664, 221 N.W.2d 683, 686 (1974) (citations omitted) (“The important factor is whether there is some particular relationship between the parties”); *see also Kailin v. Armstrong*, 252 Wis. 2d 676, 709-10, 643 N.W.2d 132, 149 (Ct. App. 2002) (applying “particular relationship” test and concluding that statements or representations made were not covered by section 100.18 because they were not made to “the public”). While there is no “bright-line” test for determining when a particular relationship exists, Wisconsin courts have held that “a statement made to the particular party with whom one has contracted is not a statement made to ‘the public.’” *Id.* at 709, 149; *see also K & S Tool & Die Corp. v. Perfection Mach. Sales, Inc.*, 301 Wis.2d 109, 124-25, 732 N.W.2d 792, 800 (2007) (“[A] plaintiff is no longer a member of ‘the public’ for the purpose of Wis. Stat. § 100.18(1) once he or she has entered into a contract to purchase the offered item.”); *Land’s End, Inc. v. Remy*, 447 F. Supp. 2d 941, 950 (W.D. Wis. 2006) (any misrepresentations by defendants, who had

entered into affiliate agreements with plaintiff, “cannot be characterized as statements made ‘to the public relating to the purchase of merchandise’” under Wis. Stat. § 100.18).

Plaintiff’s claim rests entirely on Novartis’s reporting of prices to First DataBank and First DataBank’s alleged republication of those prices. (Pl.’s Br. at 15.) Even if those claims were valid – and, as shown above, they are not – First DataBank does not publish to “the public.” Rather, it provides information to sophisticated market participants who purchase it. (NAPUF ¶ 67.) Wisconsin Medicaid’s fiscal agent, Electronic Data Systems Corporation (“EDS”), contracts with First DataBank for access to its database. (NAPUF ¶ 69.) Thus, Wisconsin Medicaid and EDS have a particular contractual relationship with First DataBank that precludes application of section 100.18(1) to representations made by First DataBank, as the case law above demonstrates. That fact alone ends the inquiry, as Plaintiff’s case rests entirely on representations allegedly made to it by First DataBank.

Wisconsin Medicaid also has long-standing and ongoing contractual relationships with Novartis that preclude application of WDTPA to alleged representations by Novartis. (NAPUF ¶¶ 91-94.) Novartis is a party to Medicaid rebate agreements with the federal government, which entered into the contracts on behalf of Wisconsin and other states. (NAPUF ¶ 91.) These agreements, which have been in place for more than fifteen years, set forth (in Section II, entitled “Manufacturer’s Responsibilities”) Novartis’s total obligations to the federal government and the states (barring any additional agreements with individual states). (NAPUF ¶ 91.) Nothing in these contracts creates an obligation for Novartis to report any prices to Wisconsin Medicaid, much less to report prices for transactions to which Novartis is not a party, such as transactions between wholesalers and retailers.

In 2004, Novartis began entering into supplemental Medicaid agreements with Wisconsin Medicaid. (NAPUF ¶ 94.) Pursuant to these agreements, Novartis pays additional rebates to Wisconsin Medicaid on certain drugs in exchange for Wisconsin Medicaid’s inclusion of those drugs on its Preferred Drug List or “PDL.” Through EDS, Wisconsin Medicaid contracts with Provider Synergies, a private consultant, which administers Wisconsin Medicaid’s PDL and negotiates with manufacturers on its behalf. (NAPUF ¶¶ 92-93.) The federal Medicaid agreements and supplemental rebate agreements define the relationship between Wisconsin Medicaid and Novartis and preclude application of WDTPA to that relationship.<sup>19</sup>

Moreover, even absent the myriad contracts governing the relationships among Wisconsin Medicaid, its sophisticated agents and contractors, First DataBank, and Novartis, Plaintiff still could not be considered a member of the public, given its position of power relative to all other market participants. WDTPA was intended to protect vulnerable consumers targeted by public sales promotions and advertisements, not industry insiders, such as Wisconsin Medicaid, which have knowledge and bargaining power equal to, if not greater than, the defendant. *See, e.g., Land’s End v. Remy*, 447 F. Supp. 2d 941, 950 (W.D. Wis. 2006) (“The purpose of Section 100.18 is ‘to protect the residents of Wisconsin from any untrue, deceptive or misleading representations made to promote the sale of a product’ to a *consumer* . . . . It is not designed to protect product manufacturers from paying commissions on the sale of their own products, however unearned those commissions may be.” (internal citations omitted) (emphasis

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<sup>19</sup> Plaintiff cites Justice Holmes’s admonition that one must “turn square corners” when dealing with the government. (Pl.’s Br. at 22.) This unremarkable proposition has little relevance to this case, as Novartis essentially is accused of publishing prices in accordance with standard industry practice to market participants who fully understood them. Novartis’s dealings with “the government” here were pursuant to contract, and Plaintiff has not made – and cannot make – any allegation that Novartis failed to do anything it was contractually required to do.

added)); *cf. In re Rezulin Prods. Liab. Litig.*, 390 F. Supp. 2d 319, 336-340 (S.D.N.Y. 2005) (dismissing health plans' New York and New Jersey consumer protection law claims because drug manufacturer's efficacy representations "were not intended for . . . patients, the ultimate consumers" and health plans that allegedly overpaid for drugs were not consumers of drugs).

Accordingly, the areas of commerce identified in WDTPA itself involve commercial relationships between vastly unequal participants – the general public on one side and commercial businesses on the other.<sup>20</sup> For example, an auto dealer could misrepresent the technical specifications of a car to a potential buyer, a securities dealer could misrepresent the risk of an investment to a potential investor, and a real estate broker could misrepresent the boundaries of a property to the potential purchaser. In such transactions, the average consumer is unaware of the technical and industry-specific elements of the transaction at issue, so the consumer directly relies upon the seller for information about that transaction.

In contrast, the undisputed record here shows that Wisconsin Medicaid had access to a wealth of information regarding the meanings of AWP and WAC, as well as information pertaining to the actual acquisition cost of providers. (DAPUF ¶¶ 10-12, 20-30.) Wisconsin Medicaid admits that – unlike any normal consumer – it could have compelled providers who it reimburses for drugs to certify that the reimbursements they seek reflect their acquisition costs for the products, yet it chose not to do so. (DAPUF ¶ 30.)

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<sup>20</sup> WDTPA was designed to protect the consuming public against misrepresentations made in connection with the specific forms of commerce enumerated in the statute. When first enacted in 1913, WDTPA only covered "merchandise." Over time, the application of WDTPA expanded to apply to other areas; the current version of § 100.18 applies only to misrepresentations concerning real estate, merchandise, securities, service, employment (Wis. Stat. §§ 100.18(1) and 9(a); *see also* §§ 100.18(3)(m) and 10(b) for additional references to "merchandise"), property (including personal property) (Wis. Stat. §§ 100.18(2),(3), and (5)), motor fuel (Wis. Stat. § 100.18(6) and (8)), motor vehicles (Wis. Stat. § 100.18(10(m))), and/or the nature or location of a business (Wis. Stat. § 100.18(10(a) and (10)(r)).

These undisputed facts describe a relationship that precludes application of Wis. Stat. 100.18(1). *Uniek v. Dollar Gen. Corp.*, 474 F. Supp. 2d 1034 (W.D. Wis. 2007) is instructive. The *Uniek* court granted the defendants' motion for summary judgment, holding that an ongoing commercial relationship between the parties meant that any representation that the defendants made to the plaintiff did not qualify as a representation made to the public. *Id.* at 1039. The court stated that "those who have long-term, established relationships are in a better position than most to protect themselves in the context of that relationship." *Id.* This principle applies to Plaintiff, who can hardly be likened to an ordinary member of the consuming public who lacks information and bargaining power. In *Uniek*, the relationship spanned thirteen years and involved the sale of up to \$12 million worth of merchandise annually. *Id.* at 1035-36. As the undisputed facts demonstrate, Plaintiff's relationships with First DataBank and the defendants are equally substantial, if not more so.<sup>21</sup>

3. Plaintiff Has Provided No Admissible Evidence of Novartis's Intent

Wis. Stat. § 100.18(1) requires Plaintiff to prove that Novartis acted 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

*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 (emphasis added).*

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<sup>21</sup> At a minimum, the facts are in dispute as to this issue and summary judgment in Plaintiff's favor is not warranted. *K & S Tool & Die Corp. v. Perfection Mach. Sales, Inc.*, 301 Wis. 2d 109, 127, 732 N.W.2d 792, 801 (2007) (where plaintiff had entered into one previous transaction with defendant several years before, a jury issue existed as to whether the buyer was a member of the public covered by Wis. Stat. 100.18(1)).

Wis. Stat. § 100.18(1). *See also K & S Tool & Die Corp. v. Perfection Mach. Sales, Inc.*, 301 Wis. 2d 109, 732 N.W.2d, 792 (2007) (plaintiff bringing Wis. Stat. § 100.18(1) claim must prove that defendant made a representation “with the intent to induce an obligation”). Plaintiff concedes that it must satisfy this intent requirement. (Pl.’s Br. at 4, 14, 15, 19.) It has utterly failed to do so. Plaintiff’s entire basis for asserting that Novartis reported AWP with the “intent to sell, distribute, or increase the consumption” of its drugs is its claim that Novartis reports AWP because it knows that third-party payors rely on AWP in determining how much to reimburse providers for Novartis drugs. (Pl.’s Br. at 15.) Even if true – and Novartis does not concede that it is – Plaintiff at most would be able to demonstrate that Novartis intended to facilitate reimbursement by third-party payors who had already decided to reimburse pharmacies for dispensing drugs to covered patients for whom the drugs were prescribed. This falls far short of proving that Novartis reported AWP with the “intent to sell, distribute, or increase the consumption” of its drugs.<sup>22</sup>

There is, therefore, no evidence supporting the allegations that Novartis reported false AWP to increase the market share of its products (Complaint at ¶¶ 1, 30, 40-41, 99). The undisputed evidence shows that pharmacies presented with prescriptions for Novartis branded drugs can dispense only those drugs (NAPUF ¶ 54); consequently, Novartis had no incentive to try to increase pharmacies’ profit margins because doing so would not increase Novartis’s market share (NAPUF ¶¶ 53-56). As Gary Rosenthal, Novartis’s Vice-President of Finance and Administration, stated: “Because retail pharmacies must provide to patients what doctors

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<sup>22</sup> Although it purports to be attempting to satisfy the first intent option of Wis. Stat. § 100.18(1), Plaintiff would similarly fail if it tried to satisfy the second intent option (*i.e.*, “intent to induce the public in any manner to enter into any contract or obligation”). Plaintiff has proffered no evidence that Novartis reported AWP to induce Wisconsin Medicaid into entering any “contract or obligation.”

prescribe . . . [Novartis] generally does not offer incentives, financial or otherwise, in connection with the sale of its patented drugs to retail pharmacies.” (NAPUF ¶ 56.)

*Land’s End, Inc. v. Remy*, 447 F. Supp. 2d 941 (W.D. Wis. 2006) demonstrates that a Wis. Stat. § 100.18.(1) claim cannot survive if the plaintiff fails to prove the requisite intent. There, a Land’s End program offered commissions to “affiliate” websites each time the affiliates, through a link on their websites, caused an Internet user to buy something on the Land’s End website. The defendant affiliates set up websites with addresses that were almost identical to Land’s End’s to trick customers looking for Land’s End’s website into logging on to the site operated by the affiliate. When the misdirected customer then placed an order, he or she would be connected to the real Land’s End site, thus generating commissions for affiliates on sales they had not really generated for Land’s End. The “false representation” that the affiliate site was a Land’s End site frustrated Land’s End’s intent to pay commissions only on sales actually generated by affiliates, but it did not cause the consumer to buy a product he or she had not intended to buy. The court therefore granted summary judgment for the defendants because the representations were not intended “to promote the sale of a product,” which is the conduct Wis. Stat. § 100.18 was designed to cover. *Land’s End* at 949-50. Likewise, Plaintiff here has failed to demonstrate that Novartis reported AWP’s with the intent to induce any doctor to prescribe a Novartis branded drug (which is a necessary precondition to one being sold), to induce any pharmacy to buy or sell one, or to induce any Wisconsin patient to buy one. Section 100.18(1) requires such proof, and Plaintiff’s summary judgment motion on this claim should be denied.

#### 4. Plaintiff’s Motion Fails Because Plaintiff Cannot Establish Causation

Plaintiff has failed to prove causation because it has not shown – and cannot show – that it sustained a pecuniary loss as a result of any alleged misrepresentations. *K & S Tool & Die Corp. v. Perfection Mach. Sales, Inc.*, 301 Wis. 2d 109, 121-22, 732 N.W.2d 792, 798 (2007)

“To prevail on [a section 100.18(1)] claim, the plaintiff must prove . . . that the representation caused the plaintiff a pecuniary loss.”); Wis. JI-Civil 2418 (requiring causation). To prove causation, a plaintiff must show that the representations materially induced a pecuniary loss. *K & S Tool*, 732 N.W.2d at 802 (“proving causation in the context of 100.18(1) requires a showing of material inducement”). Moreover, although reasonable reliance may not be an element of a section 100.18(1) claim,<sup>23</sup> reasonableness is relevant to determining whether, in fact, the alleged representations materially induced the pecuniary loss. *K & S Tool*, 732 N.W.2d at 802; *see also Foss v. Madison 20th Century Theaters*, 203 Wis. 2d 210, 218-19, 551 N.W.2d 862, 866 (Ct. App. 1996) (“The law will not permit a person to predicate damage upon statements which he does not believe to be true, for if he knows they are false, it cannot be said that he is deceived by them.”); *see also FDIC v. Lauterbach*, 626 F.2d 1327, 1334 (7th Cir. 1980) (under Wisconsin law, “[r]eliance on obviously false statements is not justifiable, neither is reliance upon statements the falsity of which could have been discovered through exercise of ordinary care”); *Williams v. Rank & Son Buick, Inc.*, 170 N.W.2d 807, 810 (Wis. 1969) (“it is apparent that the obviousness of a statement’s falsity vitiates reliance since no one can rely upon a known falsity”).

Accordingly, summary judgment should be denied because as shown above, (i) Plaintiff has not shown (and cannot show) that it used – let alone relied on – any AWP’s provided by Novartis for its drugs, or any representations by Novartis about the AWP’s for its drugs (*see* Sections IV.A.3 & IV.D.1, *supra*); (ii) reliance on Novartis’s AWP’s to indicate providers’ actual costs would have been unreasonable, given that Plaintiff premised its reimbursement decisions

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<sup>23</sup> Whether reliance must be reasonable for a Section 100.18(1) claim is an open question, which the Wisconsin Supreme Court recently agreed to consider on appeal from the Court of Appeals in *Novell v. Migliaccio*, No. 200 AP2852 (Wis. Ct. App. Oct. 17, 2006).

on the knowledge and belief that AWP did not reflect providers' actual acquisition costs (*see* Section IV.A.4, *supra*); and (iii) Plaintiff did not use WAC information for Novartis drugs in connection with its drug reimbursement (*see* Section IV.A.4 n.3, *supra*).

Nor can Plaintiff show that it would have acted differently had Novartis's or First DataBank's AWP reflected providers' actual costs. *K & S Tool & Die Corp. v. Perfection Mach. Sales, Inc.*, 301 Wis. 2d 109, 130, 732 N.W.2d 792, 803 (2007) (“[i]n determining whether [plaintiff's] loss was caused by the [representation], the test is whether [plaintiff] would have acted in its absence”). To the contrary, reams of undisputed evidence show that Plaintiff has not only known for decades that AWP are not equal to providers' average actual acquisition cost, but it has actually based its reimbursement decisions on that very premise, factoring in various political and economic considerations. (*See* Section IV.A.4, *supra*). The fact that Wisconsin Medicaid continues to use AWP in its reimbursement methodology for certain drugs even today (DAPUF ¶¶ 41, 43), more than 3 years after Plaintiff's commencement of this lawsuit, confirms the hollowness of its claim that it would have acted differently before.

Finally, Plaintiff does not even allege that it has ever used WAC information for Novartis's drugs as a component of, or in connection with, its drug reimbursement formulas – let alone that it relied on any misrepresentations regarding what those WACs represent. Plaintiff does not use WAC in any of its reimbursement calculations for Novartis drugs (DAPUF ¶ 45), nor does Plaintiff contend that it has made any decisions regarding provider reimbursement based on WAC.<sup>24</sup> Plaintiff's failure to establish causation mandates denial of its summary judgment motion.

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<sup>24</sup> Significantly, Plaintiff has not provided any basis for its alleged belief that Novartis's WACs reflected the price to wholesalers for Novartis drugs *net of all discounts*. To the contrary, (continued...)

E. Plaintiff Has Not Established a Violation of Wis. Stat. § 100.18(10)(b)

1. Wis. Stat. § 100.18(10)(b) Does Not Create a Separate Cause of Action

Plaintiff acknowledges that no case law holds that section 100.18(10)(b) sets forth an independent cause of action and no Wisconsin pattern jury instructions set forth the elements of such a claim. (Pl.'s Br. at 5.) Section 100.18(10)(b) is more appropriately read as definitional, providing an example of conduct that could be “deceptive” under section 100.18(1). It does not relieve Plaintiff of establishing the other elements of a WDTPA claim. Thus, Plaintiff’s claim under this section is subject to proof of the same elements as its general section 100.18(1) claim, and Plaintiff’s failure to prove those elements, as discussed, *supra*, defeats its motion for summary judgment.

2. Even If a Separate Claim Could Be Brought Under Wis. Stat. § 100.18(10)(b), That Provision Only Applies to Retailers’ Representations to the Consuming Public

Section 100.18(10)(b)’s drafting history demonstrates that its purpose is to prohibit *retailers* from representing their prices as “wholesaler’s” or “manufacturer’s” prices in order to give the *consuming public* the impression that their prices are lower than the regular retail price of comparable merchandise. *See* Drafting Record, L. 1961, c.376 (“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.”) (Grimmer Aff., Ex. 42). Novartis is a manufacturer; it does not sell to consumers, and Plaintiff nowhere alleges that

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Wisconsin’s designee James Vavra acknowledged that he did not believe that published WAC numbers factored in discounts. (DAPUF ¶ 48.) But even if Plaintiff could prove that it did believe that to be true, it has not provided any evidence that it formed its erroneous belief as a result of any representation by Novartis, or that it sustained any pecuniary loss as a result of its belief.

Novartis advertised prices to consumers. Nor is there any allegation – let alone proof – that Novartis’s price lists gave the consuming public the impression that retail prices for Novartis drugs were lower than the regular retail price of comparable merchandise. The cases cited by Plaintiff, under analogous federal law, are examples of the conduct that Section 100.18(10)(b) is designed to prevent and provide a useful contrast with the facts here.

Specifically, *Federated Nationwide Wholesaler Service v. F.T.C.* involved alleged representations *to consumers* that the petitioners’ businesses were wholesale and their prices, wholesale prices. *See* 398 F.2d 253, 255-56 (2d Cir. 1968). The court rejected the FTC’s cease and desist order, which prevented petitioners from making even true representations about the wholesale nature of their businesses and prices, but noted, “the evidence relied upon by the Commission in drawing its conclusion that the petitioners’ representations of ‘wholesale prices’ were deceptive and misleading to consumers was substantial.” *Id.* at 258.

In *L. & C. Mayers Co. v. F.T.C.*, the court upheld a FTC cease and desist order, noting, “[t]he groups to whom the petitioner is directed not to sell representing itself as a ‘wholesaler’ are *consumers*.” *See* 97 F.2d 365, 367 (2d Cir. 1938) (emphasis added). Explaining the premise of the case, the court stated,

[t]he theory of the Commission’s complaint is that the company sells to *ultimate consumers*; that in aid of such sales it uses catalogues designating itself as a wholesaler and that the *purchasing public* regards it as such- one selling to retailers at a price lower than the price at which the retailer sells; that *consumers* infer from this representation that they are buying at the prices at which retailers purchase, thereby saving an amount equal to the retailer’s profit, and that the prices as fixed in the catalogues are wholesale prices; but such is not the fact and the *consumer purchaser* is thereby deceived.

*Id.* (emphasis added).

Moreover, subsection 100.18(10)(b) of WDTPA specifically prohibits *comparative pricing statements* which represent the price at which “merchandise” is being sold as a

“wholesaler’s price” or a “manufacturer’s price” when the actual sales price is more than a retailer would pay a wholesaler or manufacturer for the “merchandise.” The legislature’s purpose in enacting this section was explained in an explanatory comment to the original draft of the bill sent to the legislature: the bill was “designed to specifically prohibit current advertising abuses by some retailers . . . who . . . represent . . . their prices as ‘wholesaler’s’ or ‘manufacturer’s’ or by similar terminology.” *See* Drafting Record, L. 1961, c.376 (Grimmer Aff., Ex. 42). Similarly, complaints brought by the FTC demonstrate that such wholesale price representation laws aim to prevent comparative price advertisements to the purchasing public. *See, e.g., In the Matter of Stereo Equipment Sales, Inc.*, 86 FTC 930 (Oct. 21, 1975) (by using the trade name “Baltimore Stereo Wholesalers” and “Stereo Wholesalers” in conjunction with advertisements in flyers, brochures and the like, *the purchasing public* believed they were buying goods at wholesale prices) (emphasis added).

In *AWP II*, the District Court explicitly rejected the argument that the FTC regulations addressing comparative pricing apply to a third party payer’s AWP claims. *In re AWP II*, 491 F.Supp.2d at 83-84 (“the factual circumstances of this case do not squarely fit within the context of [the FTC guidelines about wholesale price comparisons]”). The court noted that the FTC guidelines are aimed at the “consuming public” and published AWP’s are “not advertising prices to the consuming public . . . and [drug manufacturers] are not involved in the offering of discounts . . . to consumers.” *Id.* at 84. Moreover, third party payers making reimbursements, such as Wisconsin Medicaid, are not considered purchasers. *Id.*; *see also In re Rezulin Prods. Liab. Litig.*, 390 F. Supp.2d 319, 332-34 (holding group health benefit plans that reimburse for drugs are not “buyers” of the drugs).

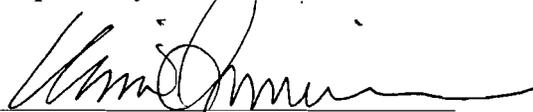
Finally, to the extent that Plaintiff is also claiming that Novartis's publication of WACs for its drugs violates this section, it is undisputed that Novartis's WACs were intended to and, in fact, did represent the actual undiscounted list price charged by Novartis to *wholesalers* – not retailers. Therefore, on its face, section 100.18(10)(b), which relates to representations that a particular price does not exceed the price offered to *retailers*, cannot apply to Novartis's publication of WAC prices for its drugs. *Id.*

**V. RELIEF SOUGHT**

For the reasons set forth above, Defendants Novartis Pharmaceuticals Corporation respectfully requests that the Court (a) deny Plaintiff's Motion for Partial Summary Judgment against Novartis (b) grant Novartis's Cross-Motion for Summary Judgment dismissing the Complaint in its entirety as to Novartis, and (c) award to Novartis its reasonable costs of defense against this action.

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Respectfully submitted,



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